Fosaprepitant dimeglumine (Emend® for injection)

Prior Authorization Drug Coverage Policy

Effective Date: 9/1/2020
Revision Date: n/a
Review Date: 9/21/21
Lines of Business: Commercial
Policy type: Prior Authorization

This Drug Coverage Policy provides parameters for the coverage of fosaprepitant dimeglumine. Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine.

Drug Description[1]

Fosaprepitant is a prodrug of aprepitant and accordingly, its antiemetic effects are attributable to aprepitant. Aprepitant is a selective high-affinity antagonist of human substance P/neurokinin 1 (NK1) receptors. Aprepitant has little or no affinity for serotonin (5-HT3), dopamine, and corticosteroid receptors, the targets of existing therapies for chemotherapy-induced nausea and vomiting (CINV). 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-HT3-receptor antagonist ondansetron and the corticosteroid dexamethasone and inhibits both the acute and delayed phases of cisplatin-induced emesis.

FDA Indications[1]

Fosaprepitant dimeglumine) is FDA indicated for the following:

- In combination with other antiemetic agents, 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

- In combination with other antiemetic agents, for the prevention of delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC)

Coverage Determinations[1,2]

Fosaprepitant dimeglumine will require prior authorization. This agent is considered medically necessary for the following oncology-related indications if all criteria below are met:

Prophylaxis of Chemotherapy-Induced Nausea and Vomiting

- The member must be on concomitant corticosteroid (e.g., dexamethasone) and a 5HT3 antagonist (e.g., ondansetron, dolasetron, palonosetron, or granisetron) unless documentation of a contraindication is provided **AND**
- The member is receiving highly emetogenic chemotherapy (HEC) or moderately emetogenic chemotherapy (MEC)

Recommended dosage:

Population	**Single-dose regimen**	**3-day dosing regimen**
Adults	HEC: 150 mg on day 1 only; administer in combination with a 5-HT3 antagonist on day 1 only and with dexamethasone on days 1 to 4.	HEC: 115 mg on day 1 followed by oral aprepitant (80 mg) on days 2 and 3; administer in combination with a 5-HT3 antagonist on day 1 only and with dexamethasone on days 1 to 4.
	MEC: 150 mg on day 1 only; administer in combination with a 5-HT3 antagonist and dexamethasone on day 1.	MEC: 115 mg on day 1 followed by oral aprepitant (80 mg) on days 2 and 3; administer in combination with a 5-HT3 antagonist on day 1 only and with dexamethasone on day 1 only.
Population	**Single-dose regimen**	**3-day dosing regimen**

Pediatrics	**Infants ≥6 months weighing ≥6 kg and Children <2 years**: 5 mg/kg once; maximum dose: 150 mg/dose; administer ~90 minutes prior to chemotherapy on day 1 only; use in combination with a 5-HT3 antagonist with or without corticosteroid.	**Infants ≥6 months weighing ≥6 kg and Children <2 years**: 3 mg/kg once; maximum dose: 115 mg/dose; administer ~90 minutes prior to chemotherapy on day 1 only followed by oral aprepitant on days 2 and 3; use in combination with a 5-HT3 antagonist with or without corticosteroid.
	Children 2 to <12 years: 4 mg/kg once; maximum dose: 150 mg/dose; administer ~90 minutes prior to chemotherapy on day 1 only; use in combination with a 5-HT3 antagonist with or without corticosteroid.	**Children 2 to <12 years**: 3 mg/kg once; maximum dose: 115 mg/dose; administer ~90 minutes prior to chemotherapy on day 1 only followed by oral aprepitant on days 2 and 3; use in combination with a 5-HT3 antagonist with or without corticosteroid.
	Children ≥12 years and Adolescents ≤17 years: 150 mg once, administered ~60 minutes prior to chemotherapy on day 1 only; use in combination with a 5-HT3 antagonist with or without corticosteroid.	**Children ≥12 years and Adolescents ≤17 years**: 115 mg once, administered ~60 minutes prior to chemotherapy on day 1 only followed by oral aprepitant on days 2 and 3; use in combination with a 5-HT3 antagonist with or without corticosteroid.

All indications:

- Fosaprepitant dimeglumine will be approved through clinical review for up to a 12-month duration.

Coverage Limitations

Treatment with fosaprepitant dimeglumine (Emend® for injection) is not considered medically necessary for members with the following concomitant conditions:

- Members not receiving concurrent moderate to highly emetogenic chemotherapy
- For treatment of established nausea and vomiting, fosaprepitant (Emend® for injection) has not been studied for this use
- Fosaprepitant dimeglumine (Emend® for injection) monotherapy (should be used in conjunction with a 5-HT3 antagonist and dexamethasone)
- Concurrent use with oral aprepitant (Emend®) if taking the 150 mg dose of fosaprepitant dimeglumine (Emend® for injection), aprepitant (Cinvanti® injectable emulsion), rolapitant (Varubi®), netupitant/palonosetron (Akynzeo® capsules) or fosnetupitant/palonosetron (Akynzeo® for injection)
- Members less than 6 months in age
- Indications not supported by NCCN category 2A or higher recommendations may not be considered medically necessary.

Contraindications[1]

- Known hypersensitivity to any component of fosaprepitant dimeglumine
- Concurrent use with pimozide

Warnings/Precautions[1]

- CYP3A4 interactions
- Hypersensitivity/infusion-site reactions
- Warfarin (CYP2C9 substrate): fosaprepitant may decrease the serum concentration of warfarin
- Hormonal contraceptives: efficacy of hormonal contraceptive may be reduced

For specific recommendations on contraindications, warnings and precautions, patient monitoring, and on dose adjustments and discontinuation, please refer to the current prescribing information.

Billing

- **Description**: inj., fosaprepitant, 1 mg
    - HCPCS: J1453

Disclaimer

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan

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References

1. Emend [package insert]. Merck Sharp & Dohme Corp., Whitehouse Station, NJ. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/022023s014lbl.pdf
2. Fosaprepitant dimeglumine. NCCN Drugs & Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/
3. Lexicomp Online®, Hudson, Ohio: Lexi-Comp, Inc. 2020.