CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 3085	**Date: October 3, 2014**
	Change Request 8647

SUBJECT: Update to Pub. 100-04, Chapter 17 to Provide Language-Only Changes for Updating ICD-10 and ASC X12

I. SUMMARY OF CHANGES: This CR contains language-only changes for updating ICD-10 and ASC X12 language in Pub 100-04, Chapter 17. Also references to previous contractor types have been changed to MACs where appropriate in sections that are included. There are no new coverage policies, payment policies, or codes introduced in this transmittal. Specific policy changes and related business requirements have been announced previously in various communications.

EFFECTIVE DATE: ICD-10: Upon Implementation of ICD-10; ASC X12: January 1, 2012
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: ICD-10: Upon Implementation of ICD-10; ASC X12: November 4, 2014

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	17/ Table of Contents
R	17/70/ Claims Processing Requirements - General
R	17/70.1/ Billing Drugs Electronically - NCPDP
R	17/80.1.4/ MSN/Claim Adjustment Message Codes for Oral Cancer Drug Denials
R	17/80.2.1/ HCPCD Codes for Oral Anti-Emetic Drugs
R	17/80.2.3/ MSN Denial/Claim Adjustment and Remark Messages for Anti-Emetic Drugs
R	17/80.2.4/ Billing and Payment Instructions for A/B MACs (A)
R	17/80.3.1/ Requirements for Billing A/B MAC (A) for Immunosuppressive Drugs
R	17/80.3.2/ MSN/Remittance Messages for Immunosuppressive Drugs
R	17/80.6/ Intravenous Immune Globulin
R	17/80.12/ Claims Processing Rules for ESAs Administered to Cancer Patients for Anti-Anemia Therapy
R	17/90.3/ Hospital Outpatient Payment Under OPPS for New, Unclassified Drugs and Biologicals After FDA Approval But Before Assignment of a Product-Specific Drug or Biological HCPCS Code
R	17/90.4/ Hospital Billing For Take-Home Drugs
R	17/100/ The Competitive Acquisition Program (CAP) for Drugs and Biologicals Not Paid on a Cost or Prospective Payment Basis
R	17/100.2.3/ Submitting the Prescription Order Numbers and No Pay Modifiers

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-04	Transmittal: 3085	Date: October 3, 2014	Change Request: 8647

SUBJECT: Update to Pub. 100-04, Chapter 17 to Provide Language-Only Changes for Updating ICD-10 and ASC X12

EFFECTIVE DATE: ICD-10: Upon Implementation of ICD-10; ASC X12: January 1, 2012
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: ICD-10: Upon Implementation of ICD-10; ASC X12: November 4, 2014

I. GENERAL INFORMATION

A. Background: This Change Request (CR) contains language-only changes for updating ICD-10 and ASC X12 language in Pub 100-04, Chapter 17.

B. Policy: There are no new coverage policies, payment policies, or codes introduced in this transmittal. Specific policy changes and related business requirements have been announced previously in various communications.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Othe
		A	B	HHH		FISS	MCS	VMS	CWF	
8647.1	All MACs shall be aware of the updated language for ICD-10 and for ASC X12 in Pub. 100 - 04, Chapter 17.	X	X	X	X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibi			
		A/B MAC			
		A	B	H H H	
	None				

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	N/A

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Not Applicable

Post-Implementation Contact(s): Contact your Contracting Office Representative (COR)

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare Claims Processing Manual
Chapter 17 - Drugs and Biologicals

Table of Contents

(Rev.3085, Issued: 10-03-14)

70 - Claims Processing Requirements - General

(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)**

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 Washington Publishing Company web site at http://www.wpc-edi.com 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 meg

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.

80.1.4 - MSN/*Claim Adjustment* Message Codes for Oral Cancer Drug Denials

(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)

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:

6.2 - Drugs not specifically classified as effective by the Food and Drug Administration are not covered. (Claim Adjustment Reason Code 114)

6.3 - Payment cannot be made for oral drugs that do not have the same active ingredients as they would have if given by injection. (Group Code-PR 46)

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.

Code	Description
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	DRONABINOL2.5mg, 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.
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.

Code	Description
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.

80.2.3 - MSN Denial */Claim Adjustment and Remark* Messages for 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)

If the claim for an anti-emetic drug is denied because FDA did not approve it or because the drug is not being used as part of an anticancer chemotherapeutic regimen, the contractor uses one of the following appropriate messages on the MSN:

6.2 - Drugs not specifically classified as effective by the Food and Drug Administration are not covered. (Claim Adjustment Reason Code 114)

6.4 - Medicare does not pay for an oral anti-emetic drug that is not administered for use immediately before, at, or within 48 hours after administration of a Medicare covered chemotherapy drug. (Group Code PR 96 with *Remittance Advice* Remark Code M100)

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.

*C*laims 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.

80.3.1 - 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 OPPS bill on *ASC X12 837 institutional format or paper* Form CMS-1450 *(if approved)* with bill type 12x (hospital inpatient Part B) or l3x (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.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)

A. MSN

MSN messages for denied Immunosuppressive Drugs are as follows:

If no transplant use:

> 6.2 - Drugs not specifically classified as effective by the Food and Drug Administration are not covered.

If the claim for an immunosuppressive drug is partially denied because of the 30-day supply limitation, use the following message:

> 4.3 - Prescriptions for immunosuppressive drugs are limited to a 30-day supply.

B. Remittance

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

If the claim is denied because the immunosuppressive drug is not approved by the FDA, the *A/B MAC (A)* uses claim adjustment reason code/message 114, Procedure/product not approved by the Food and Drug Administration.

If the claim is denied because the benefit period has expired or because of the 30 day limitation, the FI uses claim adjustment reason code/message 35, Benefit maximum has been reached.

If the claim is denied for the immunosuppressive drug because a transplant was not covered, the FI uses claim adjustment reason code/message 107, Claim/service denied because the related or qualifying claim/service was not paid or identified on the claim.

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. 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.

80.12 - Claims Processing Rules for ESAs Administered to Cancer Patients for Anti-Anemia Therapy

(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 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, C92Z0, C92Z1, or C92Z2), 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.

Report Medicare Summary Notice message 15.20, “The following policies [NCD 110.21] were used when we made this decision”, and remittance reason code 50, “These are non-covered services because this is not deemed a `medical necessity' by the payer” for denied ESA claims.

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.

90.3 - Hospital Outpatient Payment Under OPPS 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 (OPPS).

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.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 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, beneficiary Medicare information/ Health insurance (HIC) number, 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 local *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 THRCA 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.

100.2.3 - Submitting the Prescription Order Numbers and No Pay Modifiers

(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)

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 contractors shall return the following Remittance Advice Claim Adjustment Reason Code (CARC) and Remittance Advice Remark Codes (RARCs):

CARC 16 – Claim/service lacks information which is needed for adjudication. Additional information is supplied using remittance advice remarks codes whenever appropriate. This change to be effective

4/1/2007: At least one Remark Code must be provided (may be comprised of either the Remittance Advice Remark Code or NCPDP Reject Reason Code.)

RARC MA130 - Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.

RARC N388 – Missing/incomplete/invalid prescription number.

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. *A/B MACs (B)* shall return the following messages:

RARC MA130 – Your claim contains incomplete or invalid information, and no appeals rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.

RARC N388 – Missing/incomplete/invalid prescription number.