Aloxi® (palonosetron)
(Intravenous)

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I. Length of Authorization

Coverage is provided for six months and may be renewed. Coverage cannot be renewed for the indication of PONV.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC unit]:

- Aloxi 0.25 mg/5 mL solution for injection: 1 vial per 7 day supply
- Aloxi 0.075 mg/1.5 mL solution for injection: 1 vial

B. Max Units (per dose and over time) [HCPCS Unit]:

CINV:

- 10 billable units per 7 days

PONV:

- 3 billable units as one time only

III. Initial Approval Criteria[1,2,3,4,5]

Coverage is provided in the following conditions:

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

- Patient is receiving highly emetogenic chemotherapy (HEC)*; **OR**
- Patient has failed** with another 5HT3-antagonist (i.e., ondansetron or granisetron) while receiving the current chemotherapy regimen; **AND**
- Palonosetron 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 †

- Patient is at least 1 month old and less than 17 years old; **AND**
- Patient is receiving emetogenic chemotherapy; **AND**
- Palonosetron is NOT covered for:
  - Breakthrough emesis; **OR**
  - Repeat dosing in multi-day emetogenic chemotherapy regimens

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

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

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

IV. Renewal Criteria[1,2,3]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serotonin syndrome, severe QT prolongation, hypersensitivity, etc.

V. Dosage/Administration[1]

Indication	Dose
Prevention of chemotherapy-induced nausea and vomiting in adults	0.25 mg, no more frequently than weekly, prior to highly emetogenic chemotherapy

Prevention of chemotherapy-induced nausea and vomiting in pediatrics	20 mcg/kg (max of 1.5 mg), no more frequently than weekly, prior to emetogenic chemotherapy
Post-operative nausea and vomiting	0.075 mg given immediately before anesthesia

VI. Billing Code/Availability Information

HCPCS code:

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

NDC:

- Aloxi 0.25 mg/5 mL solution for injection; single-dose vial: 62856-0797-xx
- Aloxi 0.075 mg/1.5 mL solution for injection; single-dose vial: 62856-0798-xx (not commercially available)

Generics available from multiple manufacturers

VII. References

1. Aloxi [package insert]. Switzerland; Helsinn Healthcare SA; September 2018. Accessed March 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) palonosetron. National Comprehensive Cancer Network, 2020. 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 March 2020.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Antiemesis. Version 1.2020. National Comprehensive Cancer Network, 2020. 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 March 2020.
4. Roila F, Molassiotis A, Herrstedt J, et al. MASCC and ESMO Consensus Guidelines for the Prevention of Chemotherapy and Radiotherapy-Induced Nausea and Vomiting: ESMO Clinical Practice Guidelines. Ann Oncol (2016) 27 (suppl 5): v119-v133.
5. Hesketh PJ, Kris MG, Basch E, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clin Oncol. 2017 Oct 1;35(28):3240-3261.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
R11.0	Nausea
R11.10	Vomiting, unspecified

ICD-10	ICD-10 Description
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

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs) and Local Coverage Article (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA,HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC