Akynzeo® (fosnetupitant/palonosetron)
(Intravenous)

Document Number: IC-0363

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I. Length of Authorization

Coverage is provided for six 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 must be 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:
  - Breakthrough emesis; **OR**
  - Repeat dosing in multi-day emetogenic chemotherapy regimens; **OR**
  - CINV related to an anthracycline plus cyclophosphamide chemotherapy regimen

*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	Irinotecan	Oxaliplatin	Methotrexate ≥ 250 mg/m^2
Daunorubicin	Trabectedin	Idarubicin	
The following regimen 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 [1-3]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other 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:

- J1454 – Injection (fosnetupitant 235 mg and palonosetron 0.25 mg) = 1 billable unit

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 injection (solution): 69639-0105-xx

VII. References

1. Akynzeo [package insert]. Helsinn Therapeutics (U.S.), Inc., Iselin, NJ, under license of Helsinn Healthcare SA, Switzerland. May 2020. Accessed September 2020.
2. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) fosnetupitant/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 September 2020.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Antiemesis. Version 2.2020. 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 September 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.
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.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
R11.0	Nausea
R11.10	Vomiting, unspecified
R11.11	Vomiting without nausea

ICD-10	ICD-10 Description
R11.12	Projectile vomiting
R11.2	Nausea with vomiting, unspecified
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
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: 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 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