

Medical Policy:

Palonosetron (Aloxi®) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.69	March 3, 2025	September 2019

Medical Guideline Disclaimer Property of EmblemHealth. All rights reserved.

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Aloxi (palonosetron) is a selective 5-HT3 receptor antagonist.

Length of Authorization

Coverage will be provided for six months and may be renewed, unless otherwise specified.

PONV: Coverage will be provided for 1 dose. Coverage cannot be renewed for the indication of prevention of post-operative nausea and vomiting (PONV) in Adults.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

Chemo-induced N/V:

- 10 billable units per 7 days for adults

Post-Op N/V:

- 3 billable units as one time only for adults

Guideline

I. INITIAL APPROVAL CRITERIA

Coverage is provided in the following conditions:

1. Prevention of Chemotherapy induced Nausea and vomiting (CINV) in Adults †

- A. Patient is receiving highly or moderately emetogenic chemotherapy (HEC/MEC)*; **OR**
- B. Patient has failed** with other 5HT3-antagonist (i.e. ondansetron or granisetron) while receiving the current chemotherapy regimen; **AND**
- C. Palonosetron is NOT covered for:
 - i. Breakthrough emesis; **OR**
 - ii. Repeat dosing in multi-day emetogenic chemotherapy regimens

2. Prevention of Chemotherapy induced Nausea and vomiting (CINV) in Pediatric Patients †

- A. Patient is at least 1 month old and less than 18 years old; **AND**
- B. Patient is receiving emetogenic chemotherapy; **AND**
- C. Is NOT being used for acute nausea and vomiting

3. Prevention of post-operative nausea and vomiting (PONV) in Adults †

- A. Documentation that nausea and vomiting medically required to be avoided during the postoperative period in this patient; **AND**
- B. Patient is 18 years of age or older; **AND**
- C. Aloxi (palonosetron) will be administered within 24 hours of surgery

*Highly emetogenic chemotherapy (HEC):

Highly Emetogenic Chemotherapy (HEC)			
Carboplatin	Carmustine	Cisplatin	Cyclophosphamide
Dacarbazine	Doxorubicin	Epirubicin	Ifosfamide
Mechlorethamine	Streptozocin	Melphalan ≥ 140 mg/m ²	Fam-trastuzumab deruxtecan-nxki
Sacituzumab govitecan-hzi			
Moderately Emetogenic Chemotherapy (MEC)			
Aldesleukin >12-15 million IU/m ²	Amifostine >300mg/m ²	Bendamustine	Busulfan
Clofarabine	Cytarabine >200mg/m ²	Dinutuximab	Daunorubicin Liposomal; Cytarabine Liposomal
Irinotecan Liposomal	Lurbinectedin	Melphalan <140 mg/m ²	Naxitamab-ggqk
Romidepsin	Temozolomide		

The following can be considered HEC in certain patients

Dactinomycin	Daunorubicin	Idarubicin
Irinotecan	Methotrexate ≥ 250 mg/m ²	Oxaliplatin
Trabectedin		

The following regimens can be considered HEC

FOLFOX	FOLFIRI	FOLFIRINOX; FOLFOXIRI	AC (any anthracycline + cyclophosphamide)
--------	---------	--------------------------	-------------------------------------------

**** Failure is defined as:**

Two or more documented episodes of vomiting attributed to the current chemotherapy regimen

† FDA-approved indication(s)

II. RENEWAL CRITERIA

Coverage can be renewed based upon the following criteria:

1. Patient continues to meet criteria identified above; **AND**
2. Disease response; **AND**
3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serotonin syndrome, severe QT prolongation, hypersensitivity, etc.

Dosing/Administration

Indication	Dose
Prevention of chemotherapy-induced nausea and vomiting in adults	0.25 mg weekly prior to highly emetogenic chemotherapy
Prevention of chemotherapy-induced nausea and vomiting in pediatrics	20 mcg/kg prior to emetogenic chemotherapy (max 1.5mg weekly)
Post-operative nausea and vomiting	0.075 mg given immediately before anesthesia

Applicable Procedure Codes

Code	Description
J2469	Injection, palonosetron HCl, 25 mcg: 1 billable unit = 25 mcg (0.025 mg)

Applicable NDCs

Code	Description
69639-0103-xx	Aloxi 0.25 mg/5 mL solution for injection; single-dose vial
69639-0103-xx	Aloxi 0.075 mg/1.5 mL solution for injection; single-dose vial

ICD-10 Diagnoses

Code	Description
R11.0	Nausea
R11.10	Vomiting, unspecified
R11.11	Vomiting without nausea
R11.12	Projectile vomiting
R11.2	Nausea with vomiting, unspecified
T41.0X5A	Adverse effect of inhaled anesthetics, initial encounter
T41.1X5A	Adverse effect of intravenous anesthetics, initial encounter
T41.205A	Adverse effect of unspecified general anesthetics, initial encounter
T41.295A	Adverse effect of other general anesthetics, initial encounter
T41.45XA	Adverse effect of unspecified anesthetic, initial encounter
T45.1X5A	Adverse effect of antineoplastic and immunosuppressive drugs, initial encounter

T45.1X5S	Adverse effect of antineoplastic and immunosuppressive drugs, sequela
T45.95XA	Adverse effect of unspecified primarily systemic and hematological agent, initial encounter
T50.905A	Adverse effect of unspecified drugs, medicaments and biological substances, initial encounter
T88.59XA	Other complications of anesthesia, initial encounter
Z51.11	Encounter for antineoplastic chemotherapy
Z51.12	Encounter for antineoplastic immunotherapy

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	03/03/2025	Annual Review: no criteria changes
EmblemHealth & ConnectiCare	4/22/2024	Annual Review: updated HEC chemotherapy charts, Length of Authorization: updated: PONV: Coverage will be provided for 1 dose; Updated dosing limits, Policy Name change from Aloxi to Palonosetron
EmblemHealth & ConnectiCare	8/9/2023	Annual Review: NDCs: removed: 62856-0797-xx, added 69639-0103-xx
EmblemHealth & ConnectiCare	3/23/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	7/20/2021	Changed pediatric dosing "Patient is at least 1 month old and less than 17 18 years old."
EmblemHealth & ConnectiCare	1/30/2020	Updated pediatric dosing guidelines (approved in Medical Policy Subcommittee Meeting on 02/06/2020)
EmblemHealth & ConnectiCare	9/30/2019	<ul style="list-style-type: none"> • Under Guidelines, Prevention of Chemotherapy induced Nausea and vomiting (CINV) in Adults, added or moderately emetogenic chemotherapy to the first bullet per FDA insert. • Under Prevention of Chemotherapy induced Nausea and vomiting (CINV) in Pediatric patients, added under third bullet that it is not being used for acute nausea and vomiting • Added Guideline and Criteria for the Prevention of post-operative nausea and vomiting (PONV) in Adults

References

1. Aloxi [package insert]. Switzerland; Helsinn Healthcare SA; December 2015. Accessed September 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium[®]) palonosetron. National Comprehensive Cancer Network, 2017. The NCCN Compendium[®] is a derivative work of the NCCN Guidelines[®]. NATIONAL COMPREHENSIVE CANCER NETWORK[®], NCCN[®], and NCCN GUIDELINES[®] are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed October 2017.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium[®]) Antiemesis. Version 2.2017. National Comprehensive Cancer Network, 2017. The NCCN Compendium[®] is a derivative work of the NCCN Guidelines[®]. NATIONAL COMPREHENSIVE CANCER NETWORK[®], NCCN[®], and

NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed October 2017.