Aloxi (palonosetron)

Humana

Pharmacy Coverage Policy

Effective Date: January 01, 2019
Revision Date: January 24, 2024
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Line of Business: Medicare, Commercial, Medicaid - South Carolina, Medicaid - Ohio
Policy Type: Prior Authorization

Products Affected
Aloxi intravenous solution palonosetron intravenous solution

Listed Indications
Prophylaxis of Chemotherapy-induced nausea and vomiting (Acute and/or Delayed) associated with moderately/highly emetogenic chemotherapy
Prophylaxis of Postoperative nausea and vomiting

Prophylaxis of Chemotherapy-induced nausea and vomiting (Acute and/or Delayed) associated with moderately/highly emetogenic chemotherapy	
Does the member meet all of the following criteria?	
Criteria #1	• Member has failed to achieve control of nausea and/or vomiting with IV ondansetron or IV granisetron at the FDA indicated dose OR has a contraindication to these agents OR has experienced significant side effects necessitating alternative therapies* **OR** •Coverage for the use of Aloxi (palonosetron) is considered reasonable and necessary without a failure of other 5-HT3 receptor antagonists for those members receiving highly emetogenic chemotherapy (HEC) or moderately emetogenic chemotherapy (MEC) **OR** • The member is aged 1 month to less than 17 years and Aloxi (palonosetron) is being used with emetogenic chemotherapy * For Medicare this criteria does not apply to medical benefits
Does the member have any of the following exclusions? If yes, approval may not be appropriate. NOTE: Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.	
Exclusion #1	Aloxi (palonosetron) may not be used concurrently (other 5-HT3 RA drugs should generally not be used within 2 days following an Aloxi (palonosetron) dose) with other 5-HT3 antagonists unless a change of therapy is warranted
Approval Duration	
Initial	Plan year duration

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Prophylaxis of Postoperative nausea and vomiting	
Does the member meet all of the following criteria?	
Criteria #1	Member has failed to achieve control of nausea and/or vomiting with both IV ondansetron AND IV granisetron at the FDA indicated dose OR has a contraindication to these agents OR has experienced significant side effects necessitating alternative therapies*. * For Medicare and Ohio Medicaid, this criteria does not apply to medical benefits
Does the member have any of the following exclusions? If yes, approval may not be appropriate. NOTE: Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.	
Exclusion #1	Aloxi (palonosetron) may not be used concurrently (other 5-HT3 RA drugs should generally not be used within

	2 days following an Aloxi (palonosetron) dose) with other 5-HT3 antagonists unless a change of therapy is warranted
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Background

This is a prior authorization policy about Aloxi (palonosetron).

- According to the 2012 NCCN Practice Guidelines in Oncology for Antiemesis, Aloxi (palonosetron) was comparable to a single IV dose of dolasetron for the prevention of acute CINV, however superior to dolasetron in preventing delayed emesis. Aloxi (palonosetron) had similar safety and side effect profiles to other 5-HT_3 receptor antagonists. Aloxi (palonosetron) has a 100-fold higher binding affinity for the 5-HT_3 receptor than other serotonin antagonists and has a mean elimination half-life of 40 hours. Repeat dosing of Aloxi (palonosetron) in the days after chemotherapy (Days 2 or 3) is likely to be safe. However in the setting of multi-day chemotherapy, the need for repeat dosing with Aloxi (palonosetron) is not yet known and increased efficacy has not been established. One study in patients receiving highly emetogenic multi-day cisplatin based chemotherapy for testicular cancer received multiple daily dosing of Aloxi (palonosetron) and dexamethasone, which prevented nausea and emesis.
- According to a consensus statement published by the International Anesthesia Research Society, there is no difference in the efficacy and safety profiles of the serotonin receptor antagonists in the prophylaxis of Postoperative Nausea and Vomiting (PONV), and these drugs are most effective when given at the end of surgery. Cost effectiveness must also be taken into consideration and the panel agreed that with equivalent efficacy and safety profiles, acquisition cost was the primary factor that differentiated the 5-HT_3 receptor antagonists from one another.

For information on Pediatric Dosing and Administration, please refer to the Prescribing Information.

Aloxi (palonosetron) should not be used in the following:

- Hypersensitivity to Aloxi (palonosetron) or any component of the product
  - Also see Coverage Limitations section of policy.

Aloxi (palonosetron) is a selective serotonin-3 5-HT_3-receptor antagonist. It has minimal or no affinity for other receptor types. 5-HT3 receptors are present on vagal nerve terminals peripherally and centrally in the chemoreceptor trigger zone; cytotoxic agents induce emesis by releasing 5-HT3 from intestinal enterochromaffin cells, with subsequent 5-HT_3binding to (activation of) vagal afferents. An advantage of Aloxi (palonosetron) over other 5-HT_3antagonists is its longer elimination half-life which allows for less frequent dosing.

Aloxi (palonosetron) injection for intravenous use is indicated for moderately emetogenic cancer chemotherapy and highly emetogenic cancer chemotherapy used for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses. Aloxi (palonosetron) is also indicated for the prevention of acute nausea and vomiting in pediatric patients associated with repeat courses of emetogenic chemotherapy, including highly emetogenic chemotherapy. This formulation is also indicated for the prevention of postoperative nausea and vomiting (PONV) for up to 24 hours following surgery. Efficacy beyond 24 hours has not been established.

Palonosetron is available as brand (Aloxi) and generic intravenous solution:

- 0.25 mg/5mL (CINV)

Provider Claim Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Aloxi; palonosetron; CINV; PONV; antiemetic; nausea; vomiting; intravenous; pharmacy

References

Aloxi® (Prescribing Information). Eisai Inc. Woodcliff Lake, NJ. September 2014.

Clinical Pharmacology Copyright © 20201 Gold Standard Inc.Updated periodically.

Lexicomp Online®, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.

Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO. Updated periodically.

National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. Updated periodically.

NCCN Guidelines: Antiemesis. Updated periodically.

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