

***Title: aprepitant (Emend)***

<b>Origination:</b> 07/28/10	<b>Revised:</b> 05/25/11	<b>Annual Review:</b> 12/15/11
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**Purpose:**

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

**Background Information:**

***Reference Statement***

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

***Medication Summary***

- Aprepitant is a selective high-affinity antagonist of human substance P/neurokinin 1 (NK1) receptors. Aprepitant has little or no affinity for serotonin (5-HT<sub>3</sub>), dopamine, and corticosteroid receptors, the targets of existing therapies for chemotherapy-induced nausea and vomiting (CINV) and postoperative nausea and vomiting (PONV).
- Aprepitant has been shown in animal models to inhibit emesis induced by cytotoxic chemotherapeutic agents, such as cisplatin, via central actions. Animal and human Positron Emission Tomography (PET) studies with aprepitant have shown that it crosses the blood brain barrier and occupies brain NK1 receptors. Animal and human studies show that aprepitant augments the antiemetic activity of the 5-HT<sub>3</sub>-receptor antagonist ondansetron and the corticosteroid dexamethasone and inhibits both the acute and delayed phases of cisplatin-induced emesis.
- Emend, in combination with other antiemetic agents, is indicated for the prevention of: acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin; and nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).
- Emend, as monotherapy, is indicated for the prevention of postoperative nausea and vomiting.
- Recommended regimens include:
  - CINV: Emend 125 mg orally one (1) hour prior to chemotherapy treatment (Day 1) and 80 mg orally once daily in the morning on Days 2 and 3 as part of a regimen that includes a corticosteroid and a 5-HT<sub>3</sub> antagonist.
  - PONV: Emend 40 mg within three (3) hours prior to induction of anesthesia.

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**Background Information, continued:**

***Eligibility Criteria***

- Member must be eligible and have applicable benefit coverage (i.e., self-injectable rider) within the specified date(s) of service.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

***Exclusion Criteria***

- Member must be at least 18 years of age.

**Procedure:**

- 1.0 Request for *initiation of therapy* with **Emend** for **chemotherapy-induced nausea/vomiting (CINV) prophylaxis** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying:
  - 1.1 Member will be receiving a moderate to highly-emetogenic chemotherapy regimen;
  - 1.2 If criteria are met, Emend is approvable for up to six (6) months or less depending on the number of cycles planned.

**References:**

1. Emend Prescribing Information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ Rev 03/2010.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2006. URL: <http://cp.gsm.com>. Updated October 2008.

**Disclaimer Information:**

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.