

Akynzeo® (fosnetupitant/palonosetron) (Intravenous)

Document Number: IC-0363

Last Review Date: 06/01/2018

Date of Origin: 05/01/2018

Dates Reviewed: 05/2018, 06/2018

I. Length of Authorization

Coverage is provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

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

B. Max Units (per dose and over time) [Medical Benefit]:

- 1 vial per 7 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Prevention of chemotherapy-induced nausea and vomiting (CINV) †

- Patient must be at least 18 years of age; **AND**
- Used in combination with dexamethasone; **AND**
- Patient has failed** with another generically available 5-HT₃ receptor antagonist (e.g. ondansetron, granisetron or palonosetron) and NK1 receptor antagonist (e.g. aprepitant, fosaprepitant or rolapitant) 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	Trabectedin
Daunorubicin	Methotrexate ≥ 250 mg/m ²		
The following regimen 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)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria 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

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

VI. Billing Code/Availability Information

Jcode:

J1454 – Injection, fosnetupitant 235 mg and palonosetron 0.25 mg (effective 1/1/19)

J3490 - Unclassified drugs

C9033 – Injection, fosnetupitant 235 mg and palonosetron 0.25 mg (inactive after 1/1/19)

NDC:

Akynzeo 235 mg fosnetupitant/0.25 mg palonosetron SDV for injection: 69639-0102-xx

VII. References

1. Akynzeo [package insert]. Helsinn Therapeutics (U.S.), Inc., Iselin, NJ, under license of Helsinn Healthcare SA, Switzerland. April 2018. Accessed April 2018.
2. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) netupitant; palonosetron. National Comprehensive Cancer Network, 2018. 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 April 2017.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Antiemesis. Version 1.2018. 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 April 2018.

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
T45.1X5S	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 Biologics. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) 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): 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