

Medicare Claims Processing Manual

Chapter 17 - Drugs and Biologicals

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(Rev. 12511; Issued: 02-15-24)

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10 - Payment Rules for Drugs and Biologicals (Rev.11764, Issued: 12-22-2022; Effective:01-01-23; Implementation:01-03-23)

Drugs for inpatient hospital and inpatient skilled nursing facility (SNF) beneficiaries are included in the respective prospective payment system (PPS) rates, except for hemophilia clotting factors for hospital inpatients under Part A.

All hospital outpatient drugs are excluded from SDP because the payment allowance for such drugs is determined by a different methodology. Non pass-through drugs with estimated per day costs less than or equal to the applicable drug packaging threshold that are furnished to hospital outpatients are packaged under the outpatient prospective payment system (OPPS). Their costs are recognized and included but paid as part of the ambulatory payment classification (APC) group payment for the service with which they are billed. Non pass-through drugs with estimated per day costs greater than the applicable drug packaging threshold are paid separately.

Drugs that are granted “pass through” payment status are required by law to be paid at either the amount paid under the physician fee schedule, or, if the drug is included in the Part B drug competitive acquisition program (CAP), at the Part B drug CAP rate. Drugs that have pass-through status may have coinsurance amounts that are less than 20 percent of the OPPS payment amount. This is because pass-through payment amounts, by law, are not subject to coinsurance. CMS considers the amount of the pass-through drug payment rate that exceeds the otherwise applicable OPPS payment rate to be the pass-through payment amount. Thus, in situations where the pass-through payment rate exceeds the otherwise applicable OPPS payment rate, the coinsurance is based on a portion of the total drug payment rate, not the full payment rate.

Hospitals must report all appropriate HCPCS codes and charges for separately payable drugs, in addition to reporting the applicable drug administration codes. Hospitals should also report the HCPCS codes and charges for drugs that are packaged into payments for the corresponding drug administration or other separately payable services. Historical hospital cost data may assist with future payment packaging decisions for such drugs. Drugs are billed in multiples of the dosage specified in the HCPCS code long descriptor. If the drug dose used in the care of a patient is not a multiple of the HCPCS code dosage descriptor, the provider rounds to the next highest unit based on the HCPCS long descriptor for the code in order to report the dose provided.

If the full dosage provided is less than the dosage for the HCPCS code descriptor specifying the minimum dosage for the drug, the provider reports one unit of the HCPCS code for the minimum dosage amount.

OPPS Pricer includes a table of drugs and prices and provides the contractor with the appropriate prices.

Section 90 relates specifically to billing for hospital outpatients. The remainder of this chapter relates to procedures for pricing and paying DME recipients, and to beneficiaries who receive drugs under special benefits such as pneumococcal, flu and hepatitis vaccines; clotting factors, immunosuppressive therapy, self administered cancer and anti emetic drugs, and drugs incident to physicians’ services.

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 defines a Specified Covered Outpatient Drug (SCOD) as a covered outpatient drug for which a separate APC has been established and that is either a radiopharmaceutical agent, or a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002. Payment for SCODs is set, by law, at the average acquisition cost. Under the OPPS, a single payment is made for SCODs that

represents payment for both the acquisition cost of the drug and any associated pharmacy overhead or nuclear medicine handling costs.

Drugs or biologicals must meet the coverage requirements in Chapter 15 of the Medicare Benefit Policy Manual. Additionally, for end stage renal disease (ESRD) patients, see the Medicare Benefit Policy Manual, Chapter 11. For ESRD patient billing for drugs and claims processing, see Chapter 8 of this manual.

The following chart describes the general payment provisions for drugs.

Table - Drug Payment Methodology

Key to the following Table:

NOTES:

DME MACs do not process claims for blood clotting factors.

Unless noted otherwise, claims for these drugs are submitted to the A/B MAC (B)

† - Drugs & biologicals outside the composite rate and/or ESRD PPS are paid as described in 2 below. Those inside the composite rate and/or ESRD PPS are paid as described in 1. (ESRD PPS effective January 1, 2011)

1 - Included in PPS rate, or other provider-type all inclusive encounter rate

2 - Price taken from CMS drug/biological pricing file effective on the specific date of service.

3 - Based on reasonable cost (101% reasonable cost in CAH)

4 - Lower of cost or 95% AWP paid for drug in addition to PPS rate, or in addition to reasonable cost if excluded from PPS

5 - OPSS-APC, whether pass-thru drug or not

6 - Cannot furnish as that “provider” type

7 - May not bill DME-MAC or MAC for drugs furnished incident-to a physicians’ service

8 - Payment made at the time of cost settlement

A - Bills are submitted to the DME MAC

++ Except in the State of Washington, where CMS permits the ESRD Facility to bill for immunosuppressive drugs due to the unique State assistance to the beneficiary provided only via the ESRD Facility.

Provider/Drug	Hepatitis Vaccine	Pneumococcal & Flu Vaccines	Hemophilia Clotting Factors	Immuno - Suppress ive	Erythrop oiesis Stimulating Agents (ESA's)	Self Admin Anti-Cancer Anti-Emetic for cancer treatment	Other Drugs
Hospital Inpatient (IP) A -Prospective Payment System (IPPS)	3	3	2	1	1	1	1
Hospital IP A - not IPPS	3	3	3	3	3	3	3
Hospital IP B - Outpatient Prospective	3	3	5	5	5	5	5

Payment System (OPPS)							
Hospital IP B - not OPPS hospital	3	3	3	3	3	3	3
Hospital Outpatient (OP) - OPPS hospital	3	3	5	5 (8 - for 30-day supply)	5	5	5
Hospital OP - not OPPS hospital	3	3	3	3 (8 - for 30-day supply)	3	3	5
Skilled Nursing Facility (SNF) IP	3	3	1	1	1	1	1
SNF OP or IP B	3	3	3	3	6	6	6
End Stage Renal Disease (ESRD) Facility	2	2	6	6++	1 or 2†	6	1 or 2†
Comprehensive Outpatient Rehabilitation Facility (CORF)/ Outpatient Rehabilitation Facility (ORF)	2	2	6	6	6	6	6
Community Mental Health Clinic (CMHC)	6	6	6	6	6	6	6
Rural Health Clinical (RHC)/Federally Qualified Health Clinic (FQHC) -hospital based	1	8	5	5	5	5	5
RHC/FQHC-independent	1	8	6	6	6	6	6
Home Health Agencies	3	3	6	6	6	6	6
Hospice	6	6	6	6	1	1	1
Physicians	2	2	2	2	2	2	2
Pharmacy	2	2	2, 7	2, A	2	2, A	2, 7
Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier	2	2	2	2	2	2	2

Critical Access Hospital (CAH) IP A or B	3	3	3	3	3	3	3
CAH OP-Method I or II	3	3	3	3 (8 - for 30-day supply)	3	3	3

NOTES:

Independent and provider-based RHCs and FQHCs generally do not bill for pneumococcal/influenza vaccines, except when the only service involved is the administration of the vaccine. Instead, RHCs/FQHCs are generally paid for pneumococcal/influenza vaccines at cost settlement via the Medicare cost report. Hepatitis B vaccine payment is bundled into the encounter rate for both Independent and provider-based RHCs and FQHCs.

Influenza, pneumococcal, and Hepatitis B vaccines are paid on a reasonable cost basis in a hospital outpatient department. Neither deductible nor coinsurance apply.

HHAs cannot bill for vaccines, except on TOB 34X, since vaccines are not part of the HH benefit and cannot be paid under HH PPS.

Influenza, PPV, and Hepatitis B vaccines are paid once for the vaccine and once for the administration of the vaccine. The provider or supplier (including physician) must enter each of the HCPCS on separate lines of the claim.

A Part B blood clotting factor claim from a Part B supplier is processed by the A/B MAC (B).

A Part A blood clotting factor claim from a Part A provider, including a hospital-based hemophilia center, is processed by the hospital’s Medicare contractor.

***10.1 - Payment Rules for Drugs and Biologicals Subject to the Inflation-Adjusted Coinsurance Policy
(Rev. 12511; Issued:02-15-24; Effective: 01-01-24; Implementation: 03-18-24)***

For calendar quarters starting April 1, 2023, if the payment amount for a rebatable drug specified in section 1847A(i)(3)(A)(ii)(I) of the Act exceeds the inflation-adjusted payment amount, two payment adjustments are necessary. First, beneficiary coinsurance for a Part B rebatable drug is to be 20 percent of the inflation-adjusted payment amount if the Medicare payment amount for a calendar quarter exceeds the inflation-adjusted payment amount. A/B MACs should find the applicable coinsurance amount for a rebatable drug in the ASP pricing file where the coinsurance is expressed as a percent of the Medicare payment amount. If adjusted beneficiary coinsurance does not apply, the percentage is 20 percent.

Second, Medicare Part B pays, subject to the deductible and sequestration, the difference between the allowed payment amount determined under section 1847A of the Act and 20 percent of the inflation-adjusted amount. In other words, the Part B payment for a rebatable drug with an inflation-adjusted coinsurance will be greater than 80 percent of the payment amount.

20 - Payment Allowance Limit for Drugs and Biologicals Not Paid on a Cost or Prospective Payment Basis

(Rev. 131, 03-26-04)

Prior to January 1, 2004, drugs and biologicals not paid on cost or prospective payment are paid based on the lower of the billed charge or 95 percent of the average wholesale price (AWP) as reflected in published sources (e.g., Red Book, Price Alert, etc.). Examples of drugs that are paid on this basis include, but are not limited to, drugs furnished incident to a physician's service, immunosuppressive drugs furnished by pharmacies, drugs furnished by pharmacies under the durable medical equipment benefit, covered oral anticancer drugs, and blood clotting factors.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, changed the basis for payment of drugs and biologicals not paid on a cost or prospective payment basis. For January 1, 2004, through December 31, 2004, such drugs or biologicals are paid as described below:

- The payment limits for blood clotting factors will be 95 percent of the 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 pneumococcal and hepatitis B drugs and biologicals will be 95 percent of the AWP.
- The payment limits for certain drugs studied by the OIG and GAO are based on the percentages of the April 1, 2003 AWP's specified on Table 1 below.
- The payment limits for infusion drugs furnished through an item of implanted durable medical equipment on or after January 1, 2004, will be 95 percent of the October 1, 2003 AWP.
- Drugs and biologicals not described above are paid at 85 percent of the April 1, 2003 AWP.

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

Table 1: Percentages of April 1, 2003 AWP for Selected Drugs

HCPCS	Applicable Percentage
J0640	80
J1100	86
J1260	80
J1440	81
J1441	81
J1561/J1563	80
J1626	80
J1642	80
J2405	87
J2430	85
J2820	80
J7320	82
J7517	86
J7608	80
J7619	80
J7631	80
J7644	80
J8520/J8521*	90
J9000	80
J9045	81
J9170	80
J9201	80
J9202	80
J9206	80
J9217	81
J9265	81
J9310	81
J9350	84
J9390	81
Q0136	87

* Use the following NDC numbers when processing claims:

- 00004-1100-20 150 mg
- 00004-1100-51 150 mg
- 00004-1101-16 500mg
- 00004-1101-50 500mg

20.1 - MMA Drug Pricing - Average Sales Price
(Rev. 1513; Issued: 05-23-08; Effective/Implementation Date: 06-23-08)

In general, CMS establishes a single, national payment limit for A/B MAC (A), A/B MAC (B), A/B MAC (HHH) and DME MAC payment for each Medicare-covered drug whose payment is determined based on the methodology described above. Drugs billed to DME MACs are still priced locally, albeit under the new statutory formula, as applicable. The four DME MACs jointly establish drug payment

limits for drugs that are billed to DME MACs.

The CMS provides an ASP file to each MAC for pricing drugs. Each MAC must accept the ASP files made available by CMS for pricing bills/claims for any drug identified on the price files.

The ASP drug pricing file shall contain 3 places after the decimal point in the currency field for the ASP file and contractors shall load the ASP file including 3 places after the decimal point. Contractors shall carry 3 places after the decimal point for the calculation of the amount due for a line item for each covered drug, then follow standard rounding procedures in determining the final allowance for that line item. The final allowed amounts will continue to carry 2 places after the decimal point.

The payment limits included in the revised ASP and Not Otherwise Classified (NOC) payment files supersede the payment limits for these codes in any publication published prior to this document.

20.1.1 - Online Pricing Files for Average Sales Price (Rev. 509, Issued: 03-18-05; Effective: 07-01-05; Implementation: 07-05-05)

Beginning July 1, 2005, the standard for the number of online pricing files maintained by DME MACs for determining the applicable allowed amount for paying drug claims is eight fee screens/pricing files for Part B drugs billed to DME MACs for payment on a fee-for-service basis.

20.1.2 - Average Sales Price (ASP) Payment Methodology (Rev. 12511; Issued:02-15-24; Effective: 01-01-24; Implementation: 03-18-24)

Section 303(c) of the Medicare Modernization Act of 2003 (MMA) revised the payment methodology for Part B covered drugs and biologicals that are not priced on a cost or prospective payment basis. Per the MMA, beginning January 1, 2005, the vast majority of drugs and biologicals not priced on a cost or prospective payment basis will be priced based on the average sales price (ASP) methodology. Pricing for compounded drugs is performed by the *A/B MAC and DME MAC*. Beginning in July 2015, claims for compounded drugs shall be submitted using a compounded drug, not otherwise classified (NOC) HCPCS code. Beginning in 2006, all ESRD drugs furnished by both independent and hospital-based ESRD facilities, as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the Outpatient Prospective Payment System (OPPS), will be priced based on the ASP methodology. The ASP methodology is based on quarterly data submitted to CMS by manufacturers. CMS will supply *MACs* with the ASP drug pricing files for Medicare Part B drugs on a quarterly basis. *MACs* will be notified of the availability of this file via a Recurring Update Notification. Visit <https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price> for more information about the ASP payment methodology.

The absence or presence of a HCPCS code and its associated payment limit does not indicate Medicare coverage of the drug or biological. Similarly, the inclusion of a payment limit within a specific column does not indicate Medicare coverage of the drug in that specific category. The *A/B MAC or DME MAC* processing the claim shall make these determinations.

Beginning January 1, 2005, in general, the payment limits for Medicare Part B drugs and biologicals that are not paid on a cost or prospective payment basis are 106 percent of the ASP. Beginning January 1, 2006, in general, the payment limits for ESRD drugs when separately billed by freestanding and hospital-based ESRD facilities, as well as specified covered outpatient drugs, and drugs and biologicals

with pass-through status under the OPPS, will be paid based on 106 percent of the ASP. CMS will update the payment limits quarterly.

In general, the payment limit for biosimilar biological products (hereafter, biosimilars) is the sum of (1) the ASP of the biosimilar and (2) 6 percent of the lesser of the WAC or ASP of the reference biological. For biosimilars that have an ASP less than the ASP of their reference biological during a calendar quarter during the applicable period, also known as a qualifying biosimilar biological product, that are furnished during the applicable 5-year period, the payment limit is the sum of (1) the ASP of the biosimilar and (2) 8 percent of the lesser of the WAC or ASP of its reference biological. For biosimilars for which payment has been made under Part B as of September 30, 2022, the applicable period is the 5-year period beginning on October 1, 2022; for those for which payment is first made under Part B between October 1, 2022 and ending December 31, 2027, the applicable period is the 5-year period beginning on the first day of the calendar quarter in which the first Part B payment is made.

As announced in late 2006, CMS has been working further to ensure that accurate and separate payment is made for single source drugs and biologicals as required by Section 1847A of the Social Security Act. As part of this effort, we have also reviewed how we have operationalized the terms “single source drug,” “multiple source drug,” and “biological product” in the context of payment under Section 1847A. For the purposes of identifying “single source drugs” and “biological products” subject to payment under Section 1847A, generally CMS (and *MACs*) will utilize a multi-step process. We will consider:

- The FDA approval;
- Therapeutic equivalents as determined by the FDA; and
- The date of first sale in the United States.

For a biological product (as evidenced by a new FDA Biologic License Application or other relevant FDA approval) or a single source drug (that is, not a drug for which there are two or more drug products that are rated as therapeutically equivalent in the most recent FDA Orange Book) first sold in the United States after October 1, 2003, the payment limit for a biological product or single source drug will be based on the pricing information for products marketed or sold under the applicable FDA approval. As appropriate, a unique HCPCS code *is* assigned to facilitate separate payment. Separate payment may be operationalized through use of “not otherwise classified” HCPCS codes.

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

(Rev. 12511; Issued:02-15-24; Effective: 01-01-24; Implementation: 03-18-24)

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 OPSS 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 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 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 *A/B MACs* with the payment limits 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.

The payment 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 OPSS where the payment limit is 95 percent of the published AWP. 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 OPSS, the payment limit for new drugs and biologicals 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 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 limits for covered drugs 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.

20.2 - Single Drug Pricer (SDP)

(Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

Effective January 1, 2003, contractors pay drug claims on the basis of the prices shown on the SDP files, if present.

On a quarterly basis, CMS furnishes three SDP files to all MACs and ROs except A/B MACs (HHH) and DME MACs, as follows:

1. "HCPCS" Drug Pricing File

a. CMS furnishes a SDP file that contains drugs identified by a code established by the Health Care Procedure Code System (HCPCS). This HCPCS drug-pricing file (HDPF) contains:

- Every HCPCS drug code for every drug for which claims are submitted to A/B MACs (B) (excluding DME MACs);
- With respect to each such HCPCS code, the unit of measure by which such HCPCS code is defined;
- With respect to each HCPCS code and unit of measure, the Medicare allowed amount;
- With respect to each HCPCS code for which the price has changed from the price determined in the previous quarter, an indication as to whether the new price is higher or lower than the price determined in the prior quarter;
- With respect to each new HCPCS code, an indicator to that effect; and
- With respect to each deleted HCPCS code, an indicator to that effect.

b. The filename convention is as follows: (1) "hdpf" in the first 4 positions (2) positions 5-8

correspond to the year and quarter for which the file is applicable (e.g., hdpf0301.xls).

c. An HDPF will be made available approximately 30 days before the beginning of each calendar quarter, i.e., on or about each February 1, May 1, August 1, and November 1.

2. “Not otherwise classified” (NOC) Drug Pricing File

a. CMS furnishes a NOC SDP file for drugs “not otherwise classified.” This NOC drug pricing file (NDPF) contains:

- With respect to every drug NOC under the HCPCS for which claims are submitted to A/B MACs (B) (excluding DME MACs), the NDC code and drug name;
- With respect to each such NDC code, the unit of measure by which such drug is covered;
- With respect to each NOC drug, the Medicare allowed amount;
- With respect to each NOC drug for which the price has changed from the price determined in the previous quarter, an indication as to whether the new price is higher or lower than the price determined in the prior quarter;
- With respect to each new NOC drug, an indicator to that effect; and
- With respect to each deleted NOC drug, an indicator to that effect.

b. The filename convention is as follows: (1) “ndpf” in the first 4 positions (2) positions 5-8 correspond to the year and quarter for which the file is applicable (e.g., the initial NOC file’s filename was “ndpf0301.xls”).

c. The CMS makes a revised NDPF available approximately 30 days before the beginning of each calendar quarter, i.e., on or about each February 1, May 1, August 1, and November 1.

NOTE TO A/B MACs (A): The NOC file does not necessarily contain all NOC drugs. A/B MACs (A) must contact A/B MACs (B) to determine if there are other drugs the A/B MAC (B) has priced separately and request the prices for those drugs as needed.

3. The CMS furnishes a pricing documentation file (PDF) that contains only new drugs and biologicals for which a Medicare price has been established since the previous quarter:

- a. The data in the drug pricing file, i.e., each HCPCS code and its Medicare allowed amount;
- b. With respect to each HCPCS drug code, every product, as identified by its NDC code, that contains the same active ingredient as specified in the definition of the HCPCS code;
- c. With respect to those NDC codes used to determine the Medicare-allowed amount, an indicator to that effect;
- d. With respect to each such NDC, the price or prices used to determine the average wholesale price (AWP) of the product;

- e. With respect to each such price, an identification of the source(s) of the price; and
- f. With respect to each such source, the date, edition, and other information necessary and sufficient to enable CMS to verify the price.

