# Palonosetron (Aloxi®)

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 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]

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. It is thought that chemotherapeutic agents produce nausea and vomiting by releasing serotonin from the enterochromaffin cells of the small intestine and that the released serotonin then activates 5-HT3 receptors located on vagal afferents to initiate the vomiting reflex.

## FDA Indications[1]

Palonosetron is FDA indicated for the following:

- Moderately emetogenic cancer chemotherapy -- prevention of acute and delayed nausea and vomiting associated with initial and repeat courses
- Highly emetogenic cancer chemotherapy -- prevention of acute nausea and vomiting associated with initial and repeat courses
- Prevention of postoperative nausea and vomiting (PONV) for up to 24 hours following surgery
- In pediatric patients aged 1 month to less than 17 years, prevention of acute nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including highly emetogenic cancer chemotherapy

## Coverage Determinations[1,2]

Palonosetron 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 is receiving highly emetogenic chemotherapy (HEC) or moderately emetogenic chemotherapy (MEC) **AND**
- The member is receiving palonosetron in combination with dexamethasone (unless documented contraindication)

Recommended dosage:

- Adults: 0.25 mg IV as a single dose approximately 30 minutes prior to the start of chemotherapy
- Infants, children, and adolescents <17 years: 20 mcg/kg IV as a single dose approximately 30 minutes prior to the start of chemotherapy; maximum dose of 1500 mcg/dose

**All indications**:

- Palonosetron will be approved through clinical review up to a 12-month determination.

## Coverage Limitations

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

- Palonosetron may not be used concurrently (other 5-HT3 antagonist drugs should not be used within 2 days following a palonosetron dose) with other 5-HT3 antagonists unless a change of therapy is warranted
- Palonosetron is not supported for the treatment of chemotherapy-induced nausea and vomiting.
- Members receiving an oral-only chemotherapy regimen with no parenteral chemotherapy component.
- Members less than 1 month in age.
- Indications not supported by NCCN category 2A or higher recommendations may not be considered medically necessary.

## Contraindications/Warnings/Precautions[1]

- Hypersensitivity to palonosetron or any of its components
- Warnings/precautions:
    - Hypersensitivity reactions
    - 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., palonosetron, 25 mcg
    - HCPCS: J2469

## 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. Aloxi [package insert]. Helsinn Therapeutics, Inc., Iselin, NJ. Available at: https://www.helsinn.com/assets/aloxi-pi.pdf
2. Palonosetron hydrochloride. NCCN Drugs & Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/
3. Lexicomp Online®, Hudson, Ohio: Lexi-Comp, Inc. 2020.