QUANTITY LIMIT CRITERIA

BRAND NAME* **(generic)**	
	AKYNZEO CAPSULES **(netupitant/palonosetron)**
	AKYNZEO INJECTION **(fosnetupitant/palonosetron)**

Status: CVS Caremark Criteria
Type: Quantity Limit   **Ref # 1211-H**

* *Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

Akynzeo capsules 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 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.

RATIONALE

Akynzeo capsules 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 cancer chemotherapy, including, but not limited to, highly emetogenic 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.[1-3]

The recommended oral dosage in adults for highly emetogenic chemotherapy, including cisplatin based chemotherapy, is one capsule of Akynzeo administered approximately 1 hour prior to the start of chemotherapy with dexamethasone 12 mg administered 30 minutes prior to chemotherapy on day 1; followed by dexamethasone 8 mg once daily on days 2 to 4. The recommended dosage in adults for anthracyclines and cyclophosphamide based chemotherapy and chemotherapy not considered highly emetogenic is one capsule of Akynzeo approximately 1 hour prior to the start of chemotherapy with dexamethasone 12 mg administered 30 minutes prior to chemotherapy on day 1. Administration of dexamethasone on days 2 to 4 is not necessary.[1-3]

The recommended injection dosage in adults for highly emetogenic chemotherapy, including cisplatin based chemotherapy, is one vial of Akynzeo administered approximately 30 minutes prior to the start of chemotherapy with

dexamethasone 12 mg administered 30 minutes prior to chemotherapy on day 1; followed by dexamethasone 8 mg once daily on days 2 to 4. Akynzeo for injection and Akynzeo injection have not been studied for the prevention of nausea and vomiting associated with anthracycline plus cyclophosphamide chemotherapy.[1-3]

The limit allows a quantity sufficient for two chemotherapy cycles per month (i.e., one chemotherapy cycle every 2 weeks). If the patient is requesting more than the initial quantity limit, then the claim will reject with a message indicating that a prior authorization is required.

REFERENCES

1. Akynzeo [package insert]. Iselin, NJ: Helsinn Therapeutics.; January 2021.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed December 2021.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed December 2021.

LIMIT CRITERIA

Limits do not accumulate together, patient is allowed the maximum limit for each drug and strength

Drug	4 Week Limit*	12 Week Limit*
Akynzeo capsules	2 capsules / 21 days	Does Not Apply*
Akynzeo for injection	2 vials / 21 days	Does Not Apply*
Akynzeo injection	40 mL / 21 days	Does Not Apply*

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.

❤CVS caremark®