Except as specifically noted, each A/B MAC (A) and (B) will:

- Upon receiving the quarterly update files, execute its normal update process using the SDP files. If necessary, the contractor shall process manually to implement SDP file prices effective with the beginning of the following quarter.
- Compare the prices it paid previously with the prices shown on the prior SDP file; taking note of the unit pricing quantity shown on the applicable SDP file and comparing it to the unit pricing quantity to ensure that any apparent price changes are real.
 - A/B MACs (B) must notify physicians of price changes.
 - A/B MACs (A) must notify ESRD facilities (with respect to ESRD drugs not included in the composite rate) and hospitals (with respect to clotting factors) of price changes to the extent and in the manner you have done previously.
- Advise the RO of any price on a SDP file it believes is not correct.
- Not substitute its price for the price shown on an SDP file unless authorized to do so by a joint memorandum from CMS.
- If updated prices, in whole or in part, are not made available on a timely basis, use the prices from the prior quarter's SDP files to the extent necessary.
- A/B MACs (B) continue to price drugs as outlined in §20.2 with respect to any drug that is not listed on the SDP files and with respect to any compounded drug that is not identified by a single NDC.
 - Report to the RO, on or before March 1 of each year, whether any drugs are being priced separately, including but not limited to NOC drugs. If one or more drugs are being priced separately, then the name of the drug, its NDC, the price determined, and the source used to price drug must also be included in the report.
- A/B MACs (A) and (B): Publish current SDP prices on their Web site immediately upon receipt of the file from CMS.
- A/B MACs (A): As needed on a quarterly basis and within seven days of receipt of the SDP files, request, from A/B MACs (B), prices of drugs that A/B MACs (B) may price separately.
 - A/B MACs (B): Upon request, on a quarterly basis and within seven days of any such request, furnish to A/B MACs (A) within jurisdiction, free of charge, the subset of files, which includes drugs that are priced separately.
- A/B MACs (A) and (B): Respond to questions about price changes and the implementation of AWP pricing as done previously. Contractors respond to questions about the SDP on the basis of

these instructions. Questions that cannot be answered should be referred to the RO.

- The MCS shared systems shall maintain eight fee screens/pricing files (a current period and seven prior periods) for Part B “incident to” drugs billed to A/B MACs (B) for payment on a fee-for-service basis. (**NOTE:** VIPS is waived and will continue to carry 5 pricing periods)
- Since they post the updated SDP file to their Web site upon receipt from CMS, A/B MACs (B) are waived from the requirement to give 30 days advance notice for fee schedule changes with respect to drugs.
- SDP does not preclude the use of inherent reasonableness or the establishment of local medical review policies, including the use of a least costly alternative.
 - If a least costly alternative is determined and a price for the least costly alternative exists on the SDP, the SDP price for the least costly alternative must be used.
- Medicare coverage determinations are independent of the SDP. The presence or absence of a price for a particular drug in the SDP is irrelevant to Medicare coverage determinations.
- EPO=Q codes are included in the SDP, applicable to physician claims. The statutory limit for EPO applies to nonphysician claims.
- “Unit Measurement” means the amount of whatever measurement is used in the code description (e.g., milligrams (mg)).

ROs:

1. Advise A/B MACs (B) concerning the implementation of the SDP.
2. Respond to questions about drug price changes.
3. Respond to questions about the implementation of the AWP pricing methodology.
4. Respond to questions about the SDP on the basis of these instructions.
5. Refer any questions that cannot be answered to central office (CO) per item 6, below.
6. Advise CO of matters that require CO attention.

20.3 - Calculation of the Payment Allowance Limit for DME MAC Drugs (Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

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 AWP specified on Table 1 in §20.

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

20.4 - Calculation of the AWP

(Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

See Business Requirements and Excel Spreadsheets at:

<http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R54CP.pdf>

and

<http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R55CP.pdf>

A/B MACs (B) must ensure that if any NDCs are added or deleted, the formulae are applied appropriately.

A separate AWP is calculated for each drug as defined by a HCPCS code. Within each HCPCS code there may be a single source or there may be many sources, or there may be no source.

- For a single-source drug or biological, the AWP equals the AWP of the single product.
- For a multi-source drug or biological, the AWP is equal to the lesser of;
 - The median AWP of all generic forms of the drug or biological; or
 - The lowest brand name product AWP.

A “brand name” product is defined as a product that is marketed under a labeled name that is other than the generic chemical name for the drug or biological.

NOTE: Repackagers make the status of the drug a multi-source.

After determining the AWP, A/B MACs (B) multiply it by 0.85 or 0.95, or other percentage, as applicable, and round to the nearest penny. This is the drug payment allowance limit. A/B MACs (B) round it in accordance with standard rounding procedure. Part B coinsurance and deductible requirements apply.

In applying this procedure, A/B MACs (B) use the package sizes that are most commonly used for the most frequently administered dosage of the drug.

A/B MACs (A) get drug prices from the A/B MAC (B) for drugs not listed on the Single Drug Pricer.

20.5 - Detailed Procedures for Determining AWP and the Drug Payment Allowance Limits

(Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

20.5.1 - Background

(Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

Payment for drugs and biologicals under Medicare is determined by a standard methodology. Law and regulations require that a drug payment allowance limit be used as described in §20.1. (See 42 CFR 405.517 and MPDIMA, Section 303(b).)

The earliest drug payment allowance limit effective in 2004 will not be subsequently updated during 2004. When limits are initially established, A/B MACs (B) inform A/B MACs (A) and the provider community as described in paragraph §30 below.

20.5.2 - Review of Sources for Medicare Covered Drugs and Biologicals

(Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

A/B MACs (B) check updates for Medicare covered services or procedures for new codes or code description changes before updating files.

For new codes, the A/B MAC (B) Medical Staff determines coverage in accordance with the coverage rules in Chapter 15 of the Medicare Benefit Policy Manual.

A/B MACs (B) refer to common sources for drug pricing information. Examples are the various Redbook products, “Drug Facts and Comparisons,” the FDA publication Approved Drug Products with Therapeutic Equivalence (the Orange Book), or the “Hospital Formulary Pricing Guide” by MediSpan, Inc. If a price cannot be located in the available sources, they contact the manufacturer of the drug.

If a code has a description change, A/B MACs (B) adjust formulas to account for any changes in the strength or dosage of the drug. For example, if a code is listed as 50 mg, and changed to 100 mg, the drug payment allowance limit is adjusted to compensate for the difference in the dosage.

20.5.3 - Use of Generics

(Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

A/B MACs (B) identify the generic name of the drug from the code description. They always rely on the CMS HCPCS tape file or an official HCPCS publication.

A/B MACs (B) locate generic sources in the Drug Topics Redbook or other source based on the HCPCS description of the drug. They use entries that match the strength of the drug described by the HCPCS code, e.g., 50 mg, 100 mg, etc.

To determine if a drug is generic or brand, A/B MACs (B) compare the name of the drug in the HCPCS code (generic) with the name of the drug being identified. If they are the same, the drug is generic. If they are different, the drug is a brand. For example, the description for J3360 is injection, diazepam, up to 5 mg. Diazepam is the generic name. The HCPCS code for Valium is listed as J3360. Valium is a brand name.

If there is a question as to whether a drug is brand or generic, A/B MACs (B) consult the PDR Generics, or telephone the drug company.

20.5.4 - Find the Strength and Dosage

(Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

A/B MACs (B) use ampules, single dose and multiple dose vials and repacks to compare the strength and dosage. If multiple dose vials are used, A/B MACs (B) must determine how they are used, based on the strength indicator compared with the HCPCS code description (i.e., if the strength on the vial matches the HCPCS description, multi-dose vials should be used).

A/B MACs (B) must determine which of the following conditions are true before pricing the drug:

1. The strength and dosage of the drugs in the price source match the HCPCS code and description.

A/B MACs (B) calculate allowable reimbursements for drugs using “all” the NDCs for a given active drug ingredient and calculate a unit price that is associated with the HCPCS descriptor. If, for example, the HCPCS code descriptor specifies 50 ml and there is a 50 ml size shown in the Redbook or other source material, they may use only the 50 ml size (and not use 10-5 ml vials) or may use all products that meet the strength based on strength and volume of the drug. In the latter case price per unit is calculated and then converted to the HCPCS units definition.

2. The strength and dosage from the HCPCS code description are not found in the price source.

A/B MACs (B) use the closest dosage to the HCPCS definition without exceeding the dosage.

3. The strength and dosage in the price source do not include a generic form but do include a brand form.

A/B MACs (B) use the lowest brand price.

20.5.5 - Restrictions

(Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

To determine AWP and Payment Allowance Limits, A/B MACs (B):

- Exclude special sized packaging, e.g., Institutional Use.
- Do not use flip top vial, carpu-ject, tubes, cartridge, rapi-ject, lure lock syringe, blunt point abject, rapi-ject, leurlock, advantage, min-i-jet, unless it is the only source available. These items are considered convenience and tend to inflate the price.
- Do not use drugs marked preservative free, sulfite free, piggy back, or sterile unless the HCPCS description specifies otherwise.
- Do not use drugs with an Orange Book Code (OBC) other than “A” if more than one source exists. This restriction applies to SADMERC only (reference CMS Memorandum PUB 60 AB.94-2, 60 dated March 1994).

20.5.6 - Inherent Reasonableness for Drugs and Biologicals

(Rev. 11140, Issued: 12-02-21, Effective :01-04-22, Implementation: 01-04-22)

Section 4316 of the Balanced Budget Act of 1997 permits A/B MACs (B) to establish realistic and equitable payment amounts for drugs when the existing payment amounts are inherently unreasonable because they are either grossly excessive or deficient. Refer to chapter 23, for a complete description of Inherent Reasonableness rules.

Examples of the factors that may result in grossly deficient or excessive payment amounts include, but are not limited to the following:

1. Payment amounts for drugs or biologicals are grossly higher or lower than acquisition or production costs for the category of items or services.
2. There have been increases in payment amounts that cannot be explained by inflation or technology.

In some instances, the calculation of the AWP may lead to a payment limit that is not reasonable for the purpose of paying for drugs and biologicals. A/B MACs (B) can apply the principal of inherent reasonableness in selecting the drugs to be included in the calculation. For instance in situations where there are some drugs in a HCPCS grouping that are significantly more expensive due to having preservatives added, there is no effect on the quality of the drug whether or not there are preservatives. Therefore, leave the drugs with preservatives out of the calculation.

While A/B MACs (A) and (B) may determine under their inherent reasonableness authority that a greater than 15 percent increase or decrease in payment amounts is warranted, they may not increase or decrease the payment amounts for any item by greater than 15 percent in any given year. However, a contractor may determine that a 25 percent reduction is warranted, and accomplish the adjustment over 2 years, e.g., 15 percent applied the first year, and 10 percent applied the following year.

In addition, a contractor must inform CMS of any inherent reasonableness determinations. The CMS will then acknowledge receipt of the notification. The payment adjustment may not take effect until the contractor has notified CMS and received CMS's acknowledgment of the notification.

20.5.7 - Injection Services

(Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

Where the sole purpose of an office visit was for the patient to receive an injection, payment may be made only for the injection service (if it is covered). Conversely, injection services (codes 90782, 90783, 90784, 90788, and 90799) included in the Medicare Physician Fee Schedule (MPFS) are not paid for separately, if the physician is paid for any other physician fee schedule service furnished at the same time. Pay separately for those injection services only if no other physician fee schedule service is being paid. However, pay separately for cancer chemotherapy injections (CPT codes 96400-96549) in addition to the visit furnished on the same day. In either case, the drug is separately payable. All injection claims must include the specific name of the drug and dosage. Identification of the drug enables you to pay for the services.

20.5.8 - Injections Furnished to ESRD Beneficiaries

(Rev. 397, Issued: 12-16-04, Effective: 01-01-05, Implementation: 01-03-05)

When an ESRD beneficiary is given a renal related injection outside the ESRD facility or provider-setting, it should be administered by the beneficiary's monthly capitation payment (MCP) physician or his/her staff as "incident to" such physician's services.

There is no additional allowance for the physician or his staff, e.g., an office nurse. This is because payment for the administration of a renal-related injection to a dialysis patient is included in the physicians' monthly capitation payment (MCP).

The regulations governing Medicare payment for physicians' ESRD services (42 CFR 405.542) require that all physicians' outpatient ESRD-related services except declotting shunts be paid under the MCP. If a physician, other than the patient's MCP physician, administers a renal-related injection, the other physician must look to the MCP physician for compensation for the services.

Although an additional allowance for the administration of a renal-related injection to a dialysis patient may not be made, the patient's MCP physician or a physician other than the MCP physician may submit claims and be paid for the drug itself as well as supplies, e.g., needles and syringes, used to administer the drug.

EXAMPLE: Dr. Jones is Mr. White's MCP physician. Dr. Jones is unable to furnish the regular EPO injections his patient needs three times a week. It is Dr. Jones' responsibility to compensate the physician who administers the injections. The administering physician submits claims for the injectable and necessary supplies. In this case, the A/B MAC (B) makes a reasonable monthly allowance, e.g., \$3 for the cost of supplies (i.e., syringes and needles).

20.5.9 - Annual Update of AWP Payment Allowance Limit for Vaccines (Rev. 1357, Issued: 10-26-07, Effective: 09-01-07, Implementation: 11-26-07)

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. Medicare contractors will be receiving subsequent annual updates of the vaccine payment allowance limits for influenza and pneumococcal vaccines communicated by a Recurring Update Notification.

30 - A/B MAC (B) Distribution of Limit Amounts (Rev. 1, 10-01-03)

The A/B MACs (A) get drug prices from the A/B MAC (B) for drugs not listed on the SDP.

A/B MACs (B) prepare a list of the drug payment allowance limits updates (or new file depending upon local requirements) to the claims system.

A/B MACs (B) distribute, free of charge, the updated limits in an agreed upon format directly to the A/B MACs (A) in their jurisdiction.

A/B MACs (B) should contact each A/B MAC (A) to determine the preferred method of transmission. A/B MACs (B) are to send this information to all A/B MACs (A) they routinely deal with. If this method of obtaining payment allowance updates does not work for any A/B MAC (A), the A/B MAC (B) must contact the appropriate RO office.

40 - Discarded Drugs and Biologicals

(Rev. 12511; Issued:02-15-24; Effective: 01-01-24; Implementation: 03-18-24)

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 OPSP or ASC drugs, or drugs administered in the FQHC or RHC setting.

Beginning January 1, 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.

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: <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf>

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.

40.1 - Discarded Erythropoietin Stimulating Agents for Home Dialysis (Rev. 1581; Issued: 08-29-08; Effective/Implementation Date: 12-01-08)

Multiuse vials are not subject to payment for discarded amounts of drug or biological, with the exception of self administered erythropoietin stimulating agents (ESAs) by Method I home dialysis patients. The renal facility must bill the program using the modifier JW for the amount of ESAs appropriately discarded if the home dialysis patient must discard a portion of the ESA supply due to expiration of a vial, because of interruption in the patient’s plan of care, or unused ESAs on hand after a patient’s death. Specific instructions are found in chapter 8 of this manual, §60.4.4.1 “Self Administered EPO Supply”, and §60.7.4 “Darbepoetin Alfa (Aranesp) Furnished to Home Patients”.

This applies only to home dialysis patients who meet the Method I conditions described in Pub 100-2 Benefits Policy Manual, chapter 11, §90 “Epoetin (EPO)”, and does not apply to Method II home dialysis patients.

Supplies of ESAs for self administration are billed according to the pre-determined plan of care schedule provided to home dialysis patients that meet the criteria for self administered ESAs discussed in chapter 8 of this manual, §60.4 “Epoetin Alfa (EPO) For ESRD Patients” and §60.7 “Darbepoetin Alfa (Aranesp) for ESRD Patients”. The renal facility, through the amounts prescribed in the plan of care, shall ensure the patient’s ESA on hand at any time does not exceed a 2-month supply. CMS expects the facility to minimize excess dispensing of the ESAs for self administration based on the patient’s plan of care.

50 - Assignment Required for Drugs and Biologicals **(Rev. 3721, Issued: 02-24-17, Effective: 05-25-17, Implementation: 05-25-17)**

A. A/B MACs (B)

Under §114 of the Benefits Improvement Act of 2000, effective for claims with dates of service on or after February 1, 2001, payment for any drug or biological covered under Part B of Medicare may be made only on an assignment-related basis. Therefore, no charge or bill may be rendered to anyone for these drugs and biologicals for any amount except for any applicable unmet Medicare Part B deductible and coinsurance amounts. All entities (including physicians, nonphysician practitioners, pharmacies and suppliers) that bill Medicare for drugs and biologicals must take assignment on all claims for drugs and biologicals furnished to any beneficiary enrolled in Medicare Part B. Contractors apply this policy to all items paid based on the lower of the actual charge on the claim or 95 percent of the AWP. See §§20 for a description of the AWP.

Mandatory assignment does not apply to HCPCS code E0590, which represents the dispensing fee for nebulizer drugs.

A/B MACs (B) process all claims for drugs and biologicals with a date of service on or after February 1, 2001, as though the physician or nonphysician practitioner had taken assignment. If only drugs and biologicals are billed on the claim, and the claim was submitted as unassigned, contractors change the claim to assigned and process as an assigned claim. If a physician or nonphysician practitioner submits an unassigned claim that contains both codes for drugs or biologicals and codes for other services, A/B MACs (B) split the claim into two claims. The first claim will be an unassigned claim for services other than drugs or biologicals, and the second will be an assigned claim for drugs or biologicals furnished on or after February 1, 2001. The following messages apply when an A/B MAC (B) has changed the claim to assigned status (regardless of whether the contractor had to split the claim):

The contractor shall use the following remittance advice messages and associated codes when adjusting payment under this policy. The RARC below is not included in the CAQH CORE Business Scenarios.

Group Code: N/A
CARC: N/A
RARC: MA72
MSN: 16.50

Additional appropriate message for physicians, suppliers, and beneficiaries should be added as necessary.

B. DME MACs

Under §114 of BIPA, DMEPOS suppliers must accept assignment on all claims for drugs and biologicals that they bill to the DME MACs. A supplier may not render a charge or bill to anyone for these drugs and biologicals for any amount other than the Medicare Part B deductible and coinsurance amounts.

Mandatory assignment does not apply to HCPCS code E0590, which represents the dispensing fee for nebulizer drugs.

The DME MACs must inform suppliers on their Web sites and in their next bulletins that they must accept assignment on claims for drugs and biologicals furnished on or after February 1, 2001.

The DME MACs must deny any claims a beneficiary submits for drugs and biologicals with dates of service on or after February 1, 2001. The DME MACs must notify beneficiaries that suppliers must accept assignment on claims for drugs and biologicals, and therefore, the beneficiaries may not submit claims for drugs and biologicals. When denying beneficiary-submitted claims, DME MACs use the following Medicare Summary Notice (MSN) messages:

MSN 16.6 (English): “This item or service cannot be paid unless the provider accepts assignment.”

MSN 16.6 (Spanish): “Este artículo o servicio no se pagará a menos de que el proveedor acepte asignación.”

MSN 16.7 (English): “Your provider must complete and submit your claim.”

MSN 16.7 (Spanish): “Su proveedor debe completar y someter su reclamación.”

MSN 16.34 (English): “You should not be billed for this service. You do not have to pay this amount.”

MSN 16.34 (Spanish): “Usted no debería ser facturado por este servicio. Usted no tiene que pagar esta cantidad.”

MSN 16.36 (English): “If you have already paid it, you are entitled to a refund from this provider.”

MSN 16.36 (Spanish): “Si usted ya lo ha pagado, tiene derecho a un reembolso de su proveedor.”

If a supplier submits an unassigned claim with a date of service on or after February 1, 2001, to the DME MAC for a drug or biological, the DME MAC must process the claim as though the supplier accepted assignment. It is possible that a supplier may bill drugs and other items on the same claim, which would result in a claim with some assigned and some nonassigned items.

