Clinical Policy: Aprepitant (Emend)
Reference Number: HIM.PA.62
Effective Date: 12/14
Last Review Date: 08/17 Revision Log
Line of Business: Health Insurance Marketplace

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Aprepitant (Emend®) is a substance P/neurokinin 1 (NK1) receptor antagonist.

FDA approved indication
Emend is indicated:

- In combination with other antiemetic agents for patients 12 years of age and older for prevention of:
  - Acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy including high-dose cisplatin
  - Nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy
- For the prevention of postoperative nausea and vomiting in adults

Limitations of use:

- Emend has not been studied for treatment of established nausea and vomiting.
- Chronic continuous administration of Emend is not recommended.

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

I. Initial Approval Criteria

A. Prevention of Chemotherapy-Induced Nausea and Vomiting (must meet all)**:**
1. Prescribed by or in consultation with a hematologist or oncologist;
2. Member is currently or will be receiving chemotherapy of moderate to high emetic risk;
3. Prescribed in combination with a 5-HT3 serotonin receptor antagonist (ondansetron preferred) and dexamethasone;
4. Dose does not exceed 125 mg on Day 1, followed by 80 mg on Days 2 and 3.

Approval duration: Duration of chemotherapy

B. Prevention of Postoperative Nausea and Vomiting (must meet all)**:**
1. Prescribed pre-surgically by or in consultation with a surgeon;
2. Member is undergoing surgery;
3. Dose does not exceed 40 mg (1 capsule).

Approval duration: One time pre-surgical treatment

C. Other diagnoses/indications
1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized);

II. Continued Therapy

A. All Indications (must meet all)**:**
1. Member meets all initial criteria for the relevant indication.

Approval duration: Duration of chemotherapy *or* one time pre-surgical treatment

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to HIM.PA.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – HIM.PA.21 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key
5-HT3: serotonin
FDA: Food and Drug Administration
NK1: neurokinin 1

V. References

1. Emend Prescribing Information. Whitehouse Station, NJ: Merck & Company, Inc.: January 2017. Available at: http://www.emend.com. Accessed March 27, 2017.
2. Journal of Clinical Oncology, Vol 24, No 18, 2006: pp. 2932-2947. http://jco.ascopubs.org/cgi/content/abstract/24/18/2932
3. Aprepitant drug monograph. Clinical Pharmacology. Accessed June 2016
4. Basch E, Prestrud AA, Hesketh PJ et al. Antiemetics: American Society of Clinical Oncology clinical practice guideline update. Journal of Clinical Oncology. 2011 Nov 01: 29(31): 4189-4198. Available at: http://jco.ascopubs.org/content/29/31/4189.long. Accessed March 2017.
5. Antiemesis (Version 1.2017). In: National Comprehensive Cancer Network Guidelines. Available at www.NCCN.org. Accessed March 28, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Changed guideline to new format.	08/16	08/16
Converted to new template Added max doses	04/17	08/17

Reviews, Revisions, and Approvals	Date	P&T Approval Date

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.