Fosnetupitant and palonosetron (Akynzeo® injection)

Prior Authorization Drug Coverage Policy

Effective Date: 9/1/2020
Revision Date: n/a
Review Date: 9/17/2021
Lines of Business: Commercial
Policy type: Prior Authorization

This Drug Coverage Policy provides parameters for the coverage of fosnetupitant and palonosetron. 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]

Netupitant is a selective antagonist of human substance P/neurokinin 1 (NK-1) receptors. Palonosetron is a 5-HT3 receptor antagonist with a strong binding affinity for this receptor and little or no affinity for other receptors. Cancer chemotherapy may be associated with a high incidence of nausea and vomiting, particularly when certain agents, such as cisplatin, are used. 5-HT3 receptors are located on the nerve terminals of the vagus in the periphery and centrally in the chemoreceptor trigger zone of the area postrema. Chemotherapeutic agents produce nausea and vomiting by stimulating the release of serotonin from the enterochromaffin cells of the small intestine. Serotonin then activates 5-HT3 receptors located on vagal afferents to initiate the vomiting reflex. The development of acute emesis is known to depend on serotonin and its 5-HT3 receptors have been demonstrated to selectively stimulate the emetic response. Delayed emesis has been largely associated with the activation of tachykinin family neurokinin 1 (NK-1) receptors (broadly distributed in the central and peripheral nervous systems) by substance P. As shown in in vitro and in vivo studies, netupitant inhibits substance P mediated responses.

FDA Indications[1]

Fosnetupitant and palonosetron is FDA indicated for the following:

- Fosnetupitant and palonosetron is indicated in combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy. Akynzeo® for injection is a combination of palonosetron and fosnetupitant, a prodrug of netupitant: palonosetron prevents

nausea and vomiting during the acute phase and fosnetupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy.

NCCN Compendium Supported Indications[2-3]

Use in combination with dexamethasone before parenteral anticancer therapy with

- Moderate emetic risk, for select patients with additional risk factors or previous treatment failure with a corticosteroid + serotonin receptor antagonist alone.

Coverage Determinations[1,2]

Fosnetupitant and palonosetron 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**
- Fosnetupitant and palonosetron will be used in combination with dexamethasone, **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:

- 235 mg fosnetupitant/0.25 mg palonosetron infused over 30 minutes starting 30 minutes before chemotherapy
- Fosnetupitant and palonosetron regimens include a corticosteroid.

All Indications:

- Fosnetupitant and palonosetron will be approved through clinical review for up to a 12-month duration.

Coverage Limitations[1,3]

Treatment with fosnetupitant and palonosetron is not considered medically necessary for members with the following concomitant conditions:

- Fosnetupitant and palonosetron has not been studied for the treatment of established nausea and vomiting.
- Fosnetupitant and palonosetron has not been studied for the prevention of nausea and vomiting associated with anthracycline plus cyclophosphamide chemotherapy.
- 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.
- Warnings/precautions:
    - Hypersensitivity reactions including anaphylaxis
    - Serotonin Syndrome

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., fosnetupitant, palonosetron, 0.25 mg
    - J1454

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

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2. Akynzeo. 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