In the event that a supplier bills an unassigned claim to a DME MAC that contains both codes for drugs or biologicals and codes for other items, the DME MACs must replicate the claim. This will result in two claims in the DME MAC system: an unassigned claim for items other than drugs or biologicals, and an assigned claim for drugs and biologicals furnished on or after February 1, 2001. When a DME MAC changes an unassigned drug claim to an assigned claim, the contractor shall use the following

remittance advice messages and associated codes when adjusting payment under this policy. The RARC below is not included in the CAQH CORE Business Scenarios

Group Code: N/A
CARC: N/A
RARC: MA72
MSN: N/A

Suppliers that bill the DME MACs for drugs for use with DMEPOS must have a pharmacy license to dispense drugs. When a DME MAC denies a claim for a drug because the National Supplier Clearing House (NSC) records do not show that the supplier has a pharmacy license, the DME MAC must also deny any equipment, accessories, and supplies related to the drug, when the supplier bills the drug on the same claim as the equipment. (Suppliers should bill drugs for use with DMEPOS on the same claim as the equipment itself, if they are also providing and billing for the equipment.) In situations when a supplier bills unassigned drugs and equipment, accessories, or supplies on the same claim, the DME MAC and VMS Shared System Maintainer must ensure that they apply nonlicensed pharmacy equipment, accessory and supply edits and denials before they replicate the claim. Even if the system denies a line due to the nonlicensed pharmacy edit prior to replicating the claim, the system must still replicate any unassigned claims for drugs and biologicals and change the assignment indicator.

The contractor shall use the following remittance advice messages and associated codes when adjusting payment under this policy. The RARC below is not included in the CAQH CORE Business Scenarios.

Group Code: N/A
CARC: N/A
RARC: MA72
MSN: N/A

OR

The contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Three.

Group Code: CO
CARC: B7
RARC: M143
MSN: N/A

Or

The contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Two.

Group Code: CO
CARC: 107
RARC: N/A
MSN: N/A

The DME MACs must work together to create and maintain a list of HCPCS drug codes that suppliers must bill on an assigned basis. This will enable VMS shared system maintainer and the DME MACs to implement the necessary edits in their systems. Finally, the four DME MACs must work together to create a list of drug and equipment codes to which the nonlicensed pharmacy edit would apply in this situation. For this second list, the DME MACs need add only drugs that are used with equipment, and the equipment, and related supplies and accessories, that use those drugs, as opposed to all drugs that are subjected to the licensure edit. The DME MACs must share these lists with VMS shared system maintainer and CMS Central Office.

60 - DMEPOS Suppliers Require a License to Dispense Drugs (Rev. 1, 10-01-03)

Regulations at 42 CFR 424.57(b)(4) (supplier standards) state that a “supplier that furnishes a drug used as a Medicare-covered supply with durable medical equipment or prosthetic devices must be licensed by the State to dispense drugs. (A supplier of drugs must bill and receive payment for the drug in its own name. A physician, who is enrolled as a DMEPOS supplier, may dispense, and bill for, drugs under this standard if authorized by the State as part of the physician’s license.)”

Therefore, suppliers may not bill the DME MACs for any Medicare-covered drugs unless they have a State license to dispense the drugs, regardless of whether or not the drugs require a prescription. Similarly, a physician may not dispense Medicare-covered prescription or nonprescription drugs unless he or she is authorized by the State to dispense such drugs as part of his or her physician’s license.

The DME MACs must deny claims for prescription drugs, and related equipment when billed on the same claim, if the National Supplier Clearinghouse’s (NSC) records show the supplier was not licensed to dispense the drug on the DOS (date of service).

In effect, for DOS on or after December 11, 2000, the DME MACs must deny claims for all Medicare-covered drugs dispensed by a supplier or physician who is not licensed to dispense the drug. If the DME MACs feel that it is necessary, they may coordinate to develop a list of drugs and related equipment that should be subjected to the licensure edit.

Note that these provisions do not apply to EPO. Method I beneficiaries must obtain their EPO through their dialysis facilities, and Method II beneficiaries must receive EPO from the same supplier that provides all their other dialysis supplies.

60.1 - Prescription Drugs Billed by Suppliers Not Licensed to Dispense Them (Rev. 3721, Issued: 02-24-17, Effective: 05-25-17, Implementation: 05-25-17)

Medicare does not cover a drug used as a supply with DME or a prosthetic device if the drug is dispensed by an entity that is not licensed to dispense the drug. The drug is not considered to be reasonable and necessary because CMS cannot be assured of its safety and effectiveness unless it is dispensed by an entity that has a State license that qualifies it to dispense the drug. The equipment used with the drugs dispensed by a nonlicensed entity is also considered to be not reasonable and necessary because of the related safety and efficacy concerns. Physicians are considered to have been “deemed” the right to dispense prescription drugs, and therefore do not require a pharmacy license.

The DME MACs should deny claims for a prescription drug (and related equipment when billed on the same claim as the drug) when the National Supplier Clearinghouse’s (NSC’s) files show the supplier is or was not licensed to dispense the drugs on the date of service (DOS).

An exception to this general policy is oxygen claims.

Messages for Assigned Claims:

The contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Three.

Group Code: CO

CARC: B7

RARC: M143

MSN: 8.50

Messages for Nonassigned Claims:

MSN: “This item or service is not covered when performed or ordered by this provider.”
(MSN #12.18)

Appeals should be addressed according to the instructions in Chapter 29.

70 - Claims Processing Requirements – General

(Rev. 11427; Issued: 05-20-22; Effective: 01-01-23; Implementation: 01-03-23)

NOTE: CMS seeks to reduce burden and modernize processes to ensure a reduction in improper payments and an increase in customer satisfaction. The Certificate of Medical Necessity (CMN) form and DME Information Form (DIF) were originally required to help document the medical necessity and other coverage criteria for selected Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items. In the past, a supplier received a signed CMN from the treating physician or created and signed a DIF to submit with the claim. Due to improvements in claims processing and medical records management, the information found on CMNs or DIFs is available either on the claim or in the medical record and is redundant. Therefore, to reduce burden and increase customer satisfaction, providers and suppliers no longer need to submit these forms for services rendered after January 1, 2023.

- **For claims with dates of service on or after January 1, 2023** – providers and suppliers no longer need to submit CMNs or DIFs with claims. Due to electronic filing requirements, claims received with these forms attached will be rejected and returned to the provider or supplier.
- **For claims with dates of service prior to January 1, 2023** – processes will not change and if the CMN or DIF is required, it will still need to be submitted with the claim, or be on file with a previous claim.

This statement applies throughout the Program Integrity Manual wherever CMNs and DIFs are mentioned.

A/B MACs (B) are billed with the ASC X12 837 professional claim format or, if approved, with the paper form CMS-1500. A/B MACs (A) are billed with the ASC X12 837 institutional claim format or, if approved, with the paper Form CMS-1450.

See Chapters 24, 25 and 26 for detailed claims processing requirements, including forms, data elements, and formats. See Chapters 21 and 22 for MSN and remittance record requirements. See the official Washington Publishing Company web site for information about ASC X12 formats and related training material.

In addition to requirements applicable to all claims the following apply to drug claims.

- On claims to A/B MACs (A) the drug is identified by the appropriate HCPCS code for the drug administered and billed under revenue code 0636 unless specific instruction states otherwise;
- On claims to A/B MACs (B) the drug is identified by HCPCS code;
- All drugs, including Prodrugs, are reported to DME MACs by National Drug Code (see §80.1.2);
- Where HCPCS is required, units are entered in multiples of the units shown in the HCPCS narrative description. For example, if the description for the code is 50 mg, and 200 mg are provided, units are shown as 4; See examples below.
- Where the NDC is required units are entered in multiples of the units shown in the NDC label description. For example, if the description for the code is 50 mg., and 200 mg are provided, units are shown as 4;
- If the units provided exceed the size of the units field, or require more characters to report than spaces available in the format, repeat the HCPCS or NDC code on multiple lines until all units can be reported;
- Covered administration codes for injections may be billed to the A/B MAC (B) and A/B MAC (A) in addition to billing for the drug. The drug maximum payment allowance is for the drug alone. However, if payment is under a PPS, such as OPPS, the injection would be included in the APC rate.

The examples below include the HCPCS code and indicate the dosage amount specified in the descriptor of that code. Facilities use the units field as a multiplier to arrive at the total dosage amount.

EXAMPLE 1

HCPCS	J7189
Drug	Factor VIIa
Dosage	1 mcg

Actual dosage: 13,365 mcg

On the bill, the facility shows J7189 and 13,365 in the units field (13,365 mcg divided by 1 mcg = 13,365 units).

NOTE: The process for dealing with one international unit (IU) is the same as the process of dealing with one microgram.

EXAMPLE 2

HCPCS	J9355
Drug	Trastuzumab
Dosage	10 mg

Actual dosage: 140 mg

On the bill, the facility shows J9355 and 14 in the units field (140 mg divided by 10mg = 14 units).

When the dosage amount is greater than the amount indicated for the HCPCS code, the facility rounds up to determine units. When the dosage amount is less than the amount indicated for the HCPCS code, use 1 as the unit of measure.

EXAMPLE 3

HCPCS	J3100
Drug	Tenecteplase
Dosage	50 mg

Actual Dosage: 40 mg

The provider would bill for 1 unit, even though less than 1 full unit was furnished.

See §10 for a description of drug payment rules.

70.1 - Billing Drugs Electronically - NCPDP

(Rev. 3085, Issued: 10-03-14, Effective: ICD-10: Upon Implementation of ICD-10; ASC X12: January 1, 2012, Implementation: ICD-10: Upon Implementation of ICD-10; ASC X12: November 4, 2014)

The National Council for Prescription Drug Programs (NCPDP) Telecommunications Standard Version D.0 and Batch Standard 1.2 is the HIPAA standard for electronic retail pharmacy drug claims and coordination of benefits (COB). See the NCPDP web site at <http://www.ncpdp.org> for additional information.

DME MACs that process retail pharmacy drug transactions require their retail pharmacy claimants to use this standard. Retail pharmacies must use the ASC X12 837 professional claim format to submit claims other than retail pharmacy claims to the DME MACs.

DME MACs and VMS shall accommodate quarterly and monthly NDC crosswalk updates as needed. DME MACs shall provide such crosswalks to CEDI.

DME MACs and CEDI shall reject NDC codes that have been deactivated/end dated.

A - Requirements for Implementing the NCPDP Standard

Retail pharmacies are identified by a value of A5 in the specialty code as received by the National Supplier Clearinghouse. Only suppliers with an A5 specialty code may use the NCPDP standard. DME MACs, EDI submitters, and other DME MAC trading partners are required to transmit the NDCs in the NCPDP standards for identification of prescription drugs dispensed through a retail pharmacy. NDCs replace the drug HCPCS codes for retail pharmacy drug transactions billed via the NCPDP standards.

B - Certificate of Medical Necessity (CMN)

The CMN for Parenteral Nutrition (Form CMS-852) is required. The DME Information Form for Immunosuppressive Drugs (Form DMERC-08.02) is not required when billing for immunosuppressive drugs with dates of service on or after April 1, 2006. As with other electronic formats, CMN data must be submitted within the valid transaction.

For claims submitted on the paper Form CMS-1500, retail pharmacies will continue to supply hard copy CMNs when required.

C - NCPDP Companion Document

The NCPDP Companion Guide is available at:

<http://www.cms.gov/Medicare/Billing/ElectronicBillingEDITrans/downloads/NCPDPD0CG.pdf>

CEDI provides supplemental instructions as needed to retail pharmacy drug claim submitters (either provider, billing agent, or clearinghouse) that will submit retail pharmacy drug claims to Medicare electronically.

70.1.1 - Reporting Modifiers in the Compound Drug Segment **(Rev. 1, 10-01-03)**

Certain informational modifiers are required on compound ingredients. The NCPDP format does not currently support reporting modifiers in the compound segment. Therefore, the narrative portion in the prior authorization segment must be used to report these modifiers. The following must be entered in positions 001-003 of the narrative (Example, MMN or MNF). Starting at position 355, indicate the two-byte ingredient number followed by the two-position modifier:

MMN - Indicates that the Supporting documentation that follows is Medicare modifier information and CMN information or DIF information

MNA - Indicates that the Supporting documentation that follows is Medicare modifier information, CMN information or DIF information and narrative information

MFA - Indicates that the Supporting documentation that follows is Medicare modifier information, CMN information or DIF information and Facility Name and Address

MNF - Indicates that the Supporting documentation that follows is Medicare modifier information, CMN information or DIF information, narrative information and Facility Name and Address

MAC - Indicates that the Supporting documentation that follows is Medicare modifier information and Facility Name and Address

MAN - Indicates that the Supporting documentation that follows is Medicare modifier information, narrative information and Facility Name and Address

MAR - Indicates that the Supporting documentation that follows is Medicare modifier information and narrative information

70.1.2 - Coordination of Benefits (COB) (Rev. 1, 10-01-03)

The NCPDP has approved the following use of qualifiers for reporting Medicare COB amounts:

Qualifier	Description
07	Medicare Allowed Amount
08	Medicare Paid Amount
99	1 st Occurrence - Deductible Amount
99	2 nd Occurrence - Coinsurance Amount
99	3 rd Occurrence - Co-Payment Amount

70.1.3 - Inbound NCPDP Claim (Rev. 1, 10-01-03)

The DME MAC needs to be able to determine whether a beneficiary has Medicaid coverage and in which state. In order to determine this, the provider must enter the two position state alpha code followed by the word "MEDICAID" in the Group ID field (Example, NYMEDICAID or FLMEDICAID). Therefore, "XXMEDICAID" must be accepted in the Group ID field (301-C1) in order to allow DME MAC's to determine that a beneficiary has Medicaid coverage in that specific state.

80 - Claims Processing for Special Drug Categories

(Rev. 1, 10-01-03)

NOTE: Preventive vaccines, influenza, pneumococcal and hepatitis B, 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.

80.1 - Oral Cancer Drugs

(Rev. 1, 10-01-03)

A3 3660.13, SNF 536.1

Effective January 1, 1994, oral self administered versions of covered injectable cancer drugs furnished may be paid if other coverage requirements are met. To be covered the drug must have had the same active ingredient as the injectable drug. Effective January 1, 1999, this coverage was expanded to include FDA approved Prodrugs used as anti-cancer drugs. A Prodrug may have a different chemical composition than the injectable drug but body metabolizing of the Prodrug results in the same chemical composition in the body.

80.1.1 - HCPCS Service Coding for Oral Cancer Drugs

(Rev. 1, 10-01-03)

The following codes may be used for drugs other than Prodrugs, when covered:

Generic/Chemical Name	How Supplied	HCPCS
Busulfan	2 mg/ORAL	J8510
Capecitabine	150mg/ORAL	J8520
Capecitabine	500mg/ORAL	J8521
Methotrexate	2.5 mg/ORAL	J8610
Cyclophosphamide *	25 mg/ORAL	J8530
Cyclophosphamide * (Treat 50 mg. as 2 units)	50 mg/ORAL	J8530
Etoposide	50 mg/ORAL	J8560
Melphalan	2 mg/ORAL	J8600
Prescription Drug chemotherapeutic NOC	ORAL	J8999

Each tablet or capsule is equal to one unit, except for 50 mg/ORAL of cyclophosphamide (J8530), which is shown as 2 units. The 25mg and 50 mg share the same code.

NOTE: HIPAA requires that drug claims submitted to DME MACs be identified by NDC.

80.1.2 - HCPCS and NDC Reporting for Prodrugs

(Rev. 136, 04-09-04)

A/B MAC (A) claims

For oral anti-cancer Prodrugs HCPCS code J8999 is reported with revenue code 0636.

DME MAC claims

The supplier reports the NDC code on the claim. The DME MAC converts the NDC code to a “WW” HCPCS code for CWF. As new “WW” codes are established for oral anti-cancer drugs they will be communicated in a Recurring Update Notification.

80.1.3 - Other Claims Processing Issues for Oral Cancer Drugs (Rev. 1, 10-01-03)

Deductible and coinsurance apply.

A cancer diagnosis code must be reported when billing for these HCPCS codes. If there is no cancer diagnosis the claims is denied.

The number of tablets or capsules is reported as units.

80.1.4 - MSN/Claim Adjustment Message Codes for Oral Cancer Drug Denials (Rev. 3721, Issued: 02-24-17, Effective: 05-25-17, Implementation: 05-25-17)

If the claim for an oral cancer drug is denied because it was not approved by FDA, is not considered to be a medically accepted treatment for cancer, or is not the chemical equivalent of a covered injectable cancer drug (or a covered Prodrug), use the appropriate message on the MSN.

The contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Three.

Group Code: CO
CARC: 114
RARC: N/A
MSN: 6.2, 6.3

80.2 - Oral Anti-Emetic Drugs Used as Full Replacement for Intravenous Anti-Emetic Drugs as Part of a Cancer Chemotherapeutic Regimen (Rev. 2931, Issued: 04-15-14, Effective: 05-29-13, Implementation: 07-07-14)

See the Medicare Benefit Policy Manual, Chapter 15, and the National Coverage Determination (NCD) Manual, Section 110.18, for detailed coverage requirements.

Effective for dates of service on or after January 1, 1998, Medicare Part B (including institutional claims processed by A/B MACs (A) and physician/supplier claims processed by DME MACs) pays for oral anti-emetic drugs when used as full therapeutic replacement for intravenous dosage forms as part of a cancer chemotherapeutic regimen when the drug(s) is administered or prescribed by a physician for use immediately before, at, or within 48 hours after the time of administration of the chemotherapeutic agent.

The allowable period of covered therapy includes day 1, the date of service of the chemotherapy drug (beginning at the time of treatment), plus a period not to exceed 2 additional calendar days, or a maximum period up to 48 hours. Some drugs are limited to 24 hours; some to 48 hours. The hour limit

is included in the narrative description of the Health Care Common Procedure Coding System (HCPCS) code.

The oral, 3-drug combination is aprepitant, a 5HT₃ antagonist, e.g. granisetron, ondansetron, or dolasetron, and dexamethasone, a corticosteroid.

The oral anti-emetic drug(s) should be prescribed only on a per chemotherapy treatment basis. For example, only enough of the oral anti-emetic(s) for one 24- or 48-hour dosage regimen (depending upon the drug) should be prescribed/supplied for each incidence of chemotherapy treatment. The 3-drug combination protocol requires the first dose to be administered before, during, or immediately after the anti-cancer chemotherapy administration. The second day is defined as “within 24 hours” and the third day is defined as “within 48 hours” of the chemotherapy administration. These drugs may be supplied by the physician in the office, by an inpatient or outpatient provider (e.g., hospital, critical access hospital (CAH), skilled nursing facility (SNF), or through a supplier (e.g., a pharmacy).

The physician must indicate on the prescription that the beneficiary is receiving the oral anti-emetic drug(s) as a full therapeutic replacement for an intravenous anti-emetic drug as part of a cancer chemotherapeutic regimen. Where the drug is provided by a facility, the beneficiary’s medical record maintained by the facility must be documented to reflect that the beneficiary is receiving the oral anti-emetic drug(s) as full therapeutic replacement for an intravenous anti-emetic drug as part of a cancer chemotherapeutic regimen. All other indications or combinations for the use of oral aprepitant that are not noted in the NCD Manual Pub. 100-03 chapter 1, section 110.18, are non-covered under Medicare Part B, but may be considered for payment under Medicare Part D.

Payment for drugs used as a full replacement for intravenous anti-emetic drugs is made under Part B. Beginning January 1, 2005, the payment allowance limit for these Part B drugs (the term “drugs” includes biologicals) will be based on the Average Sales Price (ASP) plus 6%. Hospital outpatient department providers may either:

(1) Bill all doses of the 3-drug oral regimen that will be given in a 3-day period, including the entire Tri-Pak (3 days of aprepitant, 57 units of J8501) as well as the oral dexamethasone and oral 5HT₃ antagonist to the A/B MAC (A), or (2) Bill the first day’s supply of aprepitant along with an oral 5HT₃ antagonist and oral dexamethasone to their A/B MAC (A), and give a prescription for remaining doses of the regimen, for example the second and third days’ supply of aprepitant and oral dexamethasone, which must be billed to the DME MAC.

When billed to the A/B MAC (A), all three drugs in the combination oral anti-emetic must be on the same claim. Providers subject to the hospital outpatient PPS will be paid on the basis of an APC. If the hospital outpatient department dispenses the aprepitant for days two and three to the beneficiary and bills the DME MAC for the take home drugs, the hospital’s billing department should review all instructions for billing oral anti-emetics. Follow this link to reach the local coverage determination (LCD) for oral anti-emetics:

http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=5058&lcd_version=27&show=all

In the case of IV Emend (HCPCS code J1453 - injection, fosaprepitant, 1 mg) provided on day 1, payment for days 2 and 3 would not be made under Part B.

