

Reference number(s)

79-

# Post Limit Prior Authorization Antiemetic Neurokinin-1 (NK1) Antiemetic Agents – NK1 Receptor Antagonists

# **Products Referenced by this Document**

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
aprepitant (brand unavailable)	aprepitant	all
Cinvanti	aprepitant	all
Emend	aprepitant	all
Emend	fosaprepitant	injection
Focinvez	fosaprepitant	injection
Varubi	rolapitant	all

# **Indications**

FDA-approved Indications

Aprepitant capsules

**Prevention of Chemotherapy Induced Nausea and Vomiting (CINV)** 

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Aprepitant capsules, in combination with other antiemetic agents, are indicated in patients 12 years of age and older for the prevention of:

- acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin.
- nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).

#### **Prevention of Postoperative Nausea and Vomiting (PONV)**

Aprepitant capsules are indicated in adults for the prevention of postoperative nausea and vomiting.

#### **Limitations of Use**

- Aprepitant has not been studied for the treatment of established nausea and vomiting.
- Chronic continuous administration of aprepitant is not recommended because it has not been studied, and because the drug interaction profile may change during chronic continuous use.

#### Cinvanti (aprepitant) injectable emulsion

Cinvanti, in combination with other antiemetic agents, is indicated in adults for the prevention of:

- acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin as a single dose regimen.
- delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) as a single dose regimen.
- nausea and vomiting associated with initial and repeat courses of MEC as a 3-day regimen.

#### **Limitations of Use**

Cinvanti has not been studied for the treatment of established nausea and vomiting.

#### Emend (aprepitant) capsules and oral suspension

Emend for oral suspension, in combination with other antiemetic agents, is indicated in patients 6 months of age and older for the prevention of:

- acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin.
- nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).

Emend capsules, in combination with other antiemetic agents, is indicated in patients 