#### **Cigna National Preferred Formulary Coverage Policy**



# **Drug Quantity Management – Per Rx Antiemetics – Substance P/Neurokinin-1 Receptor Antagonists (Oral)**

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# Product Identifer(s)

Effective 1/1/23 to 2/27/23: 108301, 108623, 109118

Effective 2/28/23: 35676, 48435, 52739

#### 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. 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.

# **National Formulary Medical Necessity**

#### **Drugs Affected**

- Akynzeo<sup>®</sup> (netupitant/palonosetron capsules)
- Emend® (aprepitant capsules, powder for oral suspension generic for capsules only)
- Varubi<sup>®</sup> (rolapitant tablets)

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of the oral substance P-NK<sub>1</sub> 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	Home Delivery
		Maximum Quantity per Rx	Maximum Quantity per Rx
Akynzeo <sup>®</sup> (netupitant/palonosetron capsules)	300 mg/0.5 mg capsules  (one capsule in one blister)	1 capsule	3 capsules
Emend® (aprepitant capsules [generic] and powder oral suspension)	40 mg capsules	1 capsule	3 capsules
	80 mg capsules	2 capsules	6 capsules
	125 mg capsules (obsolete)	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	3 packets	9 packets
Varubi <sup>®</sup> (rolapitant tablets)	90 mg tablets (two tablets per 180 mg wallet)	2 tablets (1 wallet)	6 tablets (3 wallets)

#### Criteria

#### Cigna covers quantities as medically necessary when the following criteria are met:

#### Akynzeo 300 mg/0.5 mg capsules

1. If the individual 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 (Emend, generic)

No overrides recommended.

#### Aprepitant 80 mg capsules (Emend, generic)

1. If the individual 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 (Emend, generic)

1. If the individual 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 individual 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 TriPacks (18 tablets) per dispensing at retail and 18 TriPacks (48 tablets) per dispensing at home delivery.

#### Emend 125 mg powder for oral suspension packets

1. If the individual 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 48 packets per dispensing at home delivery.

#### Varubi 90 mg tablets

1. If the individual 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.

#### **Conditions Not Covered**

Any other exception is considered not medically necessary.

### **Background**

#### Overview

#### **Indications and Dosing**

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 (HEC).<sup>1</sup> Emend is indicated in combination with other antiemetics for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of HEC, including high-dose cisplatin, and for the prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC).<sup>2</sup> Varubi is indicated in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, HEC.3 Refer to Table 1 for the FDA-approved indications and dosing for the oral Substance P/Neurokinin-1 (NK<sub>1</sub>) receptor antagonists.

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:  • 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 <sup>®</sup> (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.		

NK<sub>1</sub> – 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.

The availability of the oral substance-P/NK<sub>1</sub> receptor antagonists is in the Drug Quantity Limits table below.

#### Guidelines

Antiemesis quidelines from the National Comprehensive Cancer Network (NCCN) [version 2.2022 – March 23. 2022] make recommendations regarding the use of the substance P/NK<sub>1</sub> receptor antagonists.<sup>1</sup> 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.

## References

- 1. Akynzeo® capsules [prescribing information]. Iselin, NJ: Helsinn; June 2021.
- 2. Emend® capsules [prescribing information]. Whitehouse Station, NJ: Merck; November 2019.
- 3. Varubi<sup>®</sup> tablets [prescribing information]. Deerfield, IL: TerSera; August 2020.
- 4. The NCCN Antiemesis Clinical Practice Guidelines in Oncology (version 2.2022 March 23, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: www.nccn.org. Accessed on August 4, 2022.

# **Revision History**

Type of Revision	Summary of Changes	Approval Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. <b>Akynzeo 300 mg/0.5 mg capsules</b> : Override for a patient who is receiving multiple courses of cancer chemotherapy within 1 month was updated to approve the requested quantity, not to exceed 6 capsules per dispensing at retail and 18 capsules per dispensing at home delivery. Previously, this override allowed for up to 8 capsules per dispensing at retail and 24 capsules per dispensing at home delivery. <b>Varubi 90 mg tablets</b> : Override for a patient who is receiving multiple courses of cancer chemotherapy within 1 month was updated to 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. Previously, this override allowed for up to 12 tablets (6 wallets) per dispensing at retail and 36 tablets (18 wallets) per dispensing at home delivery.	08/10/2022

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