**Letter of Medical Necessity Template for AKYNZEO®**

**PLEASE NOTE:** This letter is intended as an example for your consideration and may not include all the information necessary to support your appeal request or may include information inapplicable to your appeal. The requesting prescriber is entirely responsible for ensuring the accuracy, adequacy, and supportability of the information provided. You are responsible for providing true, accurate and complete information concerning requested therapy, the applicable diagnosis, the patient's medical record, and ensuring the medical necessity of the therapy.

Payer policies will vary accordingly. Prior to treatment, providers should confirm coverage and identify any limitations on diagnosis, coding or site of service requirements. Providers are responsible for making appropriate decisions related to coding and reimbursement submissions.

**Indication:**

* 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 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.
  + 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.

Distributed and marketed in the U.S. by: Helsinn Therapeutics (U.S.), Inc.

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**Instructions for completing the sample letter:**

1. Adopt to your practice letterhead and/or email format and ensure it is signed by the prescriber.
2. Customize the template based on the medical appropriateness of AKYNZEO® for your patient. Fields required for customization are **highlighted in yellow**.
3. It is important to provide the most complete and specific information to assist with the appeals process.
4. [Please click here to download Prescribing Information for AKYNZEO®](https://www.akynzeo.com/assets/pdf/Akynzeo-USPI.pdf)
5. If you have questions, please contact HelsinnCares at 1-84HELSINN-U (1-844-357-4668)

[Current Date]

[Medical Director Name]

[Insurance Name]

[Insurance Address]

[Insurance City, State, Zip Code]

**Patient:** [Patient Name]

**Date of Birth:** [Patient Date of Birth]

**ID Number:** [XXXXX]

**Date of Service:** [XXXXXXX]

**Provider Name NPI:** [HCP Name]

**NPI #:**  [Prescriber NPI #]

**Claim Number:** [XXXXX]

Dear [Medical Director Name]:

I am writing on behalf of my patient, [Patient Name], to document the medical necessity and request coverage for [CHOOSE FORMULATION: AKYNZEO® (fosnetupitant 235 mg/palonosetron 0.5 mg) injection, OR AKYNZEO® (netupitant 300 mg/palonosetron 0.25 mg) capsules)

[Patient Name] is a patient under my care for [disease]. [He/She] was first diagnosed with [diagnosis] on [date of diagnosis]. At this time, I plan to start [Patient Name] on a course of treatment with [name of chemotherapeutic agent], known to be [CHOOSE: Highly emetogenic that cause CINV in >90% of patients OR Moderately emetogenic that induce CINV in 30% to 90% of patients1]

In your initial rejection, [Please list reason(s) for rejection]

[Patient Name] \_\_(Type here reasons for medical necessity and coverage request. Please see the non-exhaustive list below for some examples)\_\_\_

[Suggestions: Has risk factors that put him/her at high risk of CINV2,3 – Has tried and failed previous anti-emetic therapy related to chemotherapy – Required rescue medication (a definition of failure) on previous anti-emetic therapy related to chemotherapy – Experienced nausea on previous anti-emetic therapy related to chemotherapy – Experienced injection site reactions or other adverse reactions on previous anti-emetic therapy (fosaprepitant contains polysorbate 80, which may be implicated in infusion hypersensitivity reactions. AKYNZEO does not contain polysorbate 80)]

Due to the patient needs and risk factors described above, in my professional opinion, AKYNZEO will provide my patient with much needed prevention of chemotherapy-induced nausea and vomiting.4

AKYNZEO is a combination of palonosetron, a serotonin-3 (5-HT3) receptor antagonist, and netupitant or fosnetupitant, substance P/neurokinin-1 (NK-1) receptor antagonists: palonosetron prevents nausea and vomiting during the acute phase and netupitant/fosnetupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy.

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) include netupitant/fosnetupitant and palonosetron fixed combination (AKYNZEO) as a component of Category 1 treatment options for parenteral Moderately Emetic Chemotherapy (MEC) and Highly Emetic Chemotherapy (HEC) regimens.5

In my professional opinion, AKYNZEO is medically necessary and an appropriate drug for my patient at this time. [Please include medical opinion. Suggestion: Without AKYNZEO, this patient is at risk of chemotherapy-induced nausea and vomiting, which can affect cancer treatment decisions and increase the chances of emergency visits and hospitalization for CINV, which could decrease the patient's quality of life and increase the total treatment cost.]

Please see the accompanying full Prescribing Information for AKYNZEO.

Sincerely,

[Prescriber Name], MD

NPI #: [Prescriber NPI #]

Contact information:

[Prescriber Name and Practice Name]

[Address]

[City], [State] [Zip]

Contact Phone No.: [Phone Number]

References:

1. Grunberg SM. Patient-centered management of chemotherapy-induced nausea and vomiting. Cancer Control. 2012;19(Suppl2):10-15.
2. Hainsworth JD. Nausea and Vomiting. In: Abeloff MD, Armitage JO, Niederhuber JE, Kastan MB, McKenna WG, eds. Abeloff’s Clinical Oncology. 4th ed. Philadelphia, PA: Churchill Livingstone Elsevier; 2008.
3. National Cancer Institute. Nausea and Vomiting (PDQ®). Updated November 8, 2022. Accessed March 27, 2023. <http://www.cancer.gov/about-cancer/treatment/side-effects/nausea/nausea-hp-pdq#section/all>.
4. AKYNZEO [package insert]. Iselin, NJ: Helsinn Therapeutics US, Inc., June 2021.
5. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Antiemesis V.1.2023. © 2023 National Comprehensive Cancer Network, Inc. All rights reserved. Accessed March 27, 2023.