

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

AKYNZEO CAPSULES
(netupitant/palonosetron)

AKYNZEO INJECTION
(fosnetupitant/palonosetron)

Status: CVS Caremark® Criteria

Type: Post Limit Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

- Akynzeo capsules 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 cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. Akynzeo capsules is a combination of palonosetron and netupitant: palonosetron prevents nausea and vomiting during the acute phase and netupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy.
- Akynzeo for injection and Akynzeo injection are 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. Akynzeo for injection is a combination of palonosetron and fosnetupitant, a prodrug of netupitant: 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.

Limitations of Use

Akynzeo for injection and Akynzeo injection have not been studied for the prevention of nausea and vomiting associated with anthracycline plus cyclophosphamide chemotherapy.

COVERAGE CRITERIA

Nausea and Vomiting Associated with Cancer Chemotherapy

Authorization may be granted when the requested drug is being prescribed for the for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy.

QUANTITY LIMITS APPLY

4 capsules of Akynzeo per 21 days*; 4 vials of Akynzeo for injection per 21 days*; 80 mL of Akynzeo injection per 21 days*. No 3 month supplies should be filled.

* The duration of 21 days is used for a 28-day fill period to allow time for refill processing.

* These drugs are for short-term acute use; therefore, the mail limit will be the same as the retail limit. The intent is for prescriptions of the requested drug to be filled one month at a time, even if filled at mail order; there should be no 3 month supplies filled.

DURATION OF APPROVAL (DOA)

- 1212-J: DOA: 6 months

REFERENCES

1. Akynzeo [package insert]. Iselin, NJ: Helsinn Therapeutics (U.S.), Inc.; February 2023.

Akynzeo Post Limit PA Policy UDR 01-2024.docx

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2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>. Accessed November 29, 2023.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 11/29/2023).
4. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Antiemesis. Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf. Accessed November 30, 2023.
5. American Society of Clinical Oncology. What is Chemotherapy? <https://www.cancer.net/navigating-cancer-care/how-cancer-treated/chemotherapy/what-chemotherapy>. May 2022. Accessed November 30, 2023.
6. American Cancer Society. How is Chemotherapy Used to Treat Cancer? <https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/chemotherapy/how-is-chemotherapy-used-to-treat-cancer.html> November 2019. Accessed November 30, 2023.