CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Antiemetics – Palonosetron Intravenous Utilization Management Medical Policy
- Palonosetron intravenous infusion (generic only)

REVIEW DATE: 05/01/2024

OVERVIEW

Palonosetron intravenous (IV) [brand name: Aloxi®], a serotonin-3 (5-HT_3) receptor antagonist, is indicated for the **prevention** of the following:[1]

- **Acute nausea and vomiting**, associated with initial and repeat courses of emetogenic chemotherapy, including highly emetogenic cancer chemotherapy, in patients ≥ 1 month of age.
- **Delayed nausea and vomiting**, associated with initial and repeat courses of moderately emetogenic cancer chemotherapy in adults.
- **Postoperative nausea and vomiting (PONV)**, in adults for up to 24 hours following surgery. The efficacy of palonosetron IV in PONV beyond 24 hours has not been demonstrated.

Disease Overview

Palonosetron has strong affinity for the 5-HT_3 receptor and little or no affinity for other receptors.[1] Chemotherapy-induced nausea and vomiting (CINV) is thought to be mediated by release of serotonin from the small intestine, which then activates 5-HT_3 receptors located on vagal afferent nerves in the gastrointestinal tract and chemoreceptor trigger zone of the brain. PONV is influenced by multiple patient, surgical, and anesthesia related factors leading to release of serotonin in the central nervous system and periphery. By blocking the 5-HT_3 receptor, palonosetron inhibits the serotonin-stimulated emetic response.

Guidelines

The 5-HT_3 receptor antagonists feature prominently in National Comprehensive Cancer Network (NCCN) antiemesis guidelines for CINV. In these guidelines (version 1. 2024 – December 13, 2023), palonosetron is supported as part of a combination regimen for both acute and delayed emesis CINV prevention.[2] American Society of Clinical Oncology (ASCO) antiemetic guidelines (2020) provide similar recommendations for the prevention of CINV.[3] The American Society of Pediatric Hematology/Oncology (ASPHO) guidelines for the prevention of acute and delayed CINV (2022) recommend palonosetron treatment strategies in selected pediatric patients requiring CINV prevention.[4]

Consensus guidelines for management of PONV (2020) support 5-HT_3 receptor antagonists as one strategy for prevention of PONV in selected patients and note that palonosetron has been found to be more effective than low doses of granisetron or ondansetron in several meta-analyses.[5]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of palonosetron IV. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. An approval duration of one month is sufficient in cases where approval is listed as one dose.

Automation: None.
*Indications and/or approval conditions noted with **[eviCore]** are managed by eviCore healthcare for those clients who use eviCore for oncology and/or oncology-related reviews. For these conditions, a prior authorization review should be directed to eviCore at www.eviCore.com.*

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of palonosetron IV is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Chemotherapy-Induced Nausea and Vomiting, Prevention.** ***[eviCore]*** Approve for 1 year.

   Dosing. Approve ONE of the following dosing regimens (A or B):
   A) Adults: Approve up to a dose of 0.25 mg administered intravenously for one dose per cycle of chemotherapy; OR
   B) Pediatrics (less than 18 years of age): Approve up to a dose of 20 mcg/kg (maximum dose 1.5 mg) administered intravenously for one dose per cycle of chemotherapy.

2. **Postoperative Nausea and Vomiting, Prevention.** Approve for one dose if the patient is ≥ 18 years of age.

   Dosing. Approve up to a dose of 0.075 mg intravenously for one dose.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of palonosetron IV is not recommended in the following situations:

1. **Radiation-Induced Nausea and Vomiting.** Ondansetron and granisetron are the recommended 5-HT_3 receptor antagonists by NCCN (version 1.2024 – December 13, 2023) and ASCO (2020).[2,3] The guidelines note insufficient evidence for use of palonosetron IV.
   Note: For patients also receiving chemotherapy in addition to radiation, refer to FDA-Approved Indication #1, Chemotherapy-Induced Nausea and Vomiting, Prevention.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Aloxi® intravenous injection or infusion [prescribing information]. Iselin, NJ: Helsinn; April 2020.
2. The NCCN Antiemesis Clinical Practice Guidelines in Oncology (version 1.2024 – December 13, 2023). © 2023 National Comprehensive Cancer Network. Available at: www.nccn.org. Accessed on April 26, 2024.
3. Hesketh PJ, Kris MG, Basch E, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol.* 2020 Aug 20; 38(24):2782-2797.
4. Patel P, Robinson PD, Cohen M, et al. Prevention of acute and delayed chemotherapy-induced nausea and vomiting in pediatric cancer patients: A clinical practice guideline. *Pediatr Blood Cancer*. 2022;69(12):e30001.
5. Gan T, Belani K, Bergese S, et al. Fourth consensus guidelines for the management of postoperative nausea and vomiting. Anesth Analg. 2020; 131:411-448.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	05/03/2023
Annual Revision	**Title**: Updated from "Antiemetics – Aloxi Intravenous" to "Antiemetics – Palonosetron Intravenous". No criteria changes.	05/01/2024