Payment allowances for these drugs dispensed in physician offices will be based on the lower of the submitted charge or the ASP file price. These drugs continue to be priced based on the date of service.

The drug payment allowance limit pricing file is distributed to contractors by the Centers for Medicare & Medicaid Services (CMS) on a quarterly basis.

The HCPCS codes shown in section 80.2.1 are used.

The common working file (CWF) edits claims with these codes to assure that the beneficiary is receiving the oral anti-emetic(s) as part of a cancer chemotherapeutic regimen by requiring a diagnosis code of an encounter for antineoplastic chemotherapy (V58.11/Z51.11).

Most drugs furnished as an outpatient hospital service are packaged under OPPS. However, chemotherapeutic agents and the supportive and adjunctive drugs used with them are paid separately.

Effective for dates of service on or after April 4, 2005, coverage for the use of the oral anti-emetic 3-drug combination of aprepitant (Emend®), a 5-HT₃ antagonist, and dexamethasone is considered reasonable and necessary for only those patients who are receiving one or more of the following anti-cancer chemotherapeutic agents:

- Carmustine
- Cisplatin
- Cyclophosphamide
- Dacarbazine
- Mechlorethamine
- Streptozocin
- Doxorubicin
- Epirubicin
- Lomustine

Effective for services on or after May 29, 2013, the following anti-cancer chemotherapeutic agents have been added to the list of anticancer chemotherapeutic agents for which the use of the oral antiemetic 3-drug combination of oral aprepitant, an oral 5HT₃ antagonist and oral dexamethasone is deemed reasonable and necessary:

- Alemtuzumab
- Azacitidine
- Bendamustine
- Carboplatin
- Clofarabine
- Cytarabine
- Daunorubicin
- Idarubicin
- Ifosfamide
- Irinotecan
- Oxaliplatin

MACs may determine coverage for other all-oral 3-drug anti-emesis regimens of aprepitant or any other Food and Drug Administration (FDA) approved oral NK-1 antagonist in combination with an oral 5HT₃ antagonist and oral dexamethasone with the chemotherapeutic agents listed above, or any other anti-cancer chemotherapeutic agents that are FD- approved and are defined as highly or moderately emetogenic. See the Medicare NCD Manual, Section 110.18, for detailed coverage requirements.

80.2.1 - HCPCS Codes for Oral Anti-Emetic Drugs

(Rev. 3085, Issued: 10-03-14, Effective: ICD-10: Upon Implementation of ICD-10; ASC X12: January 1, 2012, Implementation: ICD-10: Upon Implementation of ICD-10; ASC X12: November 4, 2014)

The physician/supplier bills for these drugs with the ASC X12 837 professional claim format, or if approved, with the paper form CMS-1500. The facility bills with the ASC X12 837 institutional claim format, or if approved, with the paper Form CMS-1450. The following HCPCS codes are assigned:

Code	Description
J8501	APREPITANT, oral, 5 mg (Note: HCPCS code is effective January 1, 2005, but coverage for aprepitant is effective April 4, 2005. Aprepitant is only covered in combination with a 5HT3 antagonist, and dexamethasone for beneficiaries who have received one or more of the specified anti-cancer chemotherapeutic agents.)
Q0161	CHLORPROMAZINE HYDROCHLORIDE 5mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
Q0162	ONDANSETRON 1mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
Q0163	DIPHENHYDRAMINE HYDROCHLORIDE, 50mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at time of chemotherapy treatment not to exceed a 48-hour dosage regimen.
Q0164	PROCHLORPERAZINE MALEATE, 5mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
Q0165	PROCHLORPERAZINE MALEATE, 10mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
Q0166	GRANISETRON HYDROCHLORIDE, 1mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 24-hour dosage regimen.
Q0167	DRONABINOL 2.5mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
Q0168	RONABINO 5mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
Q0169	PROMETHAZINE HYDROCHLORIDE, 12.5mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
Q0170	PROMETHAZINE HYDROCHLORIDE, 25mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

Code	Description
Q0171	CHLORPROMAZINE HYDROCHLORIDE, 10mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
Q0172	CHLORPROMAZINE HYDROCHLORIDE, 25mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
Q0173	TRIMETHOBENZAMIDE HYDROCHLORIDE, 250mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
Q0174	THIETHYLPERAZINE MALEATE, 10mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
Q0175	PERPHENAZINE 4mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
Q0176	PERPHENAZINE, 8mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hours dosage regimen.
Q0177	HYDROXYZINE PAMOATE, 25mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
Q0178	HYDROXYZINE PAMOATE, 50mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
Q0179	ONDANSETRON mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.
Q0180	DOLASETRON MESYLATE, 100mg, oral, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 24-hour dosage regimen.
Q0181	UNSPECIFIED ORAL DOSAGE FORM, FDA-approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen.

NOTE: The 24-hour maximum drug supply limitation on dispensing, for HCPCS Codes Q0166 and Q0180, has been established to bring the Medicare benefit as it applies to these two therapeutic entities in conformity with the “Indications and Usage” section of currently FDA-approved product labeling for each affected drug product.

**80.2.2 - Claims Processing Jurisdiction for Oral Anti-Emetic Drugs
(Rev. 2931, Issued: 04-15-14, Effective: 05-29-13, Implementation: 07-07-14)**

The following chart shows which drugs are billed to the A/B MAC (A) or (B) and which drugs are billed to the DME MAC.

Per the Balanced Budget Act of 1997, effective for claims with dates of service on or after January 1, 1998, the claims processing jurisdiction rules in Chart 1 apply. Effective July 1, 2006, claims from institutional (hospital) pharmacies are also billed as shown in this chart.

CHART 1

COMBINATION	JURISDICTION
Oral anti-cancer chemotherapy drug with oral anti-emetic drug	<p>DME MAC maintains processing responsibility for the National Drug Code (NDC) oral anti-cancer chemotherapy drug and the K0415 oral anti-emetic drug code combinations.</p> <p>DME MAC processes the NDC oral anti-cancer chemotherapy drug and Q code oral anti-emetic drug(s) when provided in the physician's office. A/B MAC (A) processes the 3-drug combination anti-emetic (Aprepitant) in the form of a Tri-Pak when dispensed by a hospital.</p> <p>A/B MAC (A) processes the initial days' supply of the 3-drug anti-emetic combination when a hospital dispenses it and writes a prescription for the second and third days' supply.</p> <p>DME MAC processes the second and third days' supply of the 3-drug anti-emetic combination.</p> <p>DME MAC processes the NDC oral anti-cancer chemotherapy drug and/or Q code oral anti-emetic drug(s) when supplied by a pharmacy, including a hospital pharmacy.</p>
Oral anti-cancer chemotherapy drug with rectal anti-emetic drug	DME MAC maintains responsibility for processing both the NDC oral anti-cancer chemotherapy drug and the K0416 rectal anti-emetic drug.
Oral anti-cancer chemotherapy drug with intravenous anti-emetic drug	DME MAC maintains responsibility for processing the NDC oral anti-cancer chemotherapy drug and the A/B MAC (B) or A/B MAC (A) for processing the intravenous anti-emetic J code drug(s).
Intravenous anti-cancer chemotherapy drug with oral anti-emetic drug	A/B MAC (B) processes the intravenous J code anti-cancer chemotherapy drug. The oral anti-emetic Q code drug(s) is processed by the DME MAC when provided in the physician's office, hospital, or when provided by a supplier.
Intravenous anti-cancer chemotherapy drug with intravenous anti-emetic drug	A/B MAC (B) processes both intravenous anti-cancer chemotherapy J code drug and intravenous anti-emetic J code drug(s).

Providers (HIPAA definition) that bill the DME MAC require a supplier number issued by the National Supplier Clearinghouse (NSC) in order to submit claims. A/B MACs (A) and (B) should instruct providers without a supplier number to contact the NSC service center at 1-866-238-9652 to request an enrollment package for a supplier number. Alternatively, providers may go to the CMS Web site, <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/EnrollmentApplications.html> and download the Form CMS-855-S in Adobe Acrobat format. The application can be completed hard copy and submitted to the NSC.

80.2.3 - MSN Denial /Claim Adjustment and Remark Messages for Anti-Emetic Drugs

(Rev. 3721, Issued: 02-24-17, Effective: 05-25-17, Implementation: 05-25-17)

If the claim for an anti-emetic drug is denied because FDA did not approve it, the contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Three.

Group Code: CO
CARC: 114
RARC: N/A
MSN: 6.2

If the claim for an anti-emetic drug is denied because the drug is not being used as part of an anticancer chemotherapeutic regimen, the contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Three.

Group Code: CO
CARC: 96
RARC: M100
MSN: 6.4

80.2.4 - Billing and Payment Instructions for A/B MACs (A)

(Rev. 3085, Issued: 10-03-14, Effective: ICD-10: Upon Implementation of ICD-10; ASC X12: January 1, 2012, Implementation: ICD-10: Upon Implementation of ICD-10; ASC X12: November 4, 2014)

Claims for the oral anti-emetic drug aprepitant, either as a 3-day supply dispensed in a Tri-Pak or as the first day supply (not dispensed in a Tri-Pak), must be billed to the A/B MAC (A) on the ASC 837 institutional claim format or on hard copy Form CMS-1450 with the appropriate cancer diagnosis and HCPCS code or Current Procedural Terminology (CPT) code.

Claims for the second and third dose of the oral anti-emetic drug aprepitant not dispensed in a Tri-Pak must be billed to the DME MAC.

The following payment methodologies apply when hospital and SNF outpatient claims are processed by the A/B MAC (A):

- Based on APC for hospitals subject to the outpatient prospective payment system (OPPS);
- Under current payment methodologies for hospitals not subject to OPPS; or
- On a reasonable cost basis for SNFs.

Institutional providers bill for aprepitant under Revenue Code 0636 (Drugs requiring detailed coding).

NOTE: Inpatient claims submitted for oral anti-emetic drugs are processed under the current payment methodologies.

Medicare contractors shall pay claims submitted for services provided by a CAH as follows: Method I technical services are paid at 101% of reasonable cost; Method II technical services are paid at 101% of reasonable cost, and, Professional services are paid at 115% of the Medicare Physician Fee Schedule Data Base.

80.3 - Billing for Immunosuppressive Drugs

(Rev.11764, Issued: 12-22-2022; Effective:01-01-23; Implementation:01-03-23)

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 430.10 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 OPPTS, 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. 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.
 1. Medicare's payment for the claim.

80.3.1 - Requirements for Billing A/B MAC (A) for Immunosuppressive Drugs

(Rev. 3085, Issued: 10-03-14, Effective: ICD-10: Upon Implementation of ICD-10; ASC X12: January 1, 2012, Implementation: ICD-10: Upon Implementation of ICD-10; ASC X12: November 4, 2014)

Hospitals not subject to OPSS bill on ASC X12 837 institutional claim format or paper Form CMS-1450 (if approved) with bill type 12x (hospital inpatient Part B) or 13x (hospital outpatient) as appropriate.

For claims with dates of service prior to April 1, 2000, providers report the following entries:

- Occurrence code 36 and date;
- Revenue code 0250; and
- Narrative description.

NOTE: Information regarding the claim form locators that correspond with these fields is found in Chapter 25.

For claims with dates of service on or after April 1, 2000, hospitals report:

- Occurrence code 36 and date;
- Revenue code 0636;
- HCPCS code of the immunosuppressive drug; and
- Number of units (the number of units billed must accurately reflect the definition of one unit of service in each code narrative. E.g.,: If fifty 10-mg. Prednisone tablets are dispensed, the hospital bills J7506, 100 units (1 unit of J7506 = 5 mg.).

NOTE: Information regarding the claim form locators that correspond with these fields is found in Chapter 25.

The hospital completes the remaining items in accordance with regular billing instructions.

80.3.2 - MSN/Remittance Messages for Immunosuppressive Drugs **(Rev. 3721, Issued: 02-24-17, Effective: 05-25-17, Implementation: 05-25-17)**

Remittance codes/messages for denied Immunosuppressive Drugs are as follows:

If the immunosuppressive drug is not approved by the FDA, contractor shall deny the claim. The contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Three.

Group Code: CO
CARC: 114
RARC: N.A
MSN: 6.2

If the claim is denied because the benefit period has expired or because of the 30 day limitation, the contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Three.

Group Code: CO
CARC: 35
RARC: N.A
MSN: 4.3

If the claim is denied for the immunosuppressive drug because a transplant was not covered, the contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Two.

Group Code: CO
CARC: 107
RARC: N.A
MSN: N/A

80.3.3 – Special Requirements for Immunosuppressive Drugs

(Rev. 3932, Issued: 12-08-17, Effective: 08-01-16, Implementation: 03-09-18)

Inpatient facilities (for example hospitals) are responsible for providing drugs during a beneficiary's inpatient stay. However, once the beneficiary has returned home, Part B suppliers (including pharmacies) provide immunosuppressive drugs, and the DME MACs make payments for Part B covered immunosuppressive drugs.

Under normal circumstances, the date of service listed on a supplier's claim must be the date the supplier actually delivered or mailed the item. However, suppliers that utilize mail-order delivery may wish to mail immunosuppressive drug prescriptions one or two days prior to the date that a beneficiary will be discharged from an inpatient facility, so that the drugs will be available at the beneficiary's home immediately after the beneficiary returns. In this situation, the systems will reject the supplier's immunosuppressive drug claim because the date of service precedes the beneficiary's

date of discharge; the hospital remains responsible for the provision of immunosuppressive drugs while the beneficiary is still an inpatient.

In order to obtain payment for immunosuppressive drug prescriptions that have been mailed one or two days before a beneficiary's discharge, the supplier may enter the date of discharge as the date of service on the first claim it submits for the beneficiary after the beneficiary is discharged from an inpatient facility. Note that this is an optional, not mandatory, process. If the supplier chooses not to mail the immunosuppressive drug(s) prior to the beneficiary's date of discharge from the hospital, they may wait for the beneficiary to be discharged before delivering the drugs, and follow all applicable Medicare and DME MAC rules for immunosuppressive drug billing (for example, the date of service will be the date of delivery).

Note that the following conditions also apply:

- 1) The facility remains responsible for all immunosuppressive drugs required by the beneficiary for the duration of the beneficiary's inpatient stay. The supplier must not receive separate payment for immunosuppressive drugs prior to the date the beneficiary is discharged.
- 2) The supplier must not mail or otherwise dispense the drugs any earlier than 2 days before the beneficiary is discharged. It is the supplier's responsibility to confirm the beneficiary's discharge date if they choose to take advantage of this option.
- 3) The supplier must not submit a claim for payment prior to the beneficiary's date of discharge.
- 4) The beneficiary's discharge must be to a qualified place of service (for example, home, or custodial facility), but not to another facility (for example, inpatient hospital or skilled nursing facility) that does not qualify as the beneficiary's home.

80.4 - Billing for Hemophilia Clotting Factors

(Rev. 1564, Issued: 07-25-08, Effective: 04-01-08, Implementation: 01-05-09)

Blood clotting factors not paid on a cost or prospective payment system basis are priced as a drug/biological under the drug pricing fee schedule effective for the specific date of service. As of January 1, 2005, the average sales price (ASP) plus 6 percent shall be used.

If a beneficiary is in a covered part A stay in a PPS hospital, the clotting factors are paid in addition to the DRG/HIPPS payment. For FY 2005, this payment is based on 95 percent of AWP. For FY 2006, the add-on payment for blood clotting factor administered to hemophilia inpatients is based on average sales price (ASP) + 6 percent and a furnishing fee. The furnishing fee is updated each calendar year. For a SNF subject to SNF/PPS, the payment is bundled into the SNF/PPS rate.

For hospitals subject to OPPS, the clotting factors, when paid under Part B, are paid the APC. For SNFs the clotting factors, when paid under Part B, are paid based on cost.

A/B MACs (B) shall process non-institutional blood clotting factor claims.

The A/B MACs (A) shall process institutional blood clotting factor claims (Part A and Part B institutional).

80.4.1 - Clotting Factor Furnishing Fee

(Rev. 12201; Issued:08-10-23; Effective: 01-01-24; Implementation: 01-02-24)

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.

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

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.

80.5 - Self-Administered Drugs

(Rev. 1539; Issued: 06-20-08; Effective/Implementation Date: 07-21-08)

See Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, section 50.2.

80.6 - Intravenous Immune Globulin

(Rev. 3085, Issued: 10-03-14, Effective: ICD-10: Upon Implementation of ICD-10; ASC X12: January 1, 2012, Implementation: ICD-10: Upon Implementation of ICD-10; ASC X12: November 4, 2014)

Beginning for dates of service on or after January 1, 2004, Medicare pays for intravenous immune globulin administered in the home. (See the Medicare Benefit Policy Manual, Chapter 15 for coverage requirements.) Contractors pay for the drug, but not the items or services related to the administration of the drug when administered in the home, if deemed medically appropriate.

Contractors may pay any entity licensed in the State to furnish intravenous immune globulin. Payment will be furnished to the entity with the authority to furnish the drug. intravenous immune globulin Beneficiaries are ineligible to receive payment for the drug.

Pharmacies and hospitals dispensing intravenous immune globulin for home use would bill the DME MAC. If the beneficiary is receiving treatment in an outpatient hospital, the bill must be sent to the A/B MAC (A). If the beneficiary is receiving treatment in a physician's office, the bill must be sent to the A/B MAC (B). Home Health Agencies dispensing intravenous immune globulin would bill the A/B MAC (HHH). Physicians furnishing intravenous immune globulin for the refilling of an external pump for home infusion would bill the DME MAC.

Effective January 1, 2006, Medicare makes an additional payment once per day per beneficiary for preadministration-related services whenever a beneficiary receives intravenous immune globulin.

80.7 - Pharmacy Supplying Fee and Inhalation Drug Dispensing Fee

(Rev. 754, Issued: 11-10-05, Effective: 01-01-06, Implementation: 01-03-06)

Section 303(e) (2) of the MMA implements 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 paid a separately billable supplying fee of \$24.00 to a pharmacy, dialysis facility in the State of

Washington or any hospital outpatient department not subject to the OPSS for each supplied prescription of the above-mentioned drugs. In addition, Medicare also paid a separately billable supplying fee of \$50.00 for the initial supplied prescription of the immunosuppressive drugs during the first month following the patient's transplant.

Effective January 1, 2006, we are changing the supplying fee when multiple prescriptions are supplied in a 30-day period. Medicare will pay \$24 for the first prescription of the above-mentioned drugs supplied by a pharmacy in a 30-day period, and will pay \$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 for the first immunosuppressive prescription after a transplant.

We are also changing the dispensing fee for inhalation drugs furnished through durable medical equipment. 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. Except in those circumstances where an initial 30-day dispensing fee is applicable, Medicare will pay 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 will pay 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:

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

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

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

Q0512 - Pharmacy supplying fee for immunosuppressive, oral anti-cancer, and oral anti-emetic drugs - each subsequent prescription in a 30-day period. 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 \$33.00 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 \$66.00 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.

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

Effective January 1, 2006, Medicare will pay an initial dispensing fee of \$57.00 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.

80.8 - Reporting of Hematocrit and/or Hemoglobin Levels (Rev. 3721, Issued: 02-24-17, Effective: 05-25-17, Implementation: 05-25-17)

Effective January 1, 2008, the following claims must report the most recent hematocrit or hemoglobin reading:

1. All claims billing for the administration of an ESA (HCPCS J0881, J0882, J0885, J0886 and Q4081).
2. All claims for the administration of a Part B anti-anemia drug (other than ESAs) used in the treatment of cancer that are not self-administered.

For institutional claims the hemoglobin reading is reported with a value code 48 and a hematocrit reading is reported with the value code 49. Claims not reporting a value code 48 or 49 will be returned to the provider.

For professional paper claims, test results are reported in item 19 of the Form CMS-1500 claim form. For electronic claims (ASC X12 837 professional claim format), providers report the hemoglobin or hematocrit readings in Loop 2400 MEA segment. The specifics are MEA01=TR (for test results), MEA02=R1 (for hemoglobin) or R2 (for hematocrit), and MEA03=the test results.

Effective for dates of service on and after January 1, 2008, contractors will return paper and electronic professional claims when the most recent hemoglobin or hematocrit test results are not reported.

The contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Two.

