



DRUG QUANTITY MANAGEMENT POLICY – PER RX

- POLICY:** Antiemetics – Substance P/Neurokinin-1 Receptor Antagonists (Oral)
Drug Quantity Management Policy – Per Rx
- Akynzeo® (netupitant/palonosetron capsules – Helsinn)
 - Emend® (aprepitant capsules, powder for oral suspension – Merck, generic for capsules only)
 - Varubi® (rolapitant tablets – TerSera)

REVIEW DATE: 09/03/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Indications and Dosing

FDA-approved indications and dosing for the oral Substance P/Neurokinin-1 (NK₁) receptor antagonists are in Table 1.

Table 1. Indications and Dosing for the Oral Substance P/NK₁ Receptor Antagonists.¹⁻³

Brand (generic)	FDA-Approved Indications	Recommended Dosing
Akynzeo® (netupitant /palonosetron capsules)	In combination with dexamethasone in adults for prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of chemotherapy, including, but not limited to, HEC.	One capsule administered approximately 1 hour prior to the start of chemotherapy.

Emend® (aprepitant capsules [generic] and oral suspension)	In combination with other antiemetic agents, in patients ≥ 6 months of age* for prevention of: <ul style="list-style-type: none"> • Acute and delayed nausea and vomiting associated with initial and repeat courses of HEC, including high-dose cisplatin • Nausea and vomiting associated with initial and repeat courses of MEC. 	Patients ≥ 12 years of age: 125 mg on Day 1, and 80 mg on Days 2 and 3. Administer 1 hour prior to chemotherapy. If no chemotherapy is given on Days 2 and 3, administer in the morning. Patients 6 months to 11 years of age, or pediatric and adult patients unable to swallow capsules: 3 mg/kg on Day 1 (maximum 125 mg), and 2 mg/kg (maximum 80 mg) on Days 2 and 3. Dosing in pediatric patients < 6 kg is not recommended.
Varubi® (rolapitant tablets)	In combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic chemotherapy, including, but not limited to, HEC.	180 mg administered within 2 hours prior to initiation of chemotherapy on Day 1. Administer prior to the initiation of each chemotherapy cycle, but at no less than 2-week intervals.

NK₁ – Neurokinin-1; HEC – Highly emetogenic chemotherapy; * Oral suspension indicated in patients 6 months of age and older, oral capsules indicated in patients 12 years of age and older; MEC – Moderately emetogenic chemotherapy.

Availability

The availability of the oral substance-P/NK₁ receptor antagonists is in the Drug Quantity Limits table below.

Guidelines

Antiemesis guidelines from the National Comprehensive Cancer Network (NCCN) [version 1.2024 – December 13, 2023] make recommendations regarding the use of the substance P/NK₁ receptor antagonists.¹ In general, recommended dosing follows along with FDA-approved labeling and also provides for antiemetic use for multiple courses or multiple days of chemotherapy. Specifically, NCCN notes that Varubi has an extended half-life and should not be administered more frequently than every 2 weeks.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of the oral substance P-NK₁ receptor antagonists. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration, unless otherwise noted below.

Drug Quantity Limits

Product	Strength and Dosage Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Akynzeo® (netupitant/palonosetron capsules)	300 mg/0.5 mg capsules (one capsule in one blister)	1 capsule	3 capsules
Emend®	40 mg capsules (generic only)	1 capsule	3 capsules
	80 mg capsules	2 capsules	6 capsules

(aprepitant capsules [generic] and powder oral suspension)	125 mg capsules (generic only)	1 capsule	3 capsules
	TriPack (one 125 mg capsule and two 80 mg capsules)	3 capsules (1 pack)	9 capsules (3 packs)
	125 mg powder packets (brand only)	3 packets	9 packets
Varubi® (rolapitant tablets)	90 mg tablets (two tablets per 180 mg wallet)	2 tablets (1 wallet)	6 tablets (3 wallets)

Antiemetics – Substance P/Neurokinin-1 Receptor Antagonists (Oral) Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Akynzeo 300 mg/0.5 mg capsules

1. If the patient is receiving Akynzeo for the prevention of nausea and vomiting associated with multiple courses of cancer chemotherapy within 1 month, approve the requested quantity, not to exceed 6 capsules per dispensing at retail and 18 capsules per dispensing at home delivery.

Aprepitant 40 mg capsules (generic only)

No overrides recommended.

Aprepitant 80 mg capsules (Emend, generic)

1. If the patient is receiving aprepitant for the prevention of nausea and vomiting associated with multiple courses or multiple days of cancer chemotherapy within 1 month, approve the requested quantity, not to exceed 12 capsules per dispensing at retail and 36 capsules per dispensing at home delivery.

Aprepitant 125 mg capsules (generic only)

1. If the patient is receiving aprepitant for the prevention of nausea and vomiting associated with multiple courses or multiple days of cancer chemotherapy within 1 month, approve the requested quantity, not to exceed 6 capsules per dispensing at retail and 18 capsules per dispensing at home delivery.

Aprepitant Tri Pack (Emend TriPack, generic) [one 125 mg capsule and two 80 mg capsules]

1. If the patient is receiving aprepitant for the prevention of nausea and vomiting associated with multiple courses or multiple days of cancer chemotherapy within 1 month, approve the requested quantity, not to exceed 18 capsules (6 TriPacks) per dispensing at retail and 54 capsules (18 TriPacks) per dispensing at home delivery.

Emend 125 mg powder for oral suspension packets

1. If the patient is receiving aprepitant for the prevention of nausea and vomiting associated with multiple courses or multiple days of cancer chemotherapy within

1 month, approve the requested quantity, not to exceed 18 packets per dispensing at retail and 54 packets per dispensing at home delivery.

Varubi 90 mg tablets

1. If the patient is receiving Varubi for the prevention of nausea and vomiting associated with multiple courses of cancer chemotherapy within 1 month, approve the requested quantity, not to exceed 4 tablets (2 wallets) per dispensing at retail and 12 tablets (6 wallets) per dispensing at home delivery.

REFERENCES

1. Akynzeo® capsules [prescribing information]. Iselin, NJ: Helsinn; June 2021.
2. Emend® capsules and oral suspension [prescribing information]. Whitehouse Station, NJ: Merck; November 2019.
3. Varubi® tablets [prescribing information]. Deerfield, IL: TerSera; August 2020.
4. The NCCN Antiemesis Clinical Practice Guidelines in Oncology (version 1.2024 – December 13, 2023). © 2024 National Comprehensive Cancer Network, Inc. Available at: www.nccn.org. Accessed on August 6, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/14/2023
Annual Revision	No criteria changes.	09/03/2024

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