

Policy: MBP 192.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Akynzeo IV (fosnetupitant/palonosetron)

I. Policy:

Akynzeo IV (fosnetupitant/palonosetron)

II. Purpose/Objective:

To provide a policy of coverage regarding Akynzeo IV (fosnetupitant/palonosetron)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

Akynzeo IV (fosnetupitant/palonosetron) is a selective 5-HT3 receptor antagonist and substance P/neurokinin 1 receptor antagonist combination. Fosnetupitant is a prodrug of netupitant, a selective substance P/neurokinin (NK1) receptor antagonist, which augments the antiemetic activity of 5-HT3 receptor antagonists and corticosteroids to inhibit acute and delayed chemotherapy-induced emesis. Palonosetron is a selective 5-HT3 receptor antagonist, which blocks serotonin, both on vagal nerve terminals in the periphery and centrally in the chemoreceptor trigger zone. Palonosetron inhibits the cross-talk between the 5-HT3 and NK1 receptors. The combination of palonosetron and netupitant works synergistically to inhibit substance P response to a greater extent than either agent alone

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Akynzeo IV (fosnetupitant/palonosetron) will be considered medically necessary for the commercial, exchange and CHIP lines of business when ALL of the following criteria are met:

- Medical record documentation that Akynzeo is being used for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy **AND**
- Medical record documentation of a treatment failure or contraindication to at least one NK-1 antagonist (e.g. fosaprepitant (Emend), aprepitant (Cinvanti), etc.). Treatment failure is defined as allergy, intolerable side-effects, significant drug-drug interaction, or lack of efficacy.

OR

- Medical record documentation that Akynzeo is being used for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy **AND**
- Medical record documentation of a treatment failure or contraindication to palonosetron (Aloxi) **AND** either ondansetron (Zofran) or granisetron (Kytril). Treatment failure is defined as allergy, intolerable side-effects, significant drug-drug interaction, or lack of efficacy.

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Akynzeo IV (fosnetupitant/palonosetron) will be considered medically necessary for the Medicare line of business when ALL of the following criteria are met:

- Medical record documentation that Akynzeo is being used for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy

OR

- Medical record documentation that Akynzeo is being used for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy **AND**
- Medical record documentation of a treatment failure or contraindication to a corticosteroid plus a serotonin receptor antagonist (5-HT3 RA) such as ondansetron or granisetron **OR** have additional patient-related risk factors for chemotherapy-induced nausea and vomiting as defined by the National Comprehensive Cancer Network (NCCN) guidelines. Treatment failure is defined as allergy, intolerable side-effects, significant drug-drug interaction, or lack of efficacy.

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Note: The following antineoplastic agents are considered highly emetogenic (refer to NCCN for complete list):

- AC combination defined as any chemotherapy regimen that contains an anthracycline and cyclophosphamide
- Carboplatin
- Carmustine
- Cisplatin
- Cyclophosphamide at doses $>1500 \text{ mg/m}^2$
- Dacarbazine
- Dactinomycin
- Daunorubicin
- Doxorubicin
- Epirubicin
- Ifosfamide
- Irinotecan
- Mechlorethamine
- Methotrexate at doses $> 250\text{mg/m}^2$
- Oxaliplatin
- Streptozocin
- Trabectedin

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Akynzeo [prescribing information]. Iselin, NJ: Helsinn Therapeutics (US) Inc; October 2020.
2. Antiemesis Version 1.2024. National Comprehensive Cancer Network (NCCN); 2023 Dec 13 [cited 2023 Dec 26]. Available from: <https://www.nccn.org/guidelines/guidelines-detail?category=3&id=1415>

This policy will be revised as necessary and reviewed no less than annually.

Devised: 3/19/19

Revised: 1/17/23 (LOB carve out), 12/29/23 (references added), 1/9/24 (Medicaid business segment)

Reviewed: 2/1/20, 1/19/21, 1/18/22

MA UM Committee approval: 12/31/23