Group Code: CO
CARC: 16
RARC: N764
MSN: N/A

80.9 - Required Modifiers for ESAs Administered to Non-ESRD Patients (Rev. 3721, Issued: 02-24-17, Effective: 05-25-17, Implementation: 05-25-17)

Effective January 1, 2008, all non-ESRD claims billing HCPCS J0881 and J0885 must begin reporting one of the following modifiers:

EA: ESA, anemia, chemo-induced

EB: ESA, anemia, radio-induced
EC: ESA, anemia, non-chemo/radio

Institutional claims that do not report one of the above modifiers will be returned to the provider.

Professional claims that are billed without the required modifiers will be returned as unprocessable.

The contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Two.

Group Code: CO
CARC: 4
RARC: N/A
MSN: N/A

ESAs administered for more than one of the indicated therapies are billed as separate line items (i.e., ESAs for chemo-induced anemia (EA modifier) are reported as separate line items (e.g., J0881EA); ESAs for radio-induced anemia (EB modifier) are reported as separate line items (e.g., J0885EB); ESAs for non-chemo/radio induced anemia (EC modifier) are reported as separate line items (e.g., J0881EC). Only one of the three ESA modifiers may be reported at the line item level.

To return HCPCS J0881 or J0885 billed with more than one ESA modifier at the line item level, the contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Two.

Group Code: CO
CARC: 16
RARC: N63
MSN: N/A

80.10 - Hospitals Billing for Epoetin Alfa (EPO) and Darbepoetin Alfa (Aranesp) for Non-ESRD Patients
(Rev. 1412, Issued: 01-11-08, Effective: 01-01-08, Implementation: 04-07-08)

NOTE: For EPO and Aranesp billing instructions for beneficiaries with ESRD, see the Claims Processing Manual, Chapter 8, sections 60.4 and 60.7.

For patients with chronic renal failure who are not yet on a regular course of dialysis, EPO and Aranesp administered in a hospital and billed as an outpatient service on type of bill 13x or inpatient Part B bill type 12x are paid under the Outpatient Prospective Payment System (OPPS). Non-OPPS hospitals are paid on reasonable charges.

Hospitals report charges under revenue code 0636. For EPO, hospitals report charges under revenue code 0636 with HCPCS code J0885 effective January 1, 2006. Aranesp is reported with HCPCS code J0881 effective January 1, 2006.

80.11 - Requirement for Providing Route of Administration Codes for Erythropoiesis Stimulating Agents (ESAs)
(Rev. 1212; Issued: 03-30-07; Effective: 01-01-07; Implementation: 06-29-07)

Patients with end stage renal disease (ESRD) receiving administrations of erythropoiesis stimulating agents (ESA), such as epoetin alfa (EPO) and Darbepoetin alfa (Aranesp) for the treatment of anemia may receive intravenous administration or subcutaneous administrations of the ESA.

Effective for claims submitted on or after February 1, 2007 with dates of services on or after January 1, 2007, all providers billing for injections of ESA for ESRD beneficiaries are encouraged to include the modifier JA on the claim to indicate an intravenous administration or modifier JB to indicate a subcutaneous administration. All providers billing for injections of ESAs for ESRD beneficiaries will be required to include route of administration when claims processing system changes are completed. Renal dialysis facilities claim including charges for administrations of the ESA by both methods must report separate lines to identify the number of administration provided using each method.

80.12 - Claims Processing Rules for ESAs Administered to Cancer Patients for Anti-Anemia Therapy
(Rev. 3721, Issued: 02-24-17, Effective: 05-25-17, Implementation: 05-25-17)

The national coverage determination (NCD) titled, “The Use of ESAs in Cancer and Other Neoplastic Conditions” lists coverage criteria for the use of ESAs in patients who have cancer and experience anemia as a result of chemotherapy or as a result of the cancer itself. The full NCD can be viewed in Publication 100-03 of the NCD Manual, section 110.21.

Effective for claims with dates of service on and after January 1, 2008, non-ESRD ESA services for HCPCS J0881 or J0885 billed with modifier EC (ESA, anemia, non-chemo/radio) shall be denied when any one of the following diagnosis codes is present on the claim:

ICD-9-CM Applicable

- any anemia in cancer or cancer treatment patients due to folate deficiency (281.2),
- B-12 deficiency (281.1, 281.3),
- iron deficiency (280.0-280.9),
- hemolysis (282.0, 282.2, 282.9, 283.0, 283.2, 283.9-283.10, 283.19), or
- bleeding (280.0, 285.1),

- anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML) (205.00-205.21, 205.80-205.91); or
- erythroid cancers (207.00-207.81).

ICD-10-CM Applicable

- any anemia in cancer or cancer treatment patients due to folate deficiency - (D52.0, D52.1, D52.8, or D52.9),
- B-12 deficiency - (D51.1, D51.2, D51.3, D51.8, D51.9, or D53.1),
- iron deficiency - (D50.0, D50.1, D50.8, and D50.9),
- hemolysis - (D55.0, D55.1, D58.0, D58.9, D59.0, D59.1, D59.2, D59.4, D59.5, D59.6, D59.8, or D59.9),
- bleeding - (D50.0, D62),
- anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML) - (C92.00, C92.01, C92.02, C92.10, C92.11, C92.12, C92.20, C92.21, C92.40, C92.41, C92.42, C92.50, C92.51, C92.52, C92.60, C92.61, C92.62, C92.90, C92.91, C92.A0, C92.A1, C92.A2, C92.Z0, C92.Z1, or C92.Z2), or
- erythroid cancers - (C94.00, C94.01, C94.02, C94.20, C94.21, C94.22, C94.30, C94.31, C94.80, C94.81, D45).

Effective for claims with dates of service on and after January 1, 2008, contractors shall deny non-ESRD ESA services for HCPCS J0881 or J0885 billed with modifier EC (ESA, anemia, non-chemo/radio) for:

- any anemia in cancer or cancer treatment patients due to bone marrow fibrosis,
- anemia of cancer not related to cancer treatment,
- prophylactic use to prevent chemotherapy-induced anemia,
- prophylactic use to reduce tumor hypoxia,
- patients with erythropoietin-type resistance due to neutralizing antibodies; and
- anemia due to cancer treatment if patients have uncontrolled hypertension.

Effective for claims with dates of service on and after January 1, 2008, non-ESRD ESA services for HCPCS J0881 or J0885 billed with modifier EB (ESA, anemia, radio-induced), shall be denied.

Effective for claims with dates of service on and after January 1, 2008, contractors shall deny non-ESRD ESA services for HCPCS J0881 or J0885 billed with modifier EA (ESA, anemia, chemo-induced) for anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia when a hemoglobin 10.0g/dL or greater or hematocrit 30.0% or greater is reported.

NOTE: ESA treatment duration for each course of chemotherapy includes the 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regime.

Effective for claims with dates of service on and after January 1, 2008, Medicare contractors shall have discretion to establish local coverage policies for those indications not included in NCD 110.21.

Denials of claims for ESAs are based on reasonable and necessary determinations established by NCD 110.21. A provider may have the beneficiary sign an Advanced Beneficiary Notice, making the beneficiary liable for services not deemed reasonable and necessary and thus not covered by Medicare.

The contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Three.

Group Code: PR or CO
CARC: 50
RARC: N/A
MSN: 15.20

Medicare contractors have the discretion to conduct medical review of claims and reverse the automated adjudication if the medical review results in a determination of clinical necessity.

80.13 – Supplier Payment Under Medicare Part B for Insulin Furnished Through Durable Medical Equipment (Rev. 12013; Issued: 05-02-23; Effective: 07-01-23; Implementation: 07-03-23)

For insulin administered through an item of DME see Pub. 100-04 Chapter 20, – Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), Section 140.1.1 for further instruction.

90 - Claims Processing Rules for Hospital Outpatient Billing and Payment (Rev. 1, 10-01-03)

90.1 - Blood/Blood Products and Drugs Classified in Separate APCs for Hospital Outpatients (Rev. 496, Issued: 03-04-05, Effective: 07-01-05, Implementation: 07-05-05)

Proper Billing for Blood Products and Blood Storage and Processing

Refer to Pub.100-04, Medicare Claims Processing Manual, Chapter 4, §231 regarding billing for blood and blood products under the Hospital Outpatient Prospective Payment System (OPPS).

90.2 - Drugs, Biologicals, and Radiopharmaceuticals

(Rev. 4204, Issued: 01-17-19, Effective: 01-01-19, Implementation: 01-07-19)

A. General Billing and Coding for Hospital Outpatient Drugs, Biologicals, and Radiopharmaceuticals

Hospitals should report charges for all drugs, biologicals, and radiopharmaceuticals, regardless of whether the items are paid separately or packaged, using the correct HCPCS codes for the items used. It is also of great importance that hospitals billing for these products make certain that the reported units of service of the reported HCPCS code are consistent with the quantity of a drug, biological, or radiopharmaceutical that was used in the care of the patient.

Payment for drugs, biologicals and radiopharmaceuticals under the OPSS is inclusive of both the acquisition cost and the associated pharmacy overhead or nuclear medicine handling cost. Hospitals should include these costs in their line-item charges for drugs, biologicals, and radiopharmaceuticals.

Under the OPSS, if commercially available products are being mixed together to facilitate their concurrent administration, the hospital should report the quantity of each product (reported by HCPCS code) used in the care of the patient. Alternatively, if the hospital is compounding drugs that are not a mixture of commercially available products, but are a different product that has no applicable HCPCS code, then the hospital should report an appropriate unlisted drug code (J9999 or J3490). In these situations, it is not appropriate to bill HCPCS code C9399. HCPCS code C9399, Unclassified drug or biological, is for new drugs and biologicals that are approved by FDA on or after January 1, 2004, for which a specific HCPCS code has not been assigned.

The HCPCS code list of retired codes and new HCPCS codes reported under the hospital OPSS is published quarterly via Recurring Update Notifications. The latest payment rates associated with each APC and HCPCS code may be found in the most current Addendum A and Addendum B, respectively that can be found under the CMS quarterly provider updates on the CMS Web site at:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>

Future updates will be issued in a Recurring Update Notification.

B. Pass-Through Drugs, Biologicals, and Radiopharmaceuticals

Payment for drugs, biologicals, and radiopharmaceuticals may be made under the pass-through provision which provides additional payments for drugs, biologicals, and radiopharmaceuticals that meet certain requirements relating to newness and relative

costs. According to section 1833(t) of the Social Security Act, transitional pass-through payments can be made for at least 2 years, but no more than 3 years. For the process and information required to apply for transitional pass-through payment status for drugs, biologicals, and radiopharmaceuticals, go to the main OPSS Web page, currently at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html> to see the latest instructions. (**NOTE:** Due to the continuing development of the new cms.hhs.gov Web site, this link may change.) Payment rates for pass-through drugs, biologicals, and radiopharmaceuticals are updated quarterly. The all-inclusive list of billable drugs, biologicals, and radiopharmaceuticals for pass-through payment is included in the current quarterly Addendum B. The most current Addendum B can be found under the CMS quarterly provider updates on the CMS website.

C. Non Pass-Through Drugs and Biologicals

Under the OPSS, drugs and biologicals that are not granted pass-through status receive either packaged payment or separate payment. Payment for drugs and biologicals with estimated per day costs equal to or below the applicable drug packaging threshold is packaged into the payment for the associated procedure, commonly a drug administration procedure. Drugs and biologicals with per day costs above the applicable drug packaging threshold are paid separately through their own APCs.

D. Radiopharmaceuticals

1. General

Beginning in CY 2008, the OPSS divides radiopharmaceuticals into two groups for payment purposes: diagnostic and therapeutic. Diagnostic radiopharmaceuticals function effectively as products that enable the provision of an independent service, specifically, a diagnostic nuclear medicine scan. Therapeutic radiopharmaceuticals are themselves the primary therapeutic modality.

Beginning January 1, 2008, the I/OCE requires claims with separately payable nuclear medicine procedures to include a radiolabeled product (i.e., diagnostic radiopharmaceutical, therapeutic radiopharmaceutical, or brachytherapy source). Hospitals are required to submit the HCPCS code for the radiolabeled product on the same claim as the HCPCS code for the nuclear medicine procedure. Hospitals are also instructed to submit the claim so that the services on the claim each reflect the date the particular service was provided. Therefore, if the nuclear medicine procedure is provided on a different date of service from the radiolabeled product, the claim will contain more than one date of service. More information regarding these edits is available on the OPSS Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html>

There are rare situations where a hospital provides a radiolabeled product to an inpatient, and then the patient is discharged and later returns to the outpatient department for a

nuclear medicine imaging procedure but does not require additional radiolabeled product. In these situations, hospitals are to include HCPCS code C9898 (Radiolabeled product provided during a hospital inpatient stay) with a token charge (of less than \$1.01) on the same claim as the nuclear medicine procedure in order to receive payment for the nuclear medicine procedure. HCPCS code C9898 should only be reported under the circumstances described above, and the date of service for C9898 should be the same as the date of service for the diagnostic nuclear medicine procedure.

2. Diagnostic Radiopharmaceuticals

Beginning in CY 2008, payment for nonpass-through diagnostic radiopharmaceuticals is packaged into the payment for the associated nuclear medicine procedure.

3. Therapeutic Radiopharmaceuticals

The OPSS will continue to pay for therapeutic radiopharmaceuticals at charges adjusted to cost from January 1, 2008 through December 31, 2009

E. Biosimilars

The payment rate for biosimilars is calculated as the Average Sales Price (ASP) of the biosimilar described by the HCPCS code + 6 percent of the ASP of the biosimilar reference product. Biosimilars will also continue to be eligible for transitional pass-through payment for which payment will be made at ASP of the biosimilar described by the HCPCS code + 6 percent of the ASP of the biosimilar reference product.

F. 340B-Acquired Drugs

Beginning January 1, 2018, separately payable Part B drugs and biologicals (assigned status indicator “K”), other than vaccines (assigned status indicator “L” or “M”) and drugs and biologicals on pass-through payment status (assigned status indicator “G”), that are acquired through the 340B Program or through the 340B prime vendor program will be paid at the ASP minus 22.5 percent of the ASP of the drug or biological when billed by a hospital paid under the OPSS that is not excepted from the payment adjustment. Biosimilars that are acquired through the 340B Program or through the 340B prime vendor program will be paid at the ASP minus 22.5 percent of the ASP of the drug or biological when billed by a hospital paid under the OPSS that is not excepted from the payment adjustment. Hospital types that are excepted from the 340B payment policy in CY 2018 include rural sole community hospitals (SCHs), children’s hospitals, and PPS-exempt cancer hospitals. Critical Access Hospitals and Maryland waiver hospitals are not paid under the OPSS and therefore are not impacted by this policy. Medicare will continue to pay separately payable drugs and biologicals that were not purchased with a 340B discount at ASP+6 percent.

In addition, effective January 1, 2018, hospitals paid under the OPSS that are not excepted from the 340B drug payment policy for CY 2018, are required to report modifier “JG” (Drug or biological acquired with 340B Drug Pricing Program Discount) on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. Since rural SCHs, children’s hospitals and PPS-exempt cancer hospitals are excepted from the

340B payment adjustment in CY 2018, these hospitals will be required to report informational modifier “TB” (Drug or Biological Acquired With 340B Drug Pricing Program Discount, Reported for Informational Purposes) for 340B-acquired drugs, and will continue to be paid ASP+6 percent.

90.2.1 - HCPCS Codes Replacements

(Rev. 2903, Issued: 03-11-14, Effective: 04-01-14, Implementation: 04-07-14)

The HCPCS code list of retired codes and new HCPCS codes reported under the hospital OPSS is published quarterly via Recurring Update Notification. The latest payment rates associated with each APC number may be found in the OPSS PRICER file available on the CMS Web site, as well as in Addendum A and B of OPSS, which is available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html>

90.3 - Hospital Outpatient Payment Under OPSS for New, Unclassified Drugs and Biologicals After FDA Approval But Before Assignment of a Product-Specific Drug or Biological HCPCS Code

(Rev. 3085, Issued: 10-03-14, Effective: ICD-10: Upon Implementation of ICD-10; ASC X12: January 1, 2012, Implementation: ICD-10: Upon Implementation of ICD-10; ASC X12: November 4, 2014)

Section 621(a) of the MMA amends Section 1833(t) of the Social Security Act by adding paragraph (15), Payment for New Drugs and Biologicals Until HCPCS Code Assigned. Under this provision, payment for an outpatient drug or biological that is furnished as part of covered outpatient department services for which a product-specific HCPCS code has not been assigned shall be paid an amount equal to 95 percent of average wholesale price (AWP). This provision applies only to payments under the hospital outpatient prospective payment system (OPSS).

Beginning January 1, 2004, hospital outpatient departments may bill for new drugs and biologicals that are approved by the FDA on or after January 1, 2004, for which a product-specific HCPCS code has not been assigned. Beginning on or after the date of FDA approval, hospitals may bill for the drug or biological using HCPCS code C9399, Unclassified drug or biological.

Hospitals report in the ASC X12 837 institutional claim format in specific locations, or in the “Remarks” section of Form CMS-1450):

- the National Drug Code (NDC),
- the quantity of the drug that was administered, expressed in the unit of measure applicable to the drug or biological, and
- the date the drug was furnished to the beneficiary.

Contractors shall manually price the drug or biological at 95 percent of AWP. They shall pay hospitals 80 percent of the calculated price and shall bill beneficiaries 20 percent of the calculated price, after the deductible is met. Drugs and biologicals that are manually priced at 95 percent of AWP are not eligible for outlier payment.

HCPCS code C9399 is only to be reported for new drugs and biologicals that are approved by FDA on or after January 1, 2004, for which there is no HCPCS code that describes the drug.

90.4 - Hospital Billing For Take-Home Drugs

(Rev. 3085, Issued: 10-03-14, Effective: ICD-10: Upon Implementation of ICD-10; ASC X12: January 1, 2012, Implementation: ICD-10: Upon Implementation of ICD-10; ASC X12: November 4, 2014)

All hospitals, including critical access hospitals (CAHs), bill the appropriate DME MAC for take-home supplies of oral anti-cancer drugs, oral anti-emetic drugs and multi-day supplies of immunosuppressive drugs, as well as the associated supplying fees. All inhalation drugs and the associated dispensing fees are also billed to the DME MAC.

Claims for these take-home drugs are billed on the NCPDP, a HIPAA-compliant telecommunication format specifically designed for drug billing. All entities billing on the NCPDP use the NDC for the particular drug being billed, and list units as multiples of the quantity represented by the NDC. Follow this link to reach the DME MAC version of the NCPDC implementation guide:

<http://www.cms.hhs.gov/transmittals/downloads/R689CP.pdf>.

When beneficiaries come to a hospital outpatient department and have an encounter with a physician or mid-level professional (e.g., a physician assistant or nurse practitioner) during which one or more specimens are collected for laboratory work, treatment is monitored (including anti-cancer drugs, either oral or infused), and a drug is administered, this is considered an outpatient visit. Only when more than a single day's supply of a drug is dispensed to the beneficiary for take home use are the drugs so dispensed to be billed to the appropriate DME MAC. When only today's drug(s) is (are) dispensed and other services are rendered in conjunction with the treatment, the entire visit is billed by the hospital to the local A/B MAC (A)

When a beneficiary in a hospital or skilled nursing facility (SNF) non-covered stay, or a hospital/SNF inpatient that has exhausted benefits (TOBs 12x or 22x, respectively) is given a covered oral anti-cancer or anti-emetic drug, or a covered immunosuppressive drug, the hospital or SNF bills its regular A/B MAC (A). Payment to hospitals is dependent on the applicable payment mechanism for the type of hospital (reasonable cost for TEFRA hospitals and CAHs, ambulatory payment classifications (APCs) for hospitals subject to the hospital outpatient PPS (OPPS).

Immunosuppressive drugs and supplying fees provided by a dialysis facility in the State of Washington are billed to and paid by the A/B MAC (A).

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

100 - The Competitive Acquisition Program (CAP) for Drugs and Biologicals Not Paid on a Cost or Prospective Payment Basis
(Rev. 4233, Issued: 02-08-19, Effective: 03-12-19, Implementation: 03-12-19)

The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.

