Clinical Policy: Netupitant and Palonosetron (Akynzeo)

Reference Number: HIM.PA.113
Effective Date: 05.01.17
Last Review Date: 05.18
Line of Business: HIM

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Netupitant/palonosetron (Akynzeo®) is an oral fixed combination product of netupitant, a substance P/neurokinin 1 (NK_1) receptor antagonist, and palonosetron hydrochloride, a serotonin-3 ($5HT_3$) receptor antagonist. Both netupitant and palonosetron hydrochloride are anti-nausea and anti-emetic agents.

FDA Approved Indication(s)

Akynzeo is indicated 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.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Akynzeo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chemotherapy-Induced Nausea/Vomiting Prophylaxis (must meet all)**:**

1. Prescribed for the prevention of chemotherapy-induced nausea/vomiting;
2. Failure of a trial of aprepitant in combination with ondansetron or granisetron at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
   ** Prior authorization is required for aprepitant*
3. Dose does not exceed netupitant 300 mg/palonosetron 0.5 mg (1 capsule) as a single dose.

Approval duration: projected course of chemotherapy

B. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Chemotherapy-Induced Nausea/Vomiting Prophylaxis (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation that member is currently receiving chemotherapy;
3. Member is responding positively to therapy;

4. Dose does not exceed netupitant 300 mg/palonosetron 0.5 mg (1 capsule) as a single dose.

Approval duration: projected course of chemotherapy

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – HIM.PHAR.21 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
NK_1: neurokinin 1
$5HT_3$: serotonin-3

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
aprepitant (Emend®)	**For prevention of chemotherapy-induced nausea/vomiting** On Day 1, give 125 mg PO 1 hour before chemotherapy. On Days 2 and 3, give 80 mg PO 1 hour before chemotherapy or if no chemotherapy is scheduled on Days 2 and 3, administer in the morning	125 mg/day PO
ondansetron (Zofran®, Zofran® ODT)	**For prevention of chemotherapy-induced nausea/vomiting** For moderately emetogenic chemotherapy: 8 mg PO BID. Give first dose 30 minutes before the start of emetogenic chemotherapy, with a subsequent dose 8 hours after the initial dose. Further doses may be given every 12 hours for 1 to 2 days after completion of chemotherapy	24 mg/day PO

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	For highly emetogenic chemotherapy: 24 mg PO once given 30 minutes before administration of single-day highly emetogenic chemotherapy	
granisetron (Kytril®)	**For prevention of chemotherapy-induced nausea/vomiting** 1 mg PO BID on days of chemotherapy administration. Give first dose up to 60 minutes before chemotherapy; give the second dose 12 hours later. Alternatively, give 2 mg as a single dose within 1 hour prior to chemotherapy.	2 mg/day PO

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

V. References

1. Akynzeo Prescribing Information. Woodcliff Lake, NJ: Eisai, Inc.; April 2015. Available at: https://www.akynzeo.com/. Accessed February 8, 2018.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/. Accessed February 6, 2018.
3. National Comprehensive Cancer Network. Antiemesis Version 2.2017. Available at: https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf. Accessed February 6, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01.17	
2Q 2018 annual review: added aprepitant as part of step therapy requirement per 2018 formulary; references reviewed and updated.	02.08.18	05.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that

has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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