The Hospital Outpatient Prospective Payment System Fact Sheet (revised January 2008), which provides general information about the Hospital Outpatient Prospective Payment System, ambulatory payment classifications, and how payment rates are set, is now available in downloadable format from the Centers for Medicare & Medicaid Services Medicare Learning Network at [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/HospitalOutpaysysfctsht.pdf](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/HospitalOutpaysysfctsht.pdf) on the CMS website.

MLN Matters Number: MM5655  Related Change Request (CR) #: 5655
Related CR Release Date: July 6, 2007  Effective Date: April 4, 2005
Related CR Transmittal #: R1281CP  Implementation Date: January 7, 2008

**Clarification on Billing for the Oral Three Drug Combination Anti-Emetic (Aprepitant)**

Note: This article was revised on June 4, 2014, to add a reference to MLN Matters® article MM8418 ([http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/MM8418.pdf](http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/MM8418.pdf)) to alert providers to the new chemotherapy drugs that have been added to the list of anticancer chemotherapeutic agents for which the use of the oral antiemetic three-drug combination of oral aprepitant, an oral 5HT3 antagonist, and oral dexamethasone is reasonable and necessary. All other information remains the same.

**Provider Types Affected**

Providers and suppliers submitting claims to Medicare Fiscal Intermediaries (FIs) and/or Part A/B Medicare Administrative Contractors (A/B MACs) for cancer chemotherapeutic services provided to Medicare beneficiaries

**Provider Action Needed**

STOP – Impact to You

This article is based on Change Request (CR) 5655 which clarifies that hospital outpatient departments may bill the entire Tri-Pack of aprepitant, an oral anti-emetic drug given in conjunction w/ two other oral anti-emetic drugs to their FI or A/B MAC as part of a cancer chemotherapeutic regimen that includes the anti-emetic three drug combination.

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This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.
**CAUTION – What You Need to Know**

If the 3-drug anti-emetic combination (Aprepitant, a 5-HT₃ antagonist (e.g. granisetron, ondansetron, or dolasetron), and Dexamethasone (a cortico-steroid)) is administered to a beneficiary, the hospital may dispense the Tri-Pak of three days of aprepitant in the hospital outpatient setting; the Tri-Pak may then be billed to the FI as 57 units of J8501 (APREPITANT, 5mg, Oral), in addition to the other 2 drugs.

**GO – What You Need to Do**

See the Background and Additional Information Sections of this article for further details regarding this issue.

**Background**

The Centers for Medicare & Medicaid Services (CMS) states that reimbursement will be provided for oral anti-emetic drugs when used as a full therapeutic replacement for intravenous dosage forms as part of a cancer chemotherapeutic regimen when the drugs are 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 oral three-drug combination is:

- **Aprepitant,**
- **A 5-HT₃ antagonist (e.g. granisetron, ondansetron, or dolasetron),** and
- **Dexamethasone (a cortico-steroid).**

Note that 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-hour 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, at, or immediately after the time of the anti-cancer chemotherapy administration. The second day, on which only aprepitant is given, is defined as “within 24 hours,” and the third day, on which only aprepitant is given, 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, or skilled nursing facility), or through a supplier, such as a pharmacy. (See the revised Medicare Claims Processing Manual, Chapter 17, Section 80.2 (Oral Anti-Emetic Drugs Used as Full Replacement for Intravenous Anti-Emetic Drugs as Part of a Cancer Chemotherapeutic Regimen, which is attached to CR5655.)
It has come to the attention of CMS that some Medicare contractors are denying payment for the entire Tri-Pak because two doses of the Tri-Pak (for days 2 and 3) are sent home with the beneficiary. This is a misinterpretation of CR 4301 (Billing for Take Home Drugs http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R882CP.pdf) which requires billing drugs that are for take home use only to the Durable Medical Equipment Medicare Administrative Contractors (DME MACs).

The purpose of CR 5655 is to clarify that hospital outpatient departments may bill the entire Tri-Pack of aprepitant to their FI or A/B MAC as part of the three drug combination oral anti-emetic. If the 3-drug combination is dispensed with a Tri-Pak of aprepitant in a hospital outpatient setting; the entire Tri-Pak may be billed to the FI as 57 units of J8501 (APREPITANT, 5mg, Oral), and all of the drugs in the three drug combination must be billed in the same claim.

This clarification is needed to prevent incorrect denials of claims from hospital outpatient departments for Aprepitant for Chemotherapy-Induced Emesis, as spelled out in the National Coverage Determination (NCD), CR 3831 at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R40NCD.pdf on the CMS website.

CR5655 further instructs that:

- Your FI or A/B MAC is to accept claims for 57 units of Aprepitant (J8501) when dispensed to the beneficiary by the hospital in the form of a Tri-Pak;
- Coverage of aprepitant is dependent upon the beneficiary’s receipt of a highly emetogenic anti-cancer chemotherapeutic agent;
- For dates of service on or after January 1, 2008, qualifying emetogenic anti-cancer chemotherapeutic agents are:
  - 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); and

If you have any questions, please contact your FI or A/B MAC at their toll-free number, which may be found at on the CMS website [http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html](http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html) on the CMS website.