Section 303 (d) of the Medicare Prescription Improvement and Modernization Act (MMA) of 2003 requires the implementation of a competitive acquisition program (CAP) for Medicare Part B drugs and biologicals not paid on a cost or prospective payment system basis. Beginning with drugs administered on or after July 1, 2006, physicians will be given a choice between buying and billing these drugs under the average sales price (ASP) system, or obtaining these drugs from vendors selected in a competitive bidding process. For purposes of the CAP, the term “a physician” includes individuals defined under §1861(s) of the Social Security Act who are authorized to provide physician services under §1861(s) of the Act and who can, within their State’s scope of practice, prescribe and order drugs covered under Medicare Part B.

For 2006, the first CAP year will run from July 1, 2006 through December 31, 2006. In subsequent years, it will run annually on a calendar year basis.

The Secretary may exclude drugs from the CAP if competitive pricing will not result in significant savings, or is likely to have an adverse impact on access to such drugs. The statute gives CMS the authority to select drugs, or categories of drugs, that will be included in the program, to establish geographic competitive acquisition areas, and to phase in these elements as appropriate.

A competition will be held every 3 years to award contracts to approved CAP vendors that will supply drugs and biologicals for the program. A 3-year contract will be awarded to qualified approved CAP vendors in each geographic area who have and maintain: 1) Sufficient means to acquire and deliver competitively biddable drugs within the specified contract area; 2) Arrangements in effect for shipping at least 5 days each week for the competitively biddable drugs under the contract and means to ship drugs in emergency situations; 3) Quality, service, financial performance, and solvency standards; and 4) A grievance and appeals process for dispute resolution. A vendor’s contract may be terminated during the contract period if they do not abide by the terms of their contract with CMS. CMS will establish a single payment amount for each of the competitively bid drugs and areas, for this 3year cycle there will be one drug category and one

geographic area. After CAP drug prices are determined and vendor contracts are awarded the information will be posted to a directory on the Medicare Web site.

Medicare physicians will be given an opportunity to elect to participate in the CAP on an annual basis. Physicians who elect to participate in CAP will continue to bill their local A/B MAC (B) for drug administration. Except where applicable State pharmacy law prohibits it, the CAP Participating Physicians will supply the following information to the approved CAP vendor at the time that a CAP drug order is placed: date of order, beneficiary name, address, and phone number, physician identifying information: name, practice location/shipping address, group practice information, NPI; drug name, strength, quantity ordered, dose, frequency/ instructions, anticipated date of administration, Medicare beneficiary identifier, supplementary insurance information (if applicable), Medicaid information (if applicable), additional patient information: date of birth, allergies, height/weight, and diagnosis if necessary. Claims for erythropoiesis stimulating agents (ESAs) must contain the most recent hematocrit or hemoglobin value. CAP drug claims for any drugs furnished to an individual for the treatment of anemia shall be returned if the most recent laboratory values for hemoglobin or hematocrit are not reported on the claim per Medicare requirements.

The participating CAP physicians will receive all of their drugs from the approved CAP vendor for the drug categories they have selected, with only one exception. The exception will be for “furnish as written” situations where the participating CAP physician requires that, due to medical necessity, the beneficiary must have a specific drug, defined by its National Drug Code (NDC), for one of the HCPCS codes within the approved CAP vendor’s drug list if that specific drug NDC is not available on the CAP drug list. The participating CAP physician may buy the drug, administer it to the beneficiary and bill Medicare using the ASP system. The local A/B MAC (B) will monitor drugs obtained using the “furnish as written” provision to ensure that the participating CAP physician is complying with Medicare payment rules.

The CAP will also allow a participating CAP physician to provide a drug to a Medicare beneficiary from his or her own stock and obtain the replacement drug from the approved CAP vendor when certain conditions are met. The A/B MAC (B) will monitor drugs ordered under the replacement provision to ensure that the participating CAP physician is complying with Medicare payment rules.

Approved CAP vendors must qualify for enrollment in Medicare as a supplier, and will be enrolled as a new provider specialty type. The approved CAP vendor’s claims for the drugs will be submitted to one designated Medicare A/B MAC (B). The approved CAP vendor will bill the Medicare designated A/B MAC (B) for the drug and the beneficiary for any applicable coinsurance and deductible under the MMA, for CAP claims submitted after July 1, 2006 but before April 1, 2007, payment to the approved CAP vendor for the drug was conditioned on verification that the drug was administered to the Medicare beneficiary. Proof that the drug was administered was established by matching the participating CAP physician’s claim for drug administration with the approved CAP vendor’s claim for the drug in the Medicare claims processing system by means of a

prescription number on both claims. When the claims matched in the claims processing system, the approved CAP vendor was paid in full.

Title II, section 108(a) of the Tax Relief and Health Care Act of 2006 (TRHCA), struck language used to develop the existing CAP claims matching process and furthermore required the implementation of a post payment review process effective April 1, 2007. The post payment review process is required to assure that drugs supplied under the CAP have been administered to a beneficiary and the process must establish a mechanism to recoup, offset or collect any overpayments to the approved CAP vendor. The CMS is implementing CAP claims processing changes in order to comply with THCA by April 1, 2007. Pending CAP claims submitted prior to April 1, 2007, and all new CAP claims submitted on or after April 1 will be subject to the post payment review process. Until drug administration is verified, the approved CAP vendor may not bill the beneficiary and/or his third party insurance for any applicable coinsurance and deductible. For more information on the CAP claims processing see FR70251.

100.1 - Physician Election and Information Transfer Between A/B MACs (B) and the Designated A/B MAC (B) for CAP Claims (Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

Prior to each annual election period, CMS will post on its Web site a list of the vendors that have been selected to participate in the CAP, the categories of drugs they will be providing, and the geographic areas within which each vendor will operate. Physicians will then elect the approved CAP vendors they choose to receive drugs from under the CAP. The election period will end each year approximately 45 days after the list of vendors is posted on the CMS Web site.

100.1.1 - Physician Information for the Designated A/B MAC (B) (Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

10 Calendar days after the end of the annual election period, the 2006 election period, by May 25, 2006 A/B MACs (B) shall create a table and forward it to the designated A/B MAC (B). The table will indicate which physicians have elected to participate in CAP, for which drugs, and with which vendors. When A/B MACs (B) receive applications, they shall verify that the chosen vendor is valid per the CMS Web site. If an invalid vendor has been chosen, an educational contact shall be made to resolve the issue.

A/B MACs (B) shall forward this table each year to the designated A/B MAC (B) by 7 calendar days after the end of the election period. Should that date fall on a weekend, it shall be extended to the following Monday.

The table shall include the physician's name, the street address, city, state, zip code, and phone number of each practice address/shipping address (the physical location where the drugs will be administered and the CAP drugs shipped to), PIN, UPIN (or NPI when effective), e-mail address (if available). If the mailing/correspondence address (where the participating CAP physician can be contacted directly) is different from the

practice/shipping address, the mailing/correspondence shall be included. If the group or individual practice has more than one practice location where drugs are administered, each practice address/shipping location where drugs will be administered shall also be included. For group practices that elect to participate in CAP, the group PIN as well as the individual PINs and UPINs (NPI when effective) shall be included.

The A/B MACs (B) shall manually add any additional practice/shipping addresses and the mailing/correspondence address to the spreadsheet provided to them by the shared system before sending the information to the designated A/B MAC (B). A/B MACs (B) shall also remove any members of a group practice who do not qualify to provide services under the CAP. In order to qualify to provide services under the cap the providers must have prescriptive authority in their state to prescribe medications. Examples of provider types that may or may not have prescriptive authority in their states are nurse practitioners and physician's assistants.

Since group practices must commit as a practice to enroll in the CAP program if they bill using the group's PIN, if the A/B MAC (B) receives from the shared system names of providers in a group for whom an election form has not been received, they shall contact the group practice to verbally request the required election form information. A/B MACs (B) shall only remove names from the CAP provider table when it has been determined that the physician is no longer a member of a group practice. A/B MACs (B) shall not allow a group practice to participate in the CAP until all election information has been obtained for each eligible practice member within that group who bills using the group's PIN.

The designated A/B MAC (B) shall transmit information to each vendor on the physicians and practitioners who have elected that particular vendor 30 days prior to the start of the CAP year.

100.1.1.1 - Quarterly Updates

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

On a quarterly basis, CMS may provide updates to the HCPCS codes that the participating CAP physician must accept for the CAP. A/B MACs (B) must add these HCPCS codes to the table created in 100.1.1 by 7 days after receipt of the changes from CMS.

100.1.2 - Format for Data

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

In order to simplify the transfer of physician election information, prior to end of the election period, the A/B MACs (B) and the designated A/B MAC (B) shall determine a common format in which to send the information to the designated A/B MAC (B). This format shall remain constant for subsequent years unless CMS issues instructions that it is to be changed.

100.1.3 - Physician Information for the Vendors

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

One month before the beginning of the calendar year, the designated A/B MAC (B) shall transmit the following information to each vendor on the physicians who have elected that particular vendor: the name, the street address, city, state, zip code, and phone number of each practice address/shipping address (physical location where the drugs will be administered), UPIN (or NPI when effective), e-mail address (if available) of the physicians who have elected to participate in CAP with that vendor and the drugs they have chosen. If the mailing/correspondence address (where the participating CAP physician can be contacted directly) is different from the practice/shipping address, the mailing/correspondence shall be included. If the group or individual practice has more than one practice location where drugs are administered, each practice address/shipping location where drugs will be administered shall also be included. **(NOTE: For the 2006 claims processing period, the information must be sent by June 1, 2006).**

For group practices that elect to participate in CAP, the individual UPINs (NPI when effective) shall be included.

Each year the date the designated A/B MAC (B) shall transmit information to each vendor on the physicians who have elected that particular vendor shall be 7 calendar days after the final date the A/B MACs (B) forward to the designated A/B MAC (B) the list of all the physicians who have elected to participate in CAP. Should that date fall on a weekend, it shall be extended to the following Monday.

The designated A/B MAC (B) shall not send a vendor any information pertaining to other vendors.

100.2 - Claims Processing Instructions for CAP Claims for the A/B MACs (B)

(Rev. 1412, Issued: 01-11-08, Effective: 01-01-08, Implementation: 04-07-08)

The A/B MAC (B) shall not process CAP claims submitted for United Mine Worker or Medicare Advantage or Railroad Board beneficiaries. A/B MACs (B) shall follow normal procedures for the disposition of these claims.

A/B MACs (B) shall pay for the administration of the drugs for which physicians have elected to receive under CAP. CAP claims are required to comply with Medicare rules and requirements for modifiers and other supporting information unless specific exceptions are made. The A/B MACs (B) shall process CAP claims from physicians per the following instructions.

100.2.1 - CAP Required Modifiers

(Rev. 3721, Issued: 02-24-17, Effective: 05-25-17, Implementation: 05-25-17)

The A/B MAC (B) shall identify physicians who have elected CAP and will no longer pay the physician for drugs under the ASP system that were obtained through CAP. A/B MACs (B) shall continue to pay physicians for the administration of CAP drugs. Unless claims for the CAP drugs include the no-pay (J1), furnish as written (J3) modifier, or MSP (M2) modifier the claim will be denied.

When physicians submit a claim for a drug they have provided under the CAP without the J1, J3, or MSP modifiers, the contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Three.

Group Code: CO
CARC: 96
RARC: N348
MSN: 7.7

A/B MACs (B) shall treat as unprocessable CAP claims with the following invalid modifier combinations on CAP claims:

J1 + J3 - invalid
J2 without a J1 - invalid
J2 + J3 - invalid

A/B MACs (B) shall treat as unprocessable claims received with invalid modifier combinations.

The contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Two.

Group Code: CO
CARC: 16
RARC: N519
MSN: N/A

100.2.2 - Submitting the Charges for the Administration of a CAP Drug and the No Pay Service Lines

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

No pay service lines are identified by the modifier code: J1 - Competitive Acquisition Program, no-pay submission for a prescription number.

On both paper and electronic claims, the physician must submit their charges for the administration of the CAP drug and an additional no-pay service line for each prescription number. Each no-pay service line shall include the no-pay modifier J1, a HCPCS drug code, and a prescription number. The J1 modifier should always be entered in the first modifier position.

The no-pay service lines shall be submitted with the regular billed charges for the administration of these drugs. No payment shall be made for services received with the CAP no-pay modifier and they shall bypass the MSP Pay module.

100.2.3 - Submitting the Prescription Order Numbers and No Pay Modifiers

(Rev. 3721, Issued: 02-24-17, Effective: 05-25-17, Implementation: 05-25-17)

On paper claims the prescription numbers must be entered in Item 19. On electronic claims the prescription number must be entered at the line level in the ASC X12 837 professional claim format, LOOP 2410 REF02 (REF01=XZ) of the 5010 version. As the Implementation Guide requires the entry of the National Drug Code (NDC) number in the LIN segment in order to enter the prescription number, the NDC will be required as well. The NDC must be submitted in LOOP 2410 LIN03 (LIN02=N4).

The prescription number will consist of the vendor identification (ID) number, the HCPCS code, and the vendor controlled prescription number. Each vendor controlled prescription number shall be a unique number and shall not consist of all zero's.

The standard system shall add the prescription number received on either paper or electronic claims to the claims screen and retain the information in history. A/B MACs (B) shall forward the prescription number on both paper and electronic claims to CWF.

For paper claims, A/B MACs (B) shall return as unprocessable paper claims submitted with the J1 modifier, but no prescription number.

The contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Two.

Group Code: CO
CARC: 16
RARC: N388
MSN: N/A

The standard system shall create a pre-pass edit to reject claims from physicians or practitioners submitted with a no-pay modifier on a line, but without a prescription number on that same line.

The contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Two.

Group Code: CO
CARC: 16

RARC: N388
MSN: N/A

**100.2.3.1 - Further Editing on the Prescription Order Number
(Rev. 3721, Issued: 02-24-17, Effective: 05-25-17, Implementation: 05-25-17)**

Prescription order numbers submitted with inappropriate spaces inserted disrupt the matching process between the physician/provider claims and the vendor claims. Effective for claims processed on or after July 7, 2008, contractors shall implement edits to treat these claims as unprocessable.

Prescription order numbers submitted with less than 10 characters on CAP claims will also be treated as unprocessable. For either of the two prior situations, the contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Two.

Group Code: CO
CARC: 16
RARC: N388
MSN: N/A

In addition, CAP physicians/providers and CAP vendors may not submit new claims (processed as entry code 1) with prescription order numbers that they have already submitted on previously adjudicated claims, even if the prior claims have been denied. The CAP physicians/providers and CAP vendors must request an adjustment to the original claim (processed as entry code 5). Claims that have been returned as unprocessable may be accepted with the original prescription order number when resubmitted after being corrected.

CWF will create a new utilization error code that will be returned when it receives a claim that has a prescription order number on it that matches a prescription order number already on file from a different claim. This claim could be from the same physician/provider/supplier or a different physician/provider/supplier. CWF coding will differentiate between claims from the physicians/providers and claims from the CAP vendors. It will be acceptable to allow a claim with a duplicate prescription order number as long as one claim is from a physician/provider and the other claim is from the vendor. This will allow the prescription order number matching process to continue.

Contractors shall treat as unprocessable the entire claim when a claim receives the new CWF utilization error code. Contractors shall not allow appeals rights on claims treated as unprocessable in response to the new error code.

The contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Two.

Group Code: CO
CARC: 18
RARC: N389, M16 and N185
MSN: N/A

100.2.4 - CAP Claims Submitted With Only the No Pay Line
(Rev. 3721, Issued: 02-24-17, Effective: 05-25-17, Implementation: 05-25-17)

Physicians must submit their charges for the administration of CAP drugs and the no-pay lines on the same claim. A/B MACs (B) shall treat as unprocessable claims received that only have services submitted with the no-pay modifier.

The contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Two.\

Group Code: CO
CARC: 16
RARC: M67
MSN: N/A

100.2.5 - Use of the “Restocking” Modifier
(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The restocking modifier is: J2 - Competitive Acquisition Program, (CAP) restocking of emergency drugs after emergency administration.

Under certain circumstances, physicians will be permitted to administer a drug they have on hand and go through the CAP program to restock it. Once the participating CAP physician orders and receives the restocking drug from the approved CAP vendor, the physician will bill for the administration fee. The physician will also include no-pay lines on the claim for each of the drugs as usual. These lines will include the restocking modifier in addition to the no-pay modifier (in the first modifier position), the procedure code for the drug, the prescription number and all other elements normally required. A/B MACs (B) shall consider “restocking” drug claims for payment when the following requirements are met:

- a) The physician has elected to receive the drug under CAP;
- b) The physician has submitted the claim with the “restocking” modifier;
- c) The physician received the drug from the CAP vendor to replace a drug he or she used from pre-existing stock.
- d) The claim was submitted with the “restocking” modifier:

J2 - Competitive Acquisition Program, (CAP) restocking of emergency drugs after emergency administration.

By including the “restocking” modifier on the claim, the physician is asserting that:

- a) The drug was required immediately;
- b) The need couldn’t be anticipated;
- d) The drug was administered in an emergency situation; and
- e) Documentation is being maintained in the file to validate the information in a - d and will be made available to the A/B MAC (B) at their request.

100.2.6 - Use of the “Furnish as Written” Modifier

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The “furnish as written” modifier is: J3 - Competitive Acquisition Program, (CAP) drug not available through CAP as written, reimbursed under average sales price methodology.

When the J3 modifier is used, the physician will be allowed to bill Medicare for a CAP drug in addition to the claim for the administration of that drug.

A/B MACs (B) shall consider “furnish as written” drug administration claims for payment outside of the CAP program when the new “furnish as written” modifier is used.

By using only the J3 modifier on the claim, the physician is asserting that:

- a) A specific drug product was medically necessary;
- b) The selected drug vendor could not provide that specific brand and/or NDC for the CAP HCPCS code;

and

- c) Documentation is being maintained on file to validate the information in a) and b) and will be made available to the A/B MAC (B) at their request.

100.2.7 - Monitoring of Claims Submitted With the J2 and/or J3 Modifiers

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

As part of their normal data analysis, A/B MACs (B) shall monitor these claims submitted with the J2, “restocking” modifier, or J3, the “furnish as written” modifier, for

patterns of abuse and follow the Progressive Corrective Action (PCA) process described in the Program Integrity Manual, Chapter 3, Section 11.

100.2.8 - Claims Submitted for Only Drugs Listed on the Approved CAP Vendor's Drug List

(Rev. 3721, Issued: 02-24-17, Effective: 05-25-17, Implementation: 05-25-17)

The A/B MAC (B) shall edit to verify that the no-pay lines (lines with the CAP drug HCPCS code and the J1 modifier) that the participating CAP physician has billed is for a drug included in the CAP and is from the particular CAP vendor they have chosen to receive drugs from.

If the A/B MAC (B) determines that the physician has billed no-pay lines along with the codes for the payment of the administration for drug HCPCS code(s) that are not provided by the approved CAP vendor that the physician had selected, it shall return as unprocessable those no-pay lines along with the lines for the codes for the payment of the administration for these drugs.

The contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Three

Group Code: CO
CARC: 96
RARC: N348
MSN: 7.8

100.2.9 - Submission of Claims With the Modifier JW, "Drug Amount Discarded/Not Administered to Any Patient"

(Rev. 1313; Issued: 07-23-07; Effective/Implementation Dates: 08-23-07)

The JW modifier must not be used on Medicare Part B Drug CAP claims; providers shall not code for wastage for drugs furnished under the CAP. Claims for drugs provided under CAP submitted with the JW modifier will be treated as unprocessable.

100.2.10 - MSP Situations Under CAP

(Rev. 1088, Issued: 10-27-06, Effective: 01-01-07, Implementation: 01-02-07)

Drugs Obtained Through the CAP for Beneficiaries With Insurance Primary to Medicare

Providers who elect into the CAP voluntarily agree to obtain CAP drugs for Medicare beneficiaries exclusively through an approved CAP vendor. In situations where participating CAP providers obtain a drug from the CAP vendor for a beneficiary who is incorrectly determined to have Medicare as their primary insurer, but the provider and the

CAP vendor must first bill the appropriate primary insurer for the drug and the administration service.

Upon receipt of the primary insurer's payment, MSP claims should then be submitted by the physician to their A/B MAC (B) for the administration service and by the approved CAP vendor to the CAP designated A/B MAC (B) for the drug. Providers are required to submit MSP claims even if they believe there is no outstanding balance due. Such claims must adhere to CAP guidelines and include the drug HCPCS code, the prescription number provided by the approved CAP vendor and an appropriate CAP no-pay modifier. Approved CAP vendor claims must also adhere to CAP requirements and include the assigned prescription number.

