



## Akynzeo® (fosnetupitant and palonosetron) injection

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### Definitions

Akynzeo (fosnetupitant and palonosetron) for injection is a combination of palonosetron, a serotonin-3 (5-HT<sub>3</sub>) receptor antagonist and fosnetupitant, a substance P/neurokinin-1 (NK-1) receptor antagonist. 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.

Akynzeo for injection is indicated in combination with dexamethasone for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy in adults.

Highly Emetogenic Chemotherapy (HEC)			
Carboplatin	Carmustine	Cisplatin	Cyclophosphamide
Dacarbazine	Doxorubicin	Epirubicin	Ifosfamide
Mechlorethamine	Streptozocin		
The following chemotherapy can be considered HEC in certain patients:			
Dacitnomycin	Irinotecan	Oxaliplatin	Trabectedin
Daunorubicin	Methotrexate $\geq 250 \text{ mg/m}^2$		
The following regimen can be considered HEC:			
FOLFOX			

## Dosing

Max units (per dose and over time):

- 1 vial (fosnetupitant 235 mg and palonosetron 0.25mg) on day 1 of chemotherapy per 7 days

## Guideline

Akynzeo (fosnetupitant and palonosetron) is considered when the following criteria are met:

- Patient is 18 years of age or older; **AND**
- Akynzeo will be used in combination with dexamethasone; **AND**
- Patient is undergoing highly emetogenic cancer chemotherapy (HEC); **AND**
- Patient has failed a trial a 5-HT3 receptor antagonist (e.g., ondansetron, granisetron, palonosetron) in combination with a NK1 receptor antagonist (e.g. aprepitant, fosaprepitant, rolapitant) while receiving the current chemotherapy regimen, as defined as:
  - Two or more episodes of vomiting attributed to the current chemotherapy regimen; **OR**
  - Clinically significant adverse effects attributed to the 5-HT3 or NK1 receptor antagonist; **OR**
  - Contraindications to alternative 5-HT3 or NK1 receptor antagonist

Coverage for Akynzeo (fosnetupitant and palonosetron) may be renewed when the following criteria are met:

- Patient continues to meet the criteria identified in the initial approval criteria above; **AND**
- Disease response; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe hypersensitivity reactions, serotonin syndrome, etc.

## Limitations/Exclusions

- Approval will be granted for 6 months and may be renewed
- Akynzeo use for the prevention of nausea and vomiting associated with anthracycline plus cyclophosphamide chemotherapy will be considered investigational and not be covered

## Applicable Procedure Codes

### Revisions

12/3/2018 – Added J1454 and removed J3590, C9033 from Applicable Procedure Codes.

J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg
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## Applicable Diagnosis Codes

R11.0	Nausea
R11.10	Vomiting, unspecified
R11.11	Vomiting without nausea

R11.12	Projectile vomiting
R11.13	Vomiting of fecal matter
R11.14	Bilious vomiting
R11.2	Nausea with vomiting, unspecified
T45.1X5A	Adverse effect of antineoplastic and immunosuppressive drugs, initial encounter
T45.1X5D	Adverse effect of antineoplastic and immunosuppressive drugs, subsequent encounter
T45.1X5S	Adverse effect of antineoplastic and immunosuppressive drugs, sequela
Z51.11	Encounter for antineoplastic chemotherapy
Z51.12	Encounter for antineoplastic immunotherapy

## References

1. Akynzeo [package insert]. Helsinn Therapeutics (U.S.), INC., Iselin, NJ. April, 2018.