Akynzeo®
fosnetupitant 235 mg/
palonosetron 0.25 mg
injection

AKYNZEO® injection Billing & Coding Guide

This document provides general billing and coding information for AKYNZEO injection. This information does not guarantee coverage or payment. Codes, coverage, and payment may vary from setting to setting, and from insurer to insurer. The provider submitting a claim is solely responsible for the accuracy of the codes submitted and for compliance with all coverage and reimbursement policies.

Healthcare Common Procedure Coding System (HCPCS)

Level II Codes

HCPCS codes are 5-digit alphanumeric codes that are assigned to drugs by the Centers for Medicare & Medicaid Services (CMS).

Code	Description
J1454	Injection (Ready-to-Use), fosnetupitant 235 mg and palonosetron 0.25 mg
J1454	Injection (To-be-Diluted), fosnetupitant 235 mg and palonosetron 0.25 mg
96367	Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour.

National Drug Codes (NDCs)

Description	NDC Code
AKYNZEO® (235 mg fosnetupitant/0.25 mg palonosetron per 20 mL) injection (Ready-to-Use) sterile, clear solution in a single dose vial with hanger	69639-106-01
AKYNZEO® (235 mg fosnetupitant/0.25 mg palonosetron) injection (To-be-Diluted) sterile, clear solution in a single dose vial to be diluted	69639-105-01

Some payers may require providers to report 11-digit NDCs when submitting a claim. Converting the 10-digit NDC for AKYNZEO to an 11-digit NDC requires the use of a leading zero in the product code section of the AKYNZEO® NDC (i.e., the middle section).

	10-digit NDC	11-digit NDC
Example NDC	AAAAA-BBB-CC	AAAAA-0BBB-CC
AKYNZEO® injection (Ready-to-Use) NDC	69639-106-01	69639-0106-01
AKYNZEO® injection (To-be-Diluted) NDC	69639-105-01	69639-0105-01

Indication

AKYNZEO (fosnetupitant/palonosetron) injection 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.

Limitations of Use

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

AKYNZEO is a combination of palonosetron, a serotonin-3 ($5\text{-}HT_3$) 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.

Please see Important Safety Information on the reverse.

For more information about AKYNZEO, please see the full US Prescribing Information.

Diagnosis Codes

Providers should use current ICD-10-CM diagnosis codes to report a patient's diagnosis on claim submissions. Below is a list of ICD-10-CM codes that may be reasonably related to a diagnosis within the product's approved label. Other codes may be appropriate.

Diagnosis Code	Description
R11.2	Nausea with vomiting, unspecified
R11.0	Nausea
R11.10	Vomiting, unspecified
R11.11	Vomiting without nausea
R11.12	Projectile vomiting

Please see FDA-approved indication for AKYNZEO® and check with the payer to verify coding or special billing requirements.

Supplementary Classification Codes

Supplementary classification codes permit the reporting of circumstances and conditions that impact the disease or injury.
When providers use supplementary codes, they should also report a diagnosis code from one of the main chapters of the ICD-10-CM coding manual.

Below is a list of ICD-10-CM supplementary classification codes that may be reasonably related to a diagnosis within the product's approved label. Other codes may be appropriate.

Supplementary Classification Code	Description
T45.1X5	Adverse effect of antineoplastic and immunosuppressive drugs
Z41.8	Encounter for other procedures for purposes other than remedying health state
Z51.11	Encounter for antineoplastic chemotherapy

We recommend verifying a payer's coding and coverage policies prior to administration of AKYNZEO®. If you have any questions, please email **accountsupport@helsinn.com**.

Important Safety Information

Warnings and Precautions

- Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving palonosetron, one of the components of AKYNZEO, with or without known hypersensitivity to other 5-HT_3 receptor antagonists
- Serotonin syndrome has been reported with 5-HT_3 receptor antagonists alone but particularly with concomitant use of serotonergic drugs. Serotonin syndrome can be life threatening. Symptoms associated with serotonin syndrome may include the following combination of signs and symptoms: mental status changes, autonomic instability, neuromuscular symptoms, seizures, and gastrointestinal symptoms. Patients should be monitored for the emergence of serotonin syndrome, and if symptoms occur, discontinue AKYNZEO and initiate supportive treatment. Patients should be informed of the increased risk of serotonin syndrome, especially if AKYNZEO is used concomitantly with other serotonergic drugs

Adverse Reactions

- Most common adverse reactions (≥3%) for AKYNZEO capsules are headache, asthenia, dyspepsia, fatigue, constipation and erythema. The safety profile of AKYNZEO injection was generally similar to AKYNZEO capsules

Drug Interactions

- Use with caution in patients receiving concomitant medications primarily metabolized by CYP3A4. The plasma concentrations of CYP3A4 substrates can increase when co-administered with AKYNZEO. The inhibitory effect on CYP3A4 can last for multiple days
  - Dexamethasone doses should be reduced when given with AKYNZEO. A more than two-fold increase in the systemic exposure of dexamethasone was observed 4 days after a single dose of netupitant or a single infusion of fosnetupitant
  - Consider the potential effects of increased plasma concentrations of midazolam or other benzodiazepines metabolized via CYP3A4 (alprazolam, triazolam) when administering with AKYNZEO. When administered with netupitant, the systemic exposure to midazolam was significantly increased
- Avoid concomitant use of AKYNZEO in patients on chronic use of a strong CYP3A4 inducer such as rifampin as this may decrease the efficacy of AKYNZEO

Use in Specific Populations

- Avoid use of AKYNZEO in patients with severe hepatic impairment, severe renal impairment, or end-stage renal disease
- Advise women of potential risk to fetus; limited data are available; may cause fetal harm

For more information about AKYNZEO, please see the full US Prescribing Information.

Reference: Akynzeo® [package insert]. Iselin, NJ: Helsinn Therapeutics (U.S.), Inc; 02/2023.

HELSINN

Akynzeo®
fosnetupitant 235 mg/
palonosetron 0.25 mg
injection