All participating CAP providers to submit MSP claims for drug administration services where the drug was obtained from the approved CAP vendor. Failure to submit an MSP claim for the drug administration prevents the processing of the vendor's MSP claim by the CAP designated A/B MAC (B).

Drugs Obtained Outside of the CAP for Beneficiaries With Medicare

In certain rare situations, participating CAP providers may mistakenly obtain drugs for Medicare beneficiaries outside of the CAP vendor because they had determined that the beneficiary had another insurer that was primary to Medicare. In order to make an appropriate payment for drugs administered under these unusual circumstances, we are allowing temporary use of the J3 modifier to bypass CAP edits and pay the participating CAP provider at the current ASP rate.

We have requested a modifier for use in this rare situation. A/B MACs (B) will be notified through the usual quarterly update process when a new modifier is available. At that time, the J3 modifier will no longer be accepted for this purpose.

As we expect the situations that require this modifier to be infrequent, A/B MACs (B) have the ability to review claims with this modifier to monitor for proper use and educational opportunities.

MSP Claims For Drugs Present on the Provider's CAP Drug List

In order to prevent processing errors for MSP claims where the drug billed on the provider's claim is present on the selected CAP drug list, A/B MACs (B) are to implement a SCF rule allowing an override of the CAP claims processing edits. This SCF rule will allow claims to be identified as MSP and not require the CAP modifiers or prescription number.

100.3 - Application of Local Medical Review Policies

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

A/B MACs (B) and/or Program Safeguard Contractors shall apply all Local Coverage Determination (LCD) policies and National Coverage Determination (NCD) policies to the administration and no-pay drug code lines on the CAP claims.

Should it be determined that a drug administration or drug code service line does not meet the requirements of the LCD, the A/B MAC (B) shall follow current processes to determine how to adjudicate the related services.

If appropriate, the A/B MACs (B) shall include messages on the MSN and RA to indicate which LCD was applied.

The A/B MACs (B) shall also apply all regular edits to the administration and no-pay drug lines and send appropriate denial messages.

100.4 - Claims Processing Instructions for the Designated A/B MAC (B) (Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The designated A/B MAC (B) shall follow normal procedures to enroll the Drug Vendors as provider specialty type, 95, Competitive Acquisition Program (CAP) for Part B Drug Vendors.

A separate 4 position, alpha-numeric vendor identification number (VIN) shall be assigned to be used in the prescription number and a master list of which numbers are assigned to which vendors shall be kept.

The designated A/B MACs (B) shall forward the VIN to the A/B MACs (B) and to CMS 14 days after new CAP vendor contractors have been announced by CMS. CMS will post the VIN on the CMS Web site. A/B MACs (B) shall download these identification codes from the CMS Web site and added them to the A/B MAC (B)'s table.

For subsequent CAP years, this date will be the first Monday in November.

These codes shall be added to the A/B MACs (B)'s table by 14 days after receipt.

The designated A/B MAC (B) shall track the name, the address, zip code, and phone number of each practice location/shipping address (location where the drugs will be administered), PIN, UPIN, (or NPI when effective), and e-mail (if available) of the physicians and physician groups and which vendors and which drugs they have chosen. In addition, the mailing/correspondence address (where the participating CAP physician can be contacted directly) for each physician shall also be tracked. This information shall be made available to CMS upon request.

On a quarterly basis, the designated A/B MAC (B) shall manually add additional HCPCS codes to the information above when received from the A/B MACs (B). They shall add this information by 14 days after its receipt from the A/B MACs (B).

The designated A/B MAC (B) shall only process CAP claims from approved drug vendors submitted in the ASC X12 837 professional claim format. All vendor claims shall be processed by the designated A/B MAC (B). These will not include claims for United Mine Worker, Railroad or Medicare Advantage beneficiaries.

100.4.1 - Creation of Internal Vendor Provider Files

(Rev. 3721, Issued: 02-24-17, Effective: 05-25-17, Implementation: 05-25-17)

The designated A/B MAC (B) shall create an internal provider file for each vendor which includes the names, addresses, and UPINs, (NPI when effective), of those physicians who have elected that vendor.

The designated A/B MAC (B) shall edit incoming vendor claims to verify that the UPIN number on the claim for the ordering physician is one of the UPINs on the provider file for that vendor. The designated A/B MAC (B) shall treat the claim as unprocessable when it receives claims from vendors with ordering physician UPINs that do not match a physician UPIN on the provider file.

The contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Two

Group Code: CO
CARC: 16
RARC: N265
MSN: 9.7 and 17.11

100.4.2 - Submission of Paper Claims by Vendors

(Rev. 3721, Issued: 02-24-17, Effective: 05-25-17, Implementation: 05-25-17)

The designated A/B MAC (B) shall treat as unprocessable paper claims submitted by vendors and the contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Three

Group Code: CO
CARC: 96
RARC: M117
MSN: N/A

100.4.3 - Submission of Claims from Vendors With the J1 No Pay Modifier

(Rev. 3721, Issued: 02-24-17, Effective: 05-25-17, Implementation: 05-25-17)

The designated A/B MAC (B) shall treat as unprocessable claims submitted by vendors with a no-pay modifier, the contractor shall use the following remittance advice messages

and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Two

Group Code: CO
CARC: 16
RARC: N265
MSN: 9.7 and 17.11

**100.4.4 - Submission of Claims from Vendors Without a Provider
Primary Identifier for the Ordering Physician
(Rev. 3721, Issued: 02-24-17, Effective: 05-25-17, Implementation: 05-25-17)**

The designated A/B MACs (B) shall edit to determine if a UPIN, (or NPI when effective), of the ordering physician has been entered on the claim. If the UPIN, (or NPI when effective), has not been entered on the claim, the designated A/B MAC (B) shall treat the claim as unprocessable.

The contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Two

Group Code: CO
CARC: 206
RARC: N265
MSN: N/A

**100.4.5 - New MSN Message to Be Included on All Vendor Claims
(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)**

On all vendor claims, whether paid or denied, the designated A/B MACs (B) shall include the following new Medicare Summary Notice Message:

Your physician participates in the Competitive Acquisition Program for Medicare Part B drugs (CAP). The drug(s) you received in your physician's office were provided by an approved CAP vendor. You will receive two separate Medicare Summary Notices (MSNs). This MSN is from the Medicare A/B MAC (B) that processes claims for your drug that came from the approved CAP vendor. You will receive another MSN from the A/B MAC (B) that processes claims for your physician, for the administration of the drug(s). If you appeal the determination for this drug vendor claim, you must send your appeal to the A/B MAC (B) address listed on the physician administration MSN, and not this vendor claim MSN.

Spanish:

Su médico participa en el Programa de Adquisición Competitiva para las medicinas cubiertas por la Parte B de Medicare (CAP, por sus siglas en inglés). Las medicinas que

usted recibió en la oficina de su médico fueron provistas por un suplidor autorizado del CAP. Usted recibirá dos Resúmenes de Medicare por separado. Este Resumen es de la empresa de seguros Medicare que procesa las reclamaciones de sus medicinas provistas por el suplidor autorizado del CAP. Usted recibirá otro Resumen de la empresa de seguros Medicare que procesa las reclamaciones de su médico, por el suministro de sus medicinas. Si usted apela la decisión de esta reclamación del suplidor de medicinas, debe enviar la apelación a la empresa de seguros Medicare que se menciona en el Resumen de la reclamación de su médico y no a la dirección que aparece en este Resumen.

100.4.6 - Additional Medical Information

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The designated A/B MAC (B) shall reserve the right to solicit, at any time, medical information to support adjudication of the drug vendor’s claim.

100.4.7 - CAP Fee Schedule

(Rev. 1055, Issued: 09-11-06; Effective: 10-01-06; Implementation: 10-02-06)

CMS will provide a fee schedule for the payment of CAP drugs to the designated A/B MAC (B) and MCS. The fees will be provided in a file on the CMS mainframe at a later date. The file layout is attached.

CAP PROGRAM FEE SCHEDULE FILE RECORD DESCRIPTION

Field Name	Position	Length	Format	Description
HCPCS	1-5	5	Character	Healthcare Common Procedure Coding System
Filler	6-7	2		Space Filled
State	8-9	2	Character	Alpha Abbreviation
Filler	10-11	2		Space Filled
Current Year	12-15	4	Character	YYYY
Filler	16-17	2		Space Filled
Current Quarter	18	1	Character	Calendar Quarter - value 1-4
Filler	19-20	2		Space Filled
Fee	21-29	9	Numeric	Fee to Pay For Drug \$\$\$\$\$¢¢¢(Pic9(6)v999)
Filler	30-80	51	Character	Space Filled

CMS will upload the CAP Part B Drug file to the Direct Connect each calendar quarter. Approximately six weeks prior to the beginning of each calendar quarter (i.e., approximately 6 weeks prior to January 1, April 1, July 1, and October 1) an email will be sent out providing notification of the availability of the updated file. The updated file will be available in the early November for the January 1 release, early February for the March 1 release, early May for the July 1 release, and early August for the September 1 release.

100.5 - Matching the Physician Claim to the Vendor Claim
(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

CWF shall match physician submitted claim lines with prescription numbers and no-pay modifiers to vendor submitted claim lines with prescription numbers.

The A/B MAC (B) shall send to CWF a pay/process indicator for each line of the claim, (including the lines with HCPCS codes for the administration of the CAP drug and the lines for the CAP drug HCPCS code), to indicate whether it is approved, not-payable due to medical necessity, or not payable due to a reason other than medical necessity.

When CWF finds a prescription number that matches a prescription number on the claim, it shall notify the designated A/B MAC (B). The designated A/B MAC (B) shall make payment for the drug lines that have a pay/process indicator of approved. It shall deny any lines not approved.

100.5.1 - Denials Due to Medical Necessity
(Rev. 3721, Issued: 02-24-17, Effective: 05-25-17, Implementation: 05-25-17)

If the lines are not approved due to medical necessity, the contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Three.

Group Code: CO
CARC: 50
RARC: N661
MSN: 16.48

100.5.2 - Denials For Reasons Other Than Medical Necessity
(Rev. 3721, Issued: 02-24-17, Effective: 05-25-17, Implementation: 05-25-17)

If the designated A/B MAC (B) denies the lines due to other reason, the contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Three.

Group Code: CO
CARC: 96
RARC: RARC most descriptive of 'other' denial reason. CARC 96 requires an accompanying RARC.
MSN: 16.10

100.5.3 - Changes to Pay/Process Indicators
(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

Should A/B MACs (B) make adjustments to the physician claims, they shall forward any changes in the pay/process indicators to CWF and CWF shall make any changes to the pay/process indicator as necessary to keep it current. CWF shall notify the designated A/B MAC (B) of any changes to the pay/process indicators so that they may respond accordingly.

100.5.4 - Post-Payment Overpayment Recovery Actions (Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

If it is determined on a post-pay basis that based on a change to the pay-process indicator the designated A/B MAC (B) has now made an overpayment, the designated A/B MAC (B) shall initiate an overpayment recovery action. If it is determined that they have made an underpayment, they shall also take appropriate action. A/B MACs (B) and the designated A/B MAC (B) shall follow the instructions in the Program Integrity Manual, Chapter 3 and the Medicare Financial Management Manual, Chapter 3, for overpayment recovery.

100.5.5 - Pending and Recycling the Claim When All Lines Do Not Have a Match (Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

If the designated A/B MAC (B) receives a claim from the vendor and CWF determines some or all of the lines on the claim do not have a match, the designated A/B MAC (B) shall pend the claim for 90 days. However, prior to the end of the 90 day period, if at the vendor's request the designated A/B MAC (B) can determine that a matching paper physician claim is on file, the designated A/B MAC (B) shall allow payment of the approved services on the claim.

The designated A/B MAC (B) may also recycle the claim back to CWF at their discretion to determine if a matching electronic claim has been received prior to the end of the 90 day period. No interest shall be paid on the pending claim.

100.5.6 - Creation of a Weekly Report for Claims That Have Pended More Than 90 Days and Subsequent Action (Rev. 3721, Issued: 02-24-17, Effective: 05-25-17, Implementation: 05-25-17)

The shared system shall create a weekly report for the designated A/B MAC (B) providing information on claims that have pended for more than 90 days. The designated A/B MAC (B) shall review the weekly report to identify and deny claim lines for which the 90 day time period has expired. Before denying the claim lines, the designated A/B MAC (B) shall determine if the physician claim had been submitted as a paper claim. If there is an approved physician paper claim for the beneficiary with the same HCPCS code and a date of service within 7 days of the date of service of the vendor drug claim posted at CWF and the details are not denied, the designated A/B MAC (B) shall pay the

claim lines. If there is no claim on file that matches these criteria, or some details are denied, the designated A/B MAC (B) shall deny the corresponding claim lines.

The contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Two.

Group Code: CO
CARC: 107
RARC: N/A
MSN: 21.21

100.6 - Coordination of Benefits

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

CWF and the designated A/B MAC (B) shall submit claims for full payment of drug claims to the Coordination of Benefits Contractor (COBC) for crossover to trading partners, in accordance with the requirements specified in Transmittal 138 (Change Request 3218).

100.7 - National Claims History

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

CWF shall pass the prescription number to National Claims History (NCH) where it will be stored.

100.8 - Adding New Drugs to CAP

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The A/B MACs (B) s and the Designated A/B MAC (B) shall develop the capacity to manually add new vendor specific HCPCS codes and identify to which vendor lists these have been added for the table developed in 4064.1.1.2.1 on a quarterly basis upon notification by CMS. A/B MACs (B) shall add these codes to their table by 7 days after receipt of notification from CMS.

100.8.1 - Updating Fee Schedule for New Drugs in CAP

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

The Designated A/B MAC (B) shall develop the capacity to add the prices for the new vendor specified HCPCS codes to the pricing table. Prices will be available on the CMS website for the quarterly update of prices to the of new drug prices.

100.8.2 - Changes to the List of Drugs Supplied by Approved CAP Vendors

(Rev. 1506; Issued: 05-16-08; Effective Date: 10-01-08; Implementation Date: 10-06-08)

The CAP will be implemented with a single category of drugs and one geographic area, however as the program evolves, additional geographic areas and additional drug categories may be created. Approved CAP vendors will also be able to request approval for changes to the lists of drugs that they supply under the CAP.

As CMS continues to develop the CAP, additional geographical areas and additional drug categories may be created. If additional drug categories are created, certain drugs may appear in more than one drug category.

Approved CAP vendors will be permitted to request certain changes to the list of drugs that they supply under the CAP. Beginning in July 2006 with changes to be effective October 1, 2006, approved CAP vendors may request that CMS (or its designee) approve the following types of changes:

- **Substitution:** Approved CAP vendor may request approval to replace one or more drug products as identified by national drug codes (NDCs) in a Healthcare Common Procedure Coding System (HCPCS) code supplied by the approved CAP vendor with one or more NDCs.
- **Add newly issued HCPCS Codes:** Approved CAP vendor may request that CMS allow it to supply additional drug products with new HCPCS codes under the CAP.
- **Additional NDCs:** Approved CAP vendor may request that CMS allow it to supply additional NDCs under a HCPCS code that the approved CAP vendor already supplies under the CAP.
- **Orphan Drugs:** Approved CAP vendor may request that CMS allowed it to supply single indication orphan drugs under the CAP.

Regulation text describing the above may be found at 42 CFR 414 Subpart K.

Changes to the drug list: Written requests for changes to the approved CAP vendor's drug list must be submitted to CMS and the CAP designated A/B MAC (B). The requests must include a rationale for the proposed change, and a discussion of the impact on the CAP, including safety, waste, and potential for cost savings. If approved, routine changes will become effective at the beginning of the following quarter. CMS will post the changes on the CMS Web site: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/CompetitiveAcquisforBios/index.html> and notify the A/B MACs (B) and participating CAP physicians of any changes on a quarterly basis via a recurring Change Request (CR). Physicians who participate in the CAP are required to obtain all CAP drugs on the updates from the approved CAP vendor unless medical necessity requires the use of a formulation not supplied by the vendor. Please note that approved

changes will apply only to the list of drugs supplied by the approved CAP vendor who submitted the request; therefore, each vendor's drug list may contain different drugs after changes to the initial drug list are approved.

Timeline for changes: There will be one timeline for the submission of changes to the approved CAP vendor's drug list. For new HCPCS and/or NDC codes, and substitutions or changes to NDC codes supplied under an existing HCPCS code, the approved CAP vendor will be required to submit requests for drug list changes no later than four months before the beginning of the quarter in which the changes will take effect. Updated tables listing the HCPCS codes under a specific vendor's drug categories will be available 30 days prior to the start of the following quarter. NDC number changes will not require associated table modifications and will not affect established payment amounts. Physicians will be notified of these changes 30 days before the start of a quarter. Price files incorporating these changes will be available 7-14 days prior to the effective date for the corresponding changes. An example of the timeline for the July 1, 2008 HCPCS and NDC code changes appears below.

Example of Timeline for HCPCS and NDC Additions

Date	Action
3/1/2008	Vendor deadline to submit request for new HCPCS and/or NDCs
3/12/2008	CMS begins approval process to evaluate vendor request
5/24/2008	HCPCS and/or NDC changes approved to become effective July 1, 2008
5/30/2008	Per the approval of all clearance processes, CMS issues a CR regarding approved drug list changes and tables that will become effective July 1, 2008
6/2/2008	Designated A/B MAC (B) downloads HCPCS changes to the drug table. List posted onto the CMS Web site. Physicians receive updated list of drugs from the CAP vendor.
6/5/2008	A/B MACs (B) shall acquire HCPCS changes from the Designated A/B MAC (B)
6/17-6/24/2008	Price file with new codes posted
7/1/2008	Effective date for additional HCPCS codes; beginning of next quarter

Payment amount: The payment amount for new HCPCS codes added to an approved CAP drug vendor's drug list will be ASP + 6%. Addition or substitution of NDC numbers under an existing HCPCS code supplied by an approved CAP vendor will not change the CAP single payment amount for that HCPCS code. CMS will update the single payment amount based on the approved CAP vendor's reported net acquisition costs for the category of drugs on an annual basis.

100.8.3 - CAP Not Otherwise Classified (NOC) Drugs
(Rev. 1034, Issued: 08-18-06; Effective: 01-01-07; Implementation: 01-02-07)

As described in Section 100.8.2, approved CAP vendors are able to request approval for changes to the list of drugs that they supply under the CAP. In an effort to improve beneficiary access to newly marketed drugs, approved CAP vendors will be able to request the addition of certain NOC drugs as defined by CMS to their drug lists for claims with dates of service on or after January 1, 2007.

The process for adding NOC drugs to an approved CAP vendor's drug list will generally follow the process for adding new drugs to the CAP. An approved CAP vendor is required to submit a written request to add specific NOC drugs to the CAP designated A/B MAC (B). The request must include a rationale for the proposed change, and a discussion of the impact on the CAP, including safety, waste, and potential for cost savings. The CAP designated A/B MAC (B) will review the application and forward the information to CMS along with a recommendation for approval or denial. CMS will make a final decision upon review of the application and the designated A/B MAC (B)'s recommendation. If approved, changes will become effective at the beginning of the following quarter. CMS will post the approved NOC additions along with other changes to the CAP Drug List on the CMS Web site:

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/CompetitiveAcquisforBios/index.html>

Additions of NOC drugs apply only to the approved CAP vendor and the CAP category identified on the request. Therefore, each vendor's drug list may contain different drugs after changes to the initial drug list are approved. The timeline for this process follows the timeline for HCPCS code changes described in manual section 100.8.2. CMS will also continue to notify A/B MACs (B) of any changes to the CAP drug list on a quarterly basis. Participating CAP physicians will also be notified of changes at least 30 days before the approved changes will become effective.

The process to approve CAP NOC drugs differs from the process for other CAP drug approvals in two significant ways. First, CMS will define a list of CAP NOC drugs that the approved CAP vendor must use when requesting the addition of NOC drugs to the CAP. The CAP NOC drug list is based on the current ASP NOC list and is limited to drugs that are likely to fit the existing CAP drug category (or categories) and drugs that have a single national ASP-based payment amount. The list of CAP NOC drugs will be posted on the CMS CAP Web site: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/CompetitiveAcquisforBios/index.html> and updated quarterly. The CAP NOC drug payment amount is set at the rate published on the ASP NOC file consistent with the next quarterly update; the CAP NOC payment amount will be updated annually.

