CMS Manual System

Pub. 100-04 Medicare Claims Processing

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 590 **Date: JUNE 24, 2005**

CHANGE REQUEST 3831

SUBJECT: Aprepitant for Chemotherapy-Induced Emesis

I. SUMMARY OF CHANGES: The CMS is extending national coverage for the use of the oral anti-emetic three drug combination of aprepitant (Emend®), a 5-HT_3 antagonist, and dexamethasone for a specified patient population. The defined patient population for which the use of the oral anti-emetic three drug combination of aprepitant (Emend®), a 5-HT_3 antagonist, and dexamethasone is reasonable and necessary as only to those patients who are receiving one or more of the following anti-cancer chemotherapeutic agents: carmustine, cisplatin, cyclophosphamide, dacarbazine, mechlorethamine, streptozocin, doxorubicin, epirubicin and lomustine.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: April 4, 2005
IMPLEMENTATION DATE: July 5, 2005

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. 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:
(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	17/Table of Contents
R	17/80.2/Oral Anti-Emetic Drugs Used as Full Replacement for Intravenous Anti-Emetic Drugs as Part of a Cancer Chemotherapeutic Regimen
R	17/80.2.1/HCPCS Codes for Oral Anti-Emetic Drugs
N	17/80.2.4/Billing and Payment Instructions for FIs

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2005 operating budgets.

IV. ATTACHMENTS:

X	**Business Requirements**
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 590	Date: June 24, 2005	Change Request 3831

SUBJECT: Coverage of Aprepitant for Chemotherapy-Induced Emesis

I. GENERAL INFORMATION

A. Background: On April 4, 2005, the Centers for Medicare & Medicaid Services (CMS) announced a National Coverage Determination (NCD) covering the use of the oral anti-emetic 3-drug combination of aprepitant (Emend®), a 5-HT_3 antagonist, and dexamethasone for a specified patient population. This document provides the system business requirements for implementing this NCD.

B. Policy: The CMS is extending national coverage for the use of the oral anti-emetic 3-drug combination of aprepitant (Emend®), a 5-HT_3 antagonist, and dexamethasone for a specified patient population. The defined patient population for which the use of the oral anti-emetic 3-drug combination of aprepitant (Emend®), a 5-HT_3 antagonist, and dexamethasone is reasonable and necessary is 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

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3831.1	Contractors shall be advised that effective for claims with dates of service on or after 04/04/05, the oral anti-emetic drug aprepitant used in combination with a 5-HT_3 antagonist and dexamethasone is eligible for coverage for beneficiaries who are receiving one or more of these anti-cancer chemotherapeutic agents: carmustine, cisplatin, cyclophosphamide, dacarbazine, mechlorethamine, streptozocin, doxorubicin, epirubicin, lomustine.	X			X			X		
3831.2	Effective for dates of service on or after 04/04/05, FIs shall accept oral anti-emetic HCPCS code J8501 (aprepitant, oral, 5mg) for chemotherapy patients when billed with revenue code 0636.	X				X				
3831.3	FIs shall pay claims submitted for aprepitant when provided by a critical access hospital (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.	X				X				
3831.4	FIs shall pay claims submitted for aprepitant when provided by a hospital or SNF outpatient as follows: • based on for hospitals subject to OPPS; • under current payment methodologies for hospitals not subject to OPPS; or • on a reasonable cost basis for SNFs	X				X				
3831.5	DMERCs shall recognize and process HCPCS code J8501 (TOS 1, G) effective for dates of service on and after 04/04/05.				X			X		

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3831.6	CWF shall recognize HCPCS code J8501 as an oral anti-emetic drug effective for dates of service on and after 4/04/05 with TOS 1 and G and CWF category 17 and 60.								X	
3831.7	As in other cases, if data analysis indicates potentially aberrant billing, DMERCs shall utilize these standards when performing medical review of claims.				X			X		
3831.8	DMERCs shall use the ASP pricing file to pay claims with dates of service on or after 04/04/05. Effective 01/01/05, the payment allowance limit is based on the ASP + 6%.				X			X		
3831.9	Contractors shall adjust claims submitted for aprepitant with dates of service 04/04/05 through 07/04/05, if brought to their attention.	X			X					

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3831.10	A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include	X			X					

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	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 and incorporated into any educational events on this topic. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.									

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: April 4, 2005 **Implementation Date:** July 5, 2005	**No additional funding will be provided by CMS; contractor activities are to be carried out**

Pre-Implementation Contact(s): Karen Daily (coverage), 410-786-0189, karen.daily@cms.hhs.gov, Pat Brocato-Simons (coverage), 410-786-0261, patricia.brocatosimons@cms.hhs.gov, Yvonne Young (FIs) 410-786-1886, Yyoung@cms.hhs.gov , WKnarr (DMERCs) 410-786-0843 (TDD), WKnarr@cms.hhs.gov, Leslie Trazzi (Carriers), 410-786-7544, leslie.trazzi@cms.hhs.gov **Post-Implementation Contact(s):** Appropriate RO office	**within their FY 2005 operating budgets.**

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

Medicare Claims Processing Manual

Chapter 17 – Drug and Biologicals

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(Rev.590, 06-24-05)

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

(Rev.590, Issued: 06-24-05, Effective: 04-04-05, Implementation: 07-05-05)

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 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. 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%. Payment allowances for drugs 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 will be distributed to contractors by CMS. CMS will update and provide this file quarterly. Carriers/DMERCs/SADMERCs shall develop payment allowance limits for covered drugs when CMS does not supply the payment allowance limit on the ASP drug pricing file.*

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*
- *Lomustine*

80.2.1 - HCPCS Codes for Oral Anti-Emetic Drugs

(Rev.590, Issued: 06-24-05, Effective: 04-04-05, Implementation: 07-05-05)

The physician/supplier bills for these drugs on Form CMS-1500 or its electronic equivalent. The facility bills for these drugs on Form CMS-1450 or its electronic equivalent. The following HCPCS codes are assigned:

J8501 *APREPITANT, 5mg, Oral (Code is Effective 1/1/05 but coverage is effective 4/4/05, Note: Aprepitant is only covered in combination with a 5-HT_3 antagonist, and dexamethasone for beneficiaries who have received one or more of the specified anti-cancer chemotherapeutic agents.*

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 DRONABINOL 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.

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 HYDROCHLORIDE 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-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.

80.2.4 - Billing and Payment Instructions for FIs

(Rev.590, Issued: 06-24-05, Effective: 04-04-05, Implementation: 07-05-05)

Claims for oral anti-emetic drug aprepitant must be billed to the FI on Form CMS-1450 (UB-92) or the electronic equivalent with the appropriate cancer diagnosis and HCPCS code or CPT code. The following payment methodologies apply when furnished to hospital and SNF outpatients:

• Based on APC for hospitals subject to 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).

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.

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