CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 1281	**Date: JULY 6, 2007**
	Change Request 5655

Subject: Clarification on Billing for Oral Three Drug Combination Anti-Emetic (Aprepitant)

I. SUMMARY OF CHANGES: The purpose of this CR is to clarify that hospital outpatient departments may bill the entire Tri-Pack to their Medicare Fiscal Intermediary as part of the three drug combination anti-emetic. It has come to CMS's attention that some contractors are denying payment for the entire Tri-Pak as two doses are sent home with the beneficiary. This is a misinterpretation of CR 4301, Billing for Take Home Drugs, which requires billing drugs that are for take home use only to the DME MACs. If aprepitant for the 3-drug combination is dispensed in a Tri-Pak in a hospital outpatient setting; the Tri-Pak may be billed to the FI as 57 units of J8501. We will also clarify instructions for billing the DME MAC for aprepitant.

Clarification
Effective Date: April 4, 2005
Implementation Date: January 7, 2008

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	17/70 Claims Processing Requirements - General
R	17/80.2 Oral Anti-Emetic Drugs Used as Full Replacement for Intravenous Anti-Emetic Drugs as Part of a Cancer Chemotherapeutic Regimen

III. FUNDING:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2008 operating budgets.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 1281	Date: July 6, 2007	Change Request: 5655

SUBJECT: Clarification on Billing for Oral Three Drug Combination Anti-Emetic (Aprepitant)

Effective Date: **April 4, 2005**

Implementation Date: January 7, 2008

I. GENERAL INFORMATION

A. Background: It has come to CMS' attention that some contractors have been denying aprepitant claims. In April CMS reminded contractors that the three 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. To facilitate coverage reviews, providers should bill all three drugs in the oral anti-emetic combination as well as the qualifying highly emetogenic anti-cancer agents on the same claim. This CR clarifies FI and A/B MAC payment of the Emend® Tri-Pak.

B. Policy: There is no change in policy.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DME RC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5655.1	Contractors shall accept claims for 57 units of aprepitant (J8501) when dispensed to the beneficiary by a hospital in the form of the Tri-Pak.	X		X								
5655.2	FIs and A/B MACs shall educate their hospital providers to follow the instructions in the LCD for oral anti-emetic drugs (L5058) when billing the second and third doses of aprepitant to the DME MAC.	X		X								
5655.3	Coverage of aprepitant is dependent upon the beneficiary's receipt of a highly emetogenic anti-cancer chemotherapeutic agent.	X		X								
5655.3.1	Effective for dates of service on or after April 4, 2005, through December 31, 2007, the following HCPCS dispensed by non-OPPS providers qualify the beneficiary to receive the 3 drug combination oral anti-emetic: Carmustine, J9050; Cisplatin, J9060, J9062; Cyclophosphamide, J9070, J9080, J9091, J9092, J9093, J9094, J9095, J9096, J9097; Dacarbazine, J9130, J9140; Mechlorethamine,	X		X								

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	J9230; Streptozocin, J9320; Doxorubicin, J9000, J9001; Epirubicin, J9178											
5655.3.2	Effective of dates of services on or after April 4, 2005, through December 31, 2007, the following HCPCS dispensed by OPPS providers qualify the beneficiary to receive the 3 drug combination oral anti-emetic: Carmustine, J9050 Cisplatin, J9060 Cyclophosphamide, J9070, J9093, Dacarbazine, J9130 Mechlorethamine, J9230; Streptozocin, J9320; Doxorubicin, J9000, J9001; Epirubicin, J9178.	X		X								
5655.3.3	Effective of dates of services on or after January 1, 2008, the following HCPCS dispensed by all providers qualify the beneficiary to receive the 3 drug combination oral anti-emetic: Carmustine, J9050; Cisplatin, J9060, J9062; Cyclophosphamide, J9070, J9080, J9091, J9092, J9093, J9094, J9095, J9096, J9097; Dacarbazine, J9130, J9140; Mechlorethamine, J9230; Streptozocin, J9320; Doxorubicin, J9000, J9001; Epirubicin, J9178.	X		X								
5655.4	Coverage of aprepitant is part of the three drug combination of aprepitant (Emend®) (J8501), a 5-HT_3 antagonist, e.g. granisetron (Q0166), ondansetron (Q0179), or dolasetron (Q0180), and dexamethasone, a cortico-steroid (J8540). All of the drugs in the three drug combination shall be billed in the same claim with the qualifying highly emetogenic anti-cancer agents.	X		X								
5655.5	Medicare contractors shall adjust denied or partially denied aprepitant (J8501) claims at the provider's request when brought to their attention within 6 months of implementation date of this instruction and may bypass timely filing to complete the adjustment.	X		X								

