

## Medical Policy

Aloxi® (palonosetron)	
<b>MEDICAL POLICY NUMBER</b>	MED_Clin_Ops-108
<b>ORIGINAL EFFECTIVE DATE</b>	5/24/2022
<b>CURRENT VERSION NUMBER</b>	3
<b>CURRENT VERSION EFFECTIVE DATE</b>	01/01/2024
<b>APPLICABLE PRODUCT AND MARKET</b>	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/ Central Health Medicare Plan policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at <http://www.cms.gov> for additional information.

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### PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Aloxi® (palonosetron) therapy.

### POLICY

#### Prior Authorization and Medical Review is required.

Coverage for Aloxi will be provided for six months and may be renewed.

- Max Units (per dose and over time):
  - o CINV: 10 billable units per 7 days
  - o PONV: 3 billable units as one time only

## Medical Policy

### Initial

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

- A. Patient is receiving highly emetogenic chemotherapy (HEC)\*; **OR**
- B. Patient has failed with another 5HT3-antagonist (i.e., ondansetron or granisetron) while receiving the current chemotherapy regimen (Failure is defined as two or more documented episodes of vomiting attributed to the current chemotherapy regimen); **AND**
- C. Aloxi will NOT be covered for:
  - a. Breakthrough emesis; **OR**
  - b. Repeat dosing in multi-day emetogenic chemotherapy regimens

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

- A. Patient is at least 1 month old and less than 17 years old; **AND**
- B. Patient is receiving emetogenic chemotherapy; **AND**
- C. Aloxi will NOT be covered for:
  - a. Breakthrough emesis; **OR**
  - b. Repeat dosing in multi-day emetogenic chemotherapy regimens

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

\*Highly Emetogenic Chemotherapy (HEC)

Carboplatin

Carmustine

Cisplatin

Cyclophosphamide

Dacarbazine

Doxorubicin

Epirubicin

Mechlorethamine

Streptozocin

Melphalan

Regimens: FOLFOX, FOLFIRI, FOLFIRINOX/FOLFOXIRI, AC (any anthracycline + cyclophosphamide)

\*The following can be considered HEC in certain patients:

Dactinomycin

Daunorubicin

Irinotecan

Oxaliplatin

Methotrexate  $\geq 250\text{mg}/\text{m}^2$

Trabectedin

Idarubicin

## Medical Policy

### Renewal

- A. Patient continues to meet initial criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc.; **AND**
- B. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serotonin syndrome, severe QT prolongation, hypersensitivity, etc.; **AND**
- C. Disease response.

### LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

### DEFINITIONS

- A. ALOXI (palonosetron HCl) Injection for Intravenous Use. Initial U.S. Approval: 2003

### CODING

Applicable NDC Codes	
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:

<sup>^</sup>Generics available from multiple manufacturers

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

Applicable ICD-10 Codes	
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
T41.45X5A	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

### Medical Policy

Applicable ICD-10 Codes	
T88.59XA	Adverse effect of unspecified drugs, medicaments and biological substances, initial encounter
Z51.11	Encounter for antineoplastic chemotherapy
Z51.12	Encounter for antineoplastic immunotherapy

### EVIDENCE BASED REFERENCES

1. Aloxi [package insert]. Switzerland; Helsinn Healthcare SA; April 2020. Accessed March 2022.

### POLICY HISTORY

<b>Original Effective Date</b>	5/24/2022
<b>Revised Date</b>	3/1/2023 – Adopted by MA UMC  01/01/2024 - Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan
<b>P&amp;T Committee Endorsement</b>	5/24/2022

Approved by Pharmacy and Therapeutics Committee