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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

**RETIRED**  
**Effective Date: 10/08/2020**

**Akynzeo®** (fosnetupitant and palonosetron injection)

**FDA approval:** 04/19/2018

**HCPCS:** C9033

**Benefit:** Medical

**Policy:**

*Requests must be supported by submission of chart notes and patient specific documentation.*

- A. Coverage of the requested drug is provided when all the following are met:
  - a. Age 18 years of age and older
  - b. Used for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy
  - c. Used in combination with dexamethasone
  - d. Trial and failure of the preferred products as specified in the BCBSM/BCN medical utilization management drug list
- B. Quantity Limitations, Authorization Period and Renewal Criteria
  - a. FDA labeled dosing
  - b. Initial authorization period: 6 months
  - c. Renewal criteria: Goals of therapy have been met

\*\*\*Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

**Therapeutic considerations:**

- A. **FDA Approved Indication/Diagnosis**
  - a. Akynzeo is indicated in combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy

*\*Please refer to most recent prescribing information.*

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

**B. Background Information**

- a. Akynzeo is a combination of palonosetron, a serotonin-3 (5-HT<sub>3</sub>) receptor antagonist, and fosnetupitant, substance P/neurokinin-1 (NK-1) receptor antagonists: palonosetron prevents nausea and vomiting during the acute phase and fosnetupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy.

**C. Efficacy**

*\*Please refer to most recent prescribing information.*

**D. Medication Safety Considerations**

Black Box Warning: No

*\*Please refer to most recent prescribing information.*

**E. Dosing and administration**

*\*Please refer to most recent prescribing information.*

**F. How supplied**

*\*Please refer to most recent prescribing information.*

**References:**

1. Akynzeo® injection [prescribing information]. Iselin, NJ: Helsinn Healthcare; April 2018.
2. Ultragenyx. Akynzeo press release. Available at: <http://ir.ultragenyx.com/news-releases/news-release-details/ultragenyx-and-kyowa-kirin-announce-fda-approval-crysvitar>. Accessed April 27, 2018.
3. Ettinger, D. S., et al. NCCN Guidelines Version 1.2018 Panel Members Antiemesis. National Comprehensive Cancer Network, Inc. 2018.
4. Highmark Medication Review New Dosage Form Antiemetics: Emetogenic Therapy Adjuncts rolapitant (Varubi). November 2017.

| Policy History   |                               |                                                                                                                                                                                                                                     |                  |                      |      |    |     |    |       |    |      |    |
|------------------|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|------|----|-----|----|-------|----|------|----|
| #                | Date                          | Change Description                                                                                                                                                                                                                  |                  |                      |      |    |     |    |       |    |      |    |
| 1.2              | Effective Date:<br>10/08/2020 | Retiring policy as this drug is no longer managed with prior authorization                                                                                                                                                          |                  |                      |      |    |     |    |       |    |      |    |
| 1.1              | Effective Date:<br>11/07/2019 | Annual Review of Medical Policy                                                                                                                                                                                                     |                  |                      |      |    |     |    |       |    |      |    |
| 1.0              | Effective Date:<br>08/09/2018 | Full Drug Review <table><tr><th>Line of Business</th><th>PA Required (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table> | Line of Business | PA Required (Yes/No) | BCBS | No | BCN | No | MAPPO | No | BCNA | No |
| Line of Business | PA Required (Yes/No)          |                                                                                                                                                                                                                                     |                  |                      |      |    |     |    |       |    |      |    |
| BCBS             | No                            |                                                                                                                                                                                                                                     |                  |                      |      |    |     |    |       |    |      |    |
| BCN              | No                            |                                                                                                                                                                                                                                     |                  |                      |      |    |     |    |       |    |      |    |
| MAPPO            | No                            |                                                                                                                                                                                                                                     |                  |                      |      |    |     |    |       |    |      |    |
| BCNA             | No                            |                                                                                                                                                                                                                                     |                  |                      |      |    |     |    |       |    |      |    |

*\* The prescribing information for a drug is subject to change. To ensure you are reading the most current information*

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*it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.*