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A / B MAC	DME MAC	FI	CARRIER	DME RC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5655.6	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X								

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:
"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
CR 3831	Coverage of aprepitant is dependent upon the beneficiary's receipt of a highly emetogenic anti-cancer chemotherapeutic agent.
CR 3831	Coverage of aprepitant is as part of the three drug combination of aprepitant (Emend®) (J8501), a 5-HT3 antagonist, e.g. granisetron (Q0166), ondansetron (Q0179), or dolasetron (Q0180), and dexamethasone, a cortico-steroid (J8540).

B. For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact(s): Sherry Murray, sherry.murray@cms.hhs.gov, 410-786-6145, or Cindy Murphy, cindy.murphy@cms.hhs.gov, 410-786-5733.

Post-Implementation Contact(s): Local Regional Office

VI. FUNDING

A. *For Fiscal Intermediaries, Carriers, and the Durable Medical Equipment Regional Carrier (DMERC)*:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2008 operating budgets.

B. *For Medicare Administrative Contractors (MAC)*:

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). 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.

70 - Claims Processing Requirements - General

(Rev. 1281; Issued: 07-06-07; Effective: 04-04-05; Implementation: 01-07-08)

No cross reference - CMS Staff developed

Carriers are billed with the Form CMS-1500 data set and FIs with the Form CMS-1450 data set (paper or approved EDI data set).
See chapters 25 and 26 for detailed claims processing requirements, including forms, data elements, and formats; and chapters 21 and 22 for MSN and remittance record requirements.

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

- On claims to FIs 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 carriers the drug is identified by HCPCS code;

- All drugs, including Prodrugs, are reported to DMERCS 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 carrier and FI 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	*Drug*	*Dosage*

J7189	*Factor VIIa*	*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	*Drug*	*Dosage*
J9355	*Trastuzumab*	*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	*Drug*	*Dosage*
J3100	*Tenecteplase*	*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.

80.2 - Oral Anti-Emetic Drugs Used as Full Replacement for Intravenous Anti-Emetic Drugs as Part of a Cancer Chemotherapeutic Regimen

(Rev. 1281; Issued: 07-06-07; Effective: 04-04-05; Implementation: 01-07-08)

See the Medicare Benefits Policy Manual, Chapter 15, for detailed coverage requirements.

Effective for dates of service on or after January 1, 1998, FIs and carriers pay 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 one, the date of service of the chemotherapy drug (beginning of the time of treatment), plus a period not to exceed two 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 HCPCS code.

The oral three drug combination is aprepitant, a 5-HT_3 antagonist, e.g. granisetron, ondansetron, or dolasetron, and dexamethasone, a cortico-steroid.

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 three 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, CAH, 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 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.

Payment for these drugs is made under Part B. Beginning 1/1/05, 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 the entire Tri-Pak to the FI (three days of aprepitant, 57 units of J8501), or

(2) Bill the first day's drug to their local FI or A/B MAC, and give a prescription for the second and third days' supply of aprepitant.

If billed to the FI, 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 LCD for oral anti-emetics: http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=5058&lcd_version=27&show=all

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 CMS *on a quarterly basis*.

The HCPCS codes shown in section 80.2.1 are used.

The 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 of cancer.

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-HT_3 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