

Title: palonosetron (Aloxi)

Origination: 07/28/10	Revised: 09/21/11	Annual Review: 12/16/10
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Reference Statement

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Medication Summary

- Aloxi (palonosetron hydrochloride) is an antiemetic and antinauseant agent. Palonosetron is a 5-HT₃ receptor antagonist with a strong binding affinity for this receptor and little or no affinity for other receptors.
- Aloxi is indicated for: Moderately and highly emetogenic cancer chemotherapy -- prevention of acute and delayed nausea and vomiting associated with initial and repeat courses.
- The recommended dosing for palonosetron for chemotherapy induced nausea and vomiting in adults is a single 0.25 mg I.V. dose administered over 30 seconds. Dosing should occur approximately 30 minutes before the start of chemotherapy.
- The recommended dosing of palonosetron for postoperative nausea and vomiting in adults is a single 0.075 mg I.V. dose administered over 10 seconds immediately before induction of anesthesia.

Eligibility Criteria

- Member must be eligible and have applicable benefit coverage (i.e., self-injectable rider) within the specified date(s) of service.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusion Criteria

- Hypersensitivity to palonosetron or any of its components.
- Safety and effectiveness in Members younger than 18 years of age have not been established.

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Procedure:

- 1.0 Request for initial therapy with Aloxi for ***Chemotherapy-induced nausea and vomiting*** requires documentation from the Member's medical; records maintained by the requesting independent practitioner verifying all of the following:
 - 1.1 Member is receiving highly emetogenic cancer chemotherapy; **OR**
 - 1.1 Member has failed (defined as two (2) or more documented episodes of vomiting attributed to the current moderately emetogenic chemotherapy regimen) one (1) of the following agents:
 - 1.1.1 Zofran; or
 - 1.1.1 Kytril;
 - 1.2 If criteria are met, Aloxi is approvable for six (6) months.
- 2.0 Request for initial therapy with Aloxi for ***Post surgery-induced nausea and vomiting*** requires documentation from the Member's medical records maintained by the requesting independent practitioner:
 - 2.1 If criteria are met, Aloxi is approvable for six (6) months.

References:

1. Aloxi Prescribing Information. MGI Pharma Inc. Bloomington, MN. Rev September 2009.
2. Facts and Comparisons 4.0, St. Louis, MO. Walters Kluwer Health URL: www.factsandcomparisons.com. Updated 2010.

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.