

## UTILIZATION MANAGEMENT MEDICAL POLICY

**POLICY:** Antiemetics – Aloxi Utilization Management Medical Policy

- Aloxi® (palonosetron intravenous injection or infusion – Helsinn)

**REVIEW DATE:** 05/04/2022

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### OVERVIEW

Aloxi, a serotonin-3 (5-HT<sub>3</sub>) receptor antagonist, is indicated for the prevention of the following uses:<sup>1</sup>

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

### Disease Overview

Aloxi has strong affinity for the 5-HT<sub>3</sub> receptor and little or no affinity for other receptors.<sup>1</sup> Chemotherapy-induced nausea and vomiting is thought to be mediated by release of serotonin from the small intestine, which then activates 5-HT<sub>3</sub> 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<sub>3</sub> receptor, Aloxi inhibits the serotonin-stimulated emetic response.

### Guidelines

The 5-HT<sub>3</sub> receptor antagonists feature prominently in National Comprehensive Cancer Network (NCCN) antiemesis guidelines for chemotherapy-induced nausea and vomiting. In these guidelines (version 2.2022 – March 23, 2022), Aloxi is supported as part of a combination regimen for both acute and delayed emesis prevention.<sup>2</sup> American Society of Clinical Oncology (ASCO) antiemetic guidelines (2020) provide similar recommendations.<sup>3</sup> Guidelines for management of PONV (2014) support 5-HT<sub>3</sub> receptor antagonists as one strategy for prevention of PONV in selected patients and note that Aloxi has been found to be more effective than low doses of granisetron or ondansetron.<sup>4</sup>

### POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Aloxi. 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.

### RECOMMENDED AUTHORIZATION CRITERIA

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

## FDA-Approved Indications

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### 1. Chemotherapy-Induced Nausea and Vomiting, Prevention. 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.

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### 2. Postoperative Nausea and Vomiting, Prevention. Approve for one dose if the patient is $\geq$ 18 years of age.

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

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## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Aloxi is not recommended in the following situations:

### 1. Radiation-Induced Nausea and Vomiting.

Ondansetron and granisetron are the recommended 5-HT<sub>3</sub> receptor antagonists by NCCN (version 2.2022 – March 23, 2022) and ASCO (2017).<sup>2,3</sup> The guidelines note insufficient evidence for use of Aloxi.

Note: For patients also receiving chemotherapy, 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<sup>®</sup> intravenous injection or infusion [prescribing information]. Iselin, NJ: Helsinn; April 2020.
2. The NCCN Antiemesis Clinical Practice Guidelines in Oncology (version 2.2022 – March 23, 2022). © 2022 National Comprehensive Cancer Network. Available at: [www.nccn.org](http://www.nccn.org). Accessed on April 25, 2022.
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. Gan TJ, Diemunsch P, Habib AS, et al. Consensus guidelines for the management of postoperative nausea and vomiting. *Anesth Analg*. 2014;118:85-113.

## HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	04/28/2021
Annual Revision	No criteria changes.	05/04/2022