Second, physician administration claims and vendor drug claims for services related to CAP NOC drugs are required to use the CAP-specific Q-code for all CAP NOC drug claims along with the appropriate CAP modifiers. This code is necessary to distinguish CAP NOC drug claims from ASP NOC claims and to provide payment for CAP NOC drugs within the CAP. In addition to the use of the CAP NOC Q-code, CAP NOC claims must identify the specific NOC drug that had been administered. All remaining

requirements concerning the proper submission of a claim continue to be effective, and claims processing for CAP NOC drug claims will follow procedures described in previous CAP CRs and applicable Manual sections. All current editing for other NOC codes shall also be applied to the CAP NOC code.

Participating CAP physicians will continue to use ASP NOC codes when billing for NOC drugs that are not included in the CAP category they have chosen. Participating CAP physicians are required to obtain all CAP drugs from the approved CAP vendor including any drugs added to the CAP drug list under this process, unless medical necessity requires the use of a formulation not supplied by the vendor.

100.8.3.1 - Editing for CAP NOC Drugs

(Rev. 3721, Issued: 02-24-17, Effective: 05-25-17, Implementation: 05-25-17)

Should the A/B MAC (B) receive a CAP NOC code, but the description does not match a CAP NOC drug on the approved list, the contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Two.

Group Code: CO
CARC: 16
RARC: N350
MSN: N/A

Should a non-CAP physician submit the CAP NOC code, the contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Two.

Group Code: CO
CARC: 16
RARC: N56
MSN: N/A

Should a CAP physician submit a J NOC code with a description of a CAP approved NOC drug, the contractor shall use the following remittance advice messages and associated codes when rejecting/denying claims under this policy. This CARC/RARC combination is compliant with CAQH CORE Business Scenario Two.

Group Code: CO
CARC: 16
RARC: N56
MSN: N/A

100.9 - Non-Participating Physicians Who Elect the CAP

(Rev. 866, Issued: 02-17-06, Effective: 07-01-06, Implementation: 07-03-06)

Participating CAP physicians must appeal drug administration denials. For a non-participating physician that elects to participate in the CAP, he or she must agree to accept assignment for all CAP drug administration charges to allow for the Medicare beneficiary's and approved CAP vendor's appeal rights.

A/B MACs (B) shall pay all HCPCS codes that provide payment for the administration of CAP drugs on an assigned basis.

101 - The Competitive Acquisition Program (CAP) for Drugs and Instructions on Special CAP Appeals Requirements and Delivery of Dispute Resolution Services

(Rev. 1076, Issued: 10-13-2006; Effective: 07-01-06; Implementation: 11-13-06)

All appeals of denied CAP claims will be processed by the local A/B MAC (B). This includes an appeal for the denial of an approved CAP vendor's drug product claim. This break from the traditional administrative appeals process is necessitated by the arrangement whereby the CAP designated A/B MAC (B) pays the approved CAP vendor claim only after a match is found in the central claims processing system indicating the corresponding participating CAP physician's drug administration claim was paid by the local A/B MAC (B). As a result, the only appealable issues attach to the decision of the local A/B MAC (B).

The CAP claims processing arrangement departs from the standard Part B claims processing routine. The A/B MAC (B) will make an initial determination on whether the participating CAP physician's claim for drug administration is payable by applying local coverage determinations (LCDs) to the administration and to the drugs billed as no-pay on the claim. If the A/B MAC (B) finds the no-pay or administration lines are contrary to the LCDs, it will deny the administration and pass on a non-approved indicator on the no-pay lines. The A/B MAC (B) sends a pay process indicator to CWF for each of the no-pay lines. When the designated A/B MAC (B) enters the vendor claim into the system, CWF looks for a match. When CWF goes to find the match, it will not match against non-approved lines. If it finds a match among the approved lines, then it lets the designated A/B MAC (B) know and the claim is paid. If it doesn't find a match, the claim recycles for 90 days. Periodically during the 90 days, the designated A/B MAC (B) looks for a match again. If it finds one, the claim pays. If after 90 days it doesn't find a match, then the claim denies. The A/B MAC (B) will notify CWF whether the approved CAP vendor's claim for the drug is payable. If the vendor's claim is not payable because of a determination of the A/B MAC (B), then the designated A/B MAC (B) will be notified. In turn, the designated A/B MAC (B) will deny the approved CAP vendor's claim. The claims processing requirements for this process have been described in previous CAP Change Requests.

Because the A/B MAC (B)'s initial determination on the drug administration claim decides the outcome of the of the approved CAP vendor's drug product claim, CMS

interprets the initial determination to be an initial determination of the approved CAP vendor's drug product claim for the purposes of the Part B appeals regulations found at 42 CFR 405.801. Accordingly, the approved CAP vendor shall not file its appeal with the CAP designated A/B MAC (B). Rather, the approved CAP vendor shall file its appeal with the A/B MAC (B), with one exception.

That exception is the case where the approved CAP vendor's drug product claim was denied because there was no matching claim filed by the participating CAP physician after 90 days of recycling. In this instance, the designated A/B MAC (B) will deny the approved CAP vendor's drug product claim and suppress appeal rights. The remittance notice will instruct the approved CAP vendor that it may request a reopening. Upon receipt of a reopening request, the designated A/B MAC (B) will contact the participating CAP physician and request that he or she fulfill his or her CAP participation agreement by filing the drug administration claim. If the participating CAP physician does not follow through as required, then the designated A/B MAC (B) will initiate the dispute resolution track discussed below.

In the role of the furnishing Medicare supplier, the approved CAP vendor is a party to any appeal of a denied drug administration claim filed by a participating CAP physician with the A/B MAC (B). The balance of the rules pertaining to the A/B MAC (B)'s adjudication of Part B appeals applies (See Pub. 100-04, Chapter 29), with the following exceptions:

- a) The A/B MAC (B) will check for duplicate appeals. If the participating CAP physician and the approved CAP vendor filed independent appeals connected with the same service, then the A/B MAC (B) will merge the two files.
- b) The A/B MAC (B) will ensure the approved CAP vendor is copied on all correspondence connected with the participating CAP physician's appeal of the denied drug administration claim.

101.1 - Dispute Resolution Services for Vendors

(Rev. 1076, Issued: 10-13-2006; Effective: 07-01-06; Implementation: 11-13-06)

The CAP designated A/B MAC (B) has responsibility to deliver dispute resolution services to the approved CAP vendor when the approved CAP vendor's drug product claims are not paid because the participating CAP physician has either failed to file a payable drug administration claim or has failed to file a successful appeal of the denied drug administration claim.

The approved CAP vendor may file its drug product claim on the day it delivers the drug to the participating CAP physician. The participating CAP physician is contractually obligated to file his or her CAP drug administration claim within 14 days of administering the drug.

The approved CAP vendor may determine its own threshold for financial exposure. If the approved CAP vendor does not receive payment within 14 days, then the approved CAP vendor may request assistance from the CAP designated A/B MAC (B) in encouraging the participating CAP physician to fulfill his or her contractual obligations. If the CAP designated A/B MAC (B)'s dispute resolution services do not yield adequate results for the approved CAP vendor, then the approved CAP vendor may request that the CAP designated A/B MAC (B) investigate the participating CAP physician's performance and recommend that the participating CAP physician's CAP election agreement be terminated. If the CAP designated A/B MAC (B) does recommend termination, then a suspension, hearing, and final termination process set forth in 42 CFR 414.916 will be employed by CMS.

101.2 - Dispute Resolution Services for Physicians

(Rev. 1076, Issued: 10-13-2006; Effective: 07-01-06; Implementation: 11-13-06)

If a participating CAP physician has an issue concerning the quality or safety of the services and/or drug delivered by the approved CAP vendor, then the participating CAP physician should address that issue through the approved CAP vendor's grievance process. If the participating CAP physician is not satisfied with the results of the approved CAP vendor's grievance process, then the participating physician may ask the CAP designated A/B MAC (B) to review the situation and encourage the approved CAP vendor to comply with its contractual obligations. If the approved CAP vendor refuses to comply with its contractual CAP obligations, then the CAP designated A/B MAC (B) may recommend to CMS that the approved CAP vendor's participation in CAP be terminated. If the CAP designated A/B MAC (B) does recommend termination, then a suspension, hearing, and final termination process set forth in 42 CFR 414.917 will be employed by CMS.

101.3 - Dispute Resolution Services for Beneficiaries

(Rev. 1076, Issued: 10-13-2006; Effective: 07-01-06; Implementation: 11-13-06)

The approved CAP vendor is not permitted to bill the beneficiary for any coinsurance or deductible until the approved CAP vendor's drug product claim has been paid by the designated A/B MAC (B). If the approved CAP vendor does bill the beneficiary before payment on the drug claim has been received, or if the approved CAP vendor bills the beneficiary too much after the drug product claim has been paid, then the beneficiary may use the approved CAP vendor's grievance process to challenge the inappropriate billing. If the approved CAP vendor's grievance process does not yield satisfactory results for the beneficiary, then the beneficiary may ask the CAP designated A/B MAC (B) to counsel the approved CAP vendor on its contractual CAP obligations.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
<u>R12511CP</u>	02/15/2024	Manual Updates to Chapters 1 and 17 of the Medicare Claims Processing Manual to Reflect Policies Finalized in the Calendar Year (CY) 2024 Physician Fee Schedule Final Rule	03/18/2024	13504
<u>R12201CP</u>	08/10/2023	Annual Clotting Factor Furnishing Fee Update 2024	01/02/2024	13313
<u>R12067CP</u>	06/02/2023	New Claims Modifier Requirement for Drugs and Biologicals from a Single-Dose Container or Single-Use Package	07/03/2023	13056
<u>R12013CP</u>	05/02/2023	Inflation Reduction Act Section 11407: Limitations on Monthly Coinsurance and Adjustments to Supplier Payment Under Medicare Part B for Insulin Furnished Through Durable Medical Equipment (DME) – IMPLEMENTATION NO LONGER SENSITIVE	07/03/2023	13014
<u>R11917CP</u>	03/21/2023	Inflation Reduction Act Section 11407: Limitations on Monthly Coinsurance and Adjustments to Supplier Payment Under Medicare Part B for Insulin Furnished Through Durable Medical Equipment (DME) – IMPLEMENTATION- Rescinded and replaced by Transmittal 12013	07/03/2023	13014
<u>R11834CP</u>	02/02/2023	Inflation Reduction Act Section 11407: Limitations on Monthly Coinsurance and Adjustments to Supplier Payment Under Medicare Part B for Insulin Furnished Through Durable Medical Equipment (DME) – IMPLEMENTATION NO LONGER SENSITIVE- Rescinded and replaced by Transmittal 11917	07/03/2023	13014
<u>R11764CP</u>	12/22/2022	New Medicare Part B Immunosuppressant Drug Benefit (PBID) – Implementation	01/03/2023	12804
<u>R11646CP</u>	10/19/2022	New Medicare Part B	01/03/2023	12804

Rev #	Issue Date	Subject	Impl Date	CR#
		Immunosuppressant Drug Benefit (PBID) – Implementation - Rescinded and replaced by Transmittal 11764		
<u>R11596CP</u>	09/13/2022	Annual Clotting Factor Furnishing Fee Update 2023	01/03/2023	12860
<u>R11567CP</u>	08/18/2022	Annual Clotting Factor Furnishing Fee Update 2023-Rescinded and replaced by Transmittal 11596	01/03/2023	12860
<u>R11427CP</u>	05/20/2022	Claims Processing Manual Update - Pub. 100.04 for Elimination of Certificates of Medical Necessity (CMNs) and Durable Medical Equipment Forms (DIFs)	01/03/2023	12734
<u>R11414CP</u>	05/12/2022	Claims Processing Manual Update - Pub. 100.04 for Elimination of Certificates of Medical Necessity (CMNs) and Durable Medical Equipment Forms (DIFs) - – Rescinded and replaced by Transmittal 11427	06/13/2022	12734
<u>R11140CP</u>	12/02/2021	Update to the Internet Only Manual (IOM) Publication 100-04, Chapters 3 and 17	01/04/2022	12525
<u>R10329CP</u>	08/28/2020	Annual Clotting Factor Furnishing Fee Update 2021	01/04/2021	11932
<u>R10236CP</u>	07/31/2020	Update to the IOM Publication (Pub) 100-04, Medicare Claims Processing Manual, Chapters 1, 6, 8, 17, 20, 22, 24, and 31 Referencing the Active Universal Resource Locators (URLs) for the Washington Publishing Company (WPC) and the ASC X12 Organizations, and Updates to the HIPAA Eligibility Transaction System (HETS)	08/31/2020	11857
<u>R4384CP</u>	08/30/2019	Annual Clotting Factor Furnishing Fee Update 2020	01/06/2020	11435
<u>R4233CP</u>	02/08/2019	Update to Publication (Pub.) 100-04 Chapters 4 and 17 to Provide Language-Only Changes for the New Medicare	03/12/2019	11084

Rev #	Issue Date	Subject	Impl Date	CR#
		Card Project		
<u>R4204CP</u>	01/17/2019	January 2019 Update of the Hospital Outpatient Prospective Payment System (OPPS)	01/07/2019	11099
<u>R4186CP</u>	12/31/2018	January 2019 Update of the Hospital Outpatient Prospective Payment System (OPPS) – Rescinded and replaced by Transmittal 4204	01/07/2019	11099
<u>R4128CP</u>	09/07/2018	Annual Clotting Factor Furnishing Fee Update 2019	01/07/2019	10918
<u>R3932CP</u>	12/08/2017	Special Requirements for Immunosuppressive Drugs	03/09/2018	10370
<u>R3941CP</u>	12/22/2017	January 2018 Update of the Hospital Outpatient Prospective Payment System (OPPS)	01/02/2018	10417
<u>R3862CP</u>	09/15/2017	Annual Clotting Factor Furnishing Fee Update 2018	01/02/2018	10254
<u>R3856CP</u>	09/01/2017	Clarification of the Billing of Immunosuppressive Drugs	10/02/2017	10235
<u>R3721CP</u>	02/24/2017	Updates to Pub. 100-04, Chapters 12, 17 and 23 to Correct Remittance Advice Messages	05/25/2017	9906
<u>R3607CP</u>	08/26/2016	Annual Clotting Factor Furnishing Fee Update 2017	01/03/2017	9759
<u>R3538CP</u>	06/09/2016	JW Modifier: Drug Amount Discarded/Not Administered to Any Patient	01/03/2017	9603
<u>R3530CP</u>	05/24/2016	JW Modifier: Drug Amount Discarded/Not Administered to Any Patient - Rescinded and replaced by Transmittal 3538	07/05/2016	9603
<u>R3508CP</u>	04/29/2016	JW Modifier: Drug Amount Discarded/Not Administered to Any Patient – Rescinded and replaced by Transmittal 3530	07/05/2016	9603

Rev #	Issue Date	Subject	Impl Date	CR#
<u>R3340CP</u>	08/21/2015	Annual Clotting Factor Furnishing Fee Update 2016	01/04/2016	9295
<u>R3292CP</u>	07/10/2015	Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - July 2015 Update	07/06/2015	9167
<u>R3254CP</u>	05/08/2015	Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes - July 2015 Update	07/06/2015	9167
<u>R3085CP</u>	10/03/2014	Update to Pub. 100-04, Chapter 17 to Provide Language-Only Changes for Updating ICD-10 and ASC X12	11/04/2014	8647
<u>R3055CP</u>	08/29/2014	Annual Clotting Factor Furnishing Fee Update 2015	01/05/2015	8891
<u>R2931CP</u>	04/15/2014	Aprepitant for Chemotherapy Induced Emesis	07/07/2014	8418
<u>R2903CP</u>	03/11/2014	April Update of the Hospital Outpatient Prospective Payment System (OPPS)	04/07/2014	8653
<u>R2894CP</u>	02/28/2014	April Update of the Hospital Outpatient Prospective Payment System (OPPS) – Rescinded and replaced by Transmittal 2903	04/07/2014	8653
<u>R2883CP</u>	02/21/2014	Aprepitant for Chemotherapy Induced Emesis – Rescinded and replaced by Transmittal 2931	07/07/2014	8418
<u>R2760CP</u>	08/09/2013	Annual Clotting Factor Furnishing Fee Update 2014	01/06/2014	8423
<u>R2554CP</u>	09/28/2012	Annual Clotting Factor Furnishing Fee Update 2013	01/07/2013	8049
<u>R2437CP</u>	04/04/2012	Pharmacy Billing for Drugs Provided “Incident to” a Physician Service (This CR rescinds and fully replaces CR 7109)	01/01/2013	7397

Rev #	Issue Date	Subject	Impl Date	CR#
<u>R2424CP</u>	03/16/2012	Influenza Virus Vaccine Annual Payment Limit Effective Date	08/01/2012	7741
<u>R2368CP</u>	12/16/2011	Pharmacy Billing for Drugs Provided "Incident to" a Physician Service (This CR rescinds and fully replaces CR 7109) – Rescinded and replaced by Transmittal 2437	01/01/2013	7397
<u>R2312CP</u>	09/23/2011	Pharmacy Billing for Drugs Provided "Incident to" a Physician Service (This CR rescinds and fully replaces CR 7109) – Rescinded and replaced by Transmittal 2368	10/01/2011	7397
<u>R2279CP</u>	08/19/2011	Annual Clotting Factor Furnishing Fee Update 2012	01/03/2012	7543
<u>R2271CP</u>	08/05/2011	Pharmacy Billing for Drugs Provided "Incident to" a Physician Service (This CR rescinds and fully replaces CR 7109) – Rescinded and replaced by Transmittal 2312	10/01/2011	7397
<u>R2251CP</u>	07/01/2011	Pharmacy Billing for Drugs Provided "Incident to" a Physician Service (This CR rescinds and fully replaces CR 7109) – rescinded and replaced by Transmittal 2271	08/15/2011	7397
<u>R2214CP</u>	05/13/2011	Pharmacy Billing for Drugs Provided "Incident to" a Physician Service (This CR rescinds and fully replaces CR 7109) – Rescinded and replaced by Transmittal 2251	06/29/2011	7397
<u>R2115CP</u>	12/10/2010	Pharmacy Billing for Drugs Provided "Incident to" a Physician Service – Rescinded and replaced by Transmittal 21214 (CR 7397)	03/14/2011	7109
<u>R2068CP</u>	10/15/2010	Annual Clotting Factor Furnishing Fee Update 2011	01/03/2011	7168

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<u>R1962CP</u>	04/30/2010	Discarded Drugs and Biologicals Updates	07/30/2010	6711
<u>R1908CP</u>	02/05/2010	Clotting Factor Furnishing Fee- Conforming Manual Change to “Unit”	03/05/2010	6811
<u>R1829CP</u>	10/16/2009	Annual Clotting Factor Furnishing Fee Update	01/04/2010	6673
<u>R1760CP</u>	06/23/2009	July 2009 Update of the Hospital Outpatient Prospective Payment System (OPPS)	07/06/2009	6492
<u>R1745CP</u>	05/22/2009	July 2009 Update of the Hospital Outpatient Prospective Payment System (OPPS) - Rescinded and replaced by Transmittal 1760	07/06/2009	6492
<u>R1657CP</u>	12/31/2008	January 2009 Update of the Hospital Outpatient Prospective Payment System (OPPS)	01/05/2009	6320
<u>R1653CP</u>	12/19/2008	Annual Clotting Factor Furnishing Fee Update	01/05/2009	6277
<u>R1599CP</u>	09/19/2008	October Update of the Hospital Outpatient Prospective Payment System (OPPS)	10/06/2008	6196
<u>R1581CP</u>	08/29/2008	Discarded Erythropoietin Stimulating Agents for Home Dialysis	12/01/2008	6133
<u>R1564CP</u>	07/25/2008	New Hemophilia Clotting Factor and HCPCS Code	01/05/2009	6006
<u>R1551CP</u>	07/18/2008	New Hemophilia Clotting Factor and HCPCS Code - Rescinded and replaced by Transmittal 1564	01/05/2009	6006
<u>R1539CP</u>	06/20/200/	Self-Administered Drug Exclusion Lists	07/21/2008	5988
<u>R1513CP</u>	05/23/2008	Average Sales Price Updates	06/23/2008	5798
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