Akynzeo® (fosnetupitant/palonosetron)
(Intravenous)

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I. Length of Authorization

Coverage is provided for 6 months and may be renewed.

II. Dosing Limits

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

- Akynzeo 235 mg/0.25 mg (fosnetupitant/palonosetron) single-dose vial: 1 vial per 7 days

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

- 1 billable unit per 7 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Prevention of chemotherapy-induced nausea and vomiting (CINV) † [1-5]

- Used in combination with dexamethasone; **AND**
- Patient has failed** with another generically available 5-HT_3 receptor antagonist (e.g., ondansetron, granisetron, palonosetron, etc.) in combination with a NK-1 receptor antagonist (e.g., aprepitant, fosaprepitant, rolapitant, etc.) while receiving the current chemotherapy regimen; **AND**
- Patient is receiving highly emetogenic chemotherapy (HEC)*; **AND**
- Akynzeo is NOT covered for any of the following:
  - Breakthrough emesis
  - Repeat dosing in multi-day emetogenic chemotherapy regimens
  - CINV related to an anthracycline plus cyclophosphamide chemotherapy regimen

*Highly emetogenic chemotherapy (HEC):

Highly Emetogenic Chemotherapy (HEC)

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Carboplatin	Carmustine	Cisplatin	Cyclophosphamide
Dacarbazine	Doxorubicin	Epirubicin	Fam-trastuzumab deruxtecan-nxki
Ifosfamide	Mechlorethamine	Melphalan ≥140 mg/m^2	Sacituzumab govitecan-hziy
Streptozocin			
The following can be considered HEC in certain patients			
Dactinomycin	Daunorubicin	Idarubicin	Irinotecan
Methotrexate ≥250mg/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); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1-3]

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: severe hypersensitivity reactions, serotonin syndrome, etc.

V. Dosage/Administration [1-3]

Indication	Dose
Prevention of chemotherapy-induced nausea and vomiting in adults	Administer the contents of 1 vial, intravenously, on Day 1 of each chemotherapy cycle approximately 30 minutes prior to the start of chemotherapy

VI. Billing Code/Availability Information

HCPCS Code:

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- J1454 – Injection, fosnetupitant 235 mg and palonosetron 0.25 mg; 1 billable unit = fosnetupitant 235 mg and palonosetron 0.25 mg

NDC(s):

- Akynzeo (235 mg fosnetupitant/0.25 mg palonosetron); single-dose vial for injection (lyophilized powder): 69639-0102-xx
- Akynzeo (235 mg fosnetupitant/0.25 mg palonosetron per 20 mL); single-dose vial for injection (solution; to-be-diluted): 69639-0105-xx
- Akynzeo (235 mg fosnetupitant/0.25 mg palonosetron per 20 mL); single-dose vial for injection (solution; ready-to-use): 69639-0106-xx

VII. References

1. Akynzeo [package insert]. Helsinn Therapeutics (U.S.), Inc., Iselin, NJ, under license of Helsinn Healthcare SA, Switzerland. February 2023. Accessed March 2023.
2. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) fosnetupitant/palonosetron. National Comprehensive Cancer Network, 2023. 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 2023.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Antiemesis. Version 1.2023. National Comprehensive Cancer Network, 2023. 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 2023.
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 Guideline Update. J Clin Oncol. 2020 Aug 20;38(24):2782-2797. Doi: 10.1200/JCO.20.01296.
6. Karthaus M, Szabo P, Voisin D, et al. Phase III study of palonosetron (PALO) given as 30-min IV infusion (IV inf) versus 30-sec IV bolus (IV bol) for prevention of chemotherapy-induced nausea and vomiting (CINV) associated with highly emetogenic chemotherapy (HEC). Journal of Clinical Oncology 35(31_suppl):227-227; November 2017. DOI: 10.1200/JCO.2017.35.31_suppl.227.
7. Schwartzberg L, Roeland E, Andric Z, et al. Phase III safety study of intravenous NEPA: a novel fixed antiemetic combination of fosnetupitant and palonosetron in patients receiving highly emetogenic chemotherapy. Ann Oncol. 2018 Jul 1;29(7):1535-1540. Doi: 10.1093/annonc/mdy169.

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
R11.0	Nausea
R11.10	Vomiting, unspecified
R11.11	Vomiting without nausea
R11.12	Projectile vomiting
R11.2	Nausea with vomiting, unspecified
T45.1X5A	Adverse effect of antineoplastic and immunosuppressive drugs, initial encounter
T45.1X5D	Adverse effect of antineoplastic and immunosuppressive drugs, subsequent encounter
T45.1X5S	Adverse effect of antineoplastic and immunosuppressive drugs, sequela
T45.95XA	Adverse effect of unspecified primarily systemic and hematological agent, initial encounter
T45.95XD	Adverse effect of unspecified primarily systemic and hematological agent, subsequent encounter
T45.95XS	Adverse effect of unspecified primarily systemic and hematological agent, sequela
T50.905A	Adverse effect of unspecified drugs, medicaments and biological substances, initial encounter
T50.905D	Adverse effect of unspecified drugs, medicaments and biological substances, subsequent encounter
T50.905S	Adverse effect of unspecified drugs, medicaments and biological substances, sequela
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 Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/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.

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Jurisdiction	**Applicable State/US Territory**	**Contractor**
J (10)	TN, GA, AL	Palmetto Government Benefit Administrators, 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.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

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Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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Fax: 763.847.4010
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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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