# Medical Policy:
## AKYNZEO® (fosnetupitant and palonosetron) Injection

| POLICY NUMBER | LAST REVIEW | ORIGIN DATE |
|---|---|---|
| MG.MM.PH.60 | August 10, 2023 | |



## Definitions

Akynzeo (fosnetupitant and palonosetron) for injection is a combination of palonosetron, a serotonin-3 (5-$HT_3$) 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 ≥ 250 mg/$m^2$ | | |
| **The following regimen can be considered HEC:** | | | |
| FOLFOX | | | |

## Dosing Limits [Medical Benefit]

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

### INITIAL CRITERIA

1. **Prevention of chemotherapy-induced nausea and vomiting (CINV)**

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

A. Patient is 18 years of age or older; **AND**

B. Akynzeo will be used in combination with dexamethasone; **AND**

C. Patient is undergoing highly emetogenic cancer chemotherapy (HEC); **AND**

D. 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

### RENEWAL CRITERIA

1. **Prevention of chemotherapy-induced nausea and vomiting (CINV)**

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

A. Patient continues to meet the criteria identified in the initial approval criteria above; **AND**

B. Disease response; **AND**

C. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe hypersensitivity reactions, serotonin syndrome, etc.

### Limitations/Exclusions

1. Approval will be granted for 6 months and may be renewed
2. 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

| Code | Description |
|---|---|
| J1454 | Injection, fosnetupitant 235 mg and palonosetron 0.25 mg |

## Applicable NDCs

| Code | Description |
|---|---|
| 69639-0102-01 | Injection, fosnetupitant 235 mg and palonosetron 0.25 mg |

| | |
|---|---|
| 69639-0105-01 | Injection, fosnetupitant 235 mg and palonosetron 0.25 mg |

## ICD-10 Diagnoses

| Code | 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 |

## Revision History

| Company(ies) | DATE | REVISION |
|---|---|---|
| EmblemHealth & ConnectiCare | 8/10/2023 | Annual Review:<br>Removed ICD-10 codes: R11.13, R11.14, T45.1X5D; Added: T45.95XA and T50.905A |
| EmblemHealth & ConnectiCare | 3/17/2022 | Updated Procedure Code to Q2055 and put on new template |
| EmblemHealth & ConnectiCare | 12/30/2020 | Annual Review |
| EmblemHealth & ConnectiCare | 9/30/2019 | Annual Review |
| EmblemHealth & ConnectiCare | 12/03/2018 | Added J1454 and removed J3590, C9033 from Applicable Procedure Codes |

## References

1. Akynzeo [package insert]. Helsinn Therapeutics (U.S.), INC., Iselin, NJ. October, 2020.