aprepitant [emulsion] (Cinvanti®)

Prior Authorization Drug Coverage Policy

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

This Drug Coverage Policy provides parameters for the coverage of aprepitant [emulsion] (Cinvanti®). 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]

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. 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]

Aprepitant [emulsion] (Cinvanti®) is FDA indicated for the following:

aprepitant [emulsion] (Cinvanti®), in combination with other antiemetic agents, is indicated in adults 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 as a single-dose regimen.
- delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) as a single-dose regimen.

- nausea and vomiting associated with initial and repeat courses of MEC as a 3-day regimen.

Coverage Determinations[1,2]

Aprepitant [emulsion] (Cinvanti®) will require prior authorization. This agent is considered medically necessary for the following oncology-related indications if all criteria below are met:

Antiemesis

- The member will be receiving parenteral anticancer therapy, AND
- Cinvanti® will be used in combination with dexamethasone and a serotonin receptor antagonist (5-HT3 RA), AND
- Chemotherapy will be deemed of high emetic risk (HEC), with or without olanzapine (preferred with olanzapine), OR
- Chemotherapy will be deemed moderate emetic risk (MEC), for select patients with additional risk factors or previous treatment failure with a corticosteroid + 5-HT3 RA alone.

Recommended dosage:

- HEC and MEC (Single-Dose Regimen): 130 mg intravenously on Day 1
- MEC (3-Day Regimen): 100 mg intravenously on Day 1 with aprepitant 80 mg capsules orally on days 2 and 3
- Cinvanti® is given as an intravenous injection over 2 minutes or an intravenous infusion over 30 minutes; complete the injection or infusion approximately 30 minutes prior to chemotherapy
- Cinvanti® regimen includes a corticosteroid and a 5-HT_3 antagonist.

All Indications:

- Aprepitant (emulsion) will be approved through clinical review up to a 12-month determination.

Coverage Limitations[1,3]

Treatment with aprepitant (emulsion) is not considered medically necessary for members with the following concomitant conditions:

- CINVANTI® has not been studied for the treatment of established nausea and vomiting.
- Aprepitant injectable emulsion and intravenous fosaprepitant are not interchangeable.
- Indications not supported by NCCN category 2A or higher recommendations may not be considered medically necessary

Contraindications/Warnings/Precautions[1]

- Known hypersensitivity to any component of this drug.
- Contradicted with concurrent use with pimozide.
- Warnings/precautions:
    - CYP3A4 Interactions
    - Hypersensitivity reactions including anaphylaxis
    - Warfarin (a CYP2C9 substrate)
    - Hormonal contraceptives

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: injection, aprepitant, 1 mg
    - J0185

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 documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from Oncology Analytics, Inc.

References

1. Cinvanti [package insert]. Heron Therapeutics, Inc, San Diego, CA. Available at: https://www.cinvanti.com/pdfs/CINVANTI_PI_10.2019.pdf
2. Cinvanti. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/
3. Antiemesis: NCCN Clinical Practice Guidelines in Oncology Version 2.2020-April 23, 2020 Available at:

https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf