CMS Manual System

Pub. 100-03 Medicare National Coverage Determinations

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

Transmittal 40 **Date: JUNE 24, 2005**

CHANGE REQUEST 3831

SUBJECT: Coverage of Aprepitant for Chemotherapy-Induced Emesis

I. SUMMARY OF CHANGES:

The Centers for Medicare & Medicaid Services (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-HT3 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.

(This addition of section 110.18, to Pub. 100-03, is a national coverage determination (NCD) made under section 1862(a)(1) of the Social Security Act. The NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, health care prepayment plans, the Medicare Appeals Council, and administrative law judges (see 42 CFR §§405.732, 405.860). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an administrative law judge may not review an NCD. (See §1869(f)(1)(A)(i) of the Social Security Act.)

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	Table of Contents
N	1/110.18/Aprepitant for Chemotherapy-Induced Emesis (Effective April 4, 2005)

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:

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

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

Medicare National Coverage Determinations Manual

Chapter 1, Part 2 (Sections 90 – 160.25)

Coverage Determinations

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(Rev.40, 06-24-05)

110.18 – Aprepitant for Chemotherapy-Induced Emesis (April 4, 2005)
(Rev.40, Issued: 06-24-05, Effective: 04-04-05, Implementation: 07-05-05)

A. General

Chemotherapy-induced nausea and vomiting (CINV) can range from mild to severe, with the most severe cases resulting in dehydration, malnutrition, metabolic imbalances, and potential withdrawal from future chemotherapy treatments. The incidence and severity of CINV are influenced by the specific chemotherapeutic agent(s) used; dosage, schedule and route of administration; and drug combinations. Patient specific risk factors such as sex, age, history of motion sickness, and prior exposure to chemotherapeutic agents can also have an effect on CINV incidence and severity. Progress has been made in reducing CINV, although it can still be hard to control symptoms that occur more than a day after chemotherapy, during repeat cycles of chemotherapy, and when chemotherapy is given on more than one day or in very high doses. No single anti-emetic agent is completely effective in all patients. As noted above, many factors influence the incidence and severity of CINV, with the specific chemotherapeutic agent as the primary factor to consider when deciding which anti-emetic to administer. Aprepitant (Emend®) is the first Food and Drug Administration-approved drug of its type. Aprepitant has been proposed to function in combination with other oral anti-emetics for a specified population of Medicare patients receiving highly emetogenic chemotherapy.

B. Nationally Covered Indications

Effective for services performed on or after April 4, 2005, the Centers for Medicare & Medicaid Services makes the following determinations regarding the use of aprepitant in the treatment of reducing chemotherapy-induced emesis:

The evidence is adequate to conclude that the use of the oral anti-emetic 3-drug combination of aprepitant (Emend®), a 5-HT3 antagonist, and dexamethasone is reasonable and necessary for a specified patient population. We have defined the patient population for which the use of the oral anti-emetic 3-drug combination of aprepitant (Emend®), a 5-HT3 antagonist, and dexamethasone is reasonable and necessary as 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*

C. Nationally Noncovered Indications

The evidence is adequate to conclude that aprepitant cannot function alone as a full replacement for intravenously administered anti-emetic agents for patients who are receiving highly emetogenic chemotherapy.

D. Other

N/A

(This NCD last reviewed June 2005.)

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