Medical Policy:
ALOXI® (palonosetron)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.69	August 9, 2023	September 2019

Definitions

Aloxi is a selective 5-HT3 receptor antagonist.

Length of Authorization

Coverage will be provided for six months and may be renewed. 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
- 60 billable units per 7 days for pediatrics

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:

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

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

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

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

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

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

***Highly emetogenic chemotherapy (HEC)**:

Highly Emetogenic Chemotherapy (HEC)			
Carboplatin	Cyclophosphamide	Epirubicin	Streptozocin
Carmustine	Dacarbazine	Ifosfamide	
Cisplatin	Doxorubicin	Mechlorethamine	
The following chemotherapy can be considered HEC in certain patients:			
Dactinomycin Daunorubicin	Irinotecan Methotrexate ≥ 250mg/m^2	Oxaliplatin	Trabectedin
The following regimens can be considered HEC:			
FOLFOX			

**** 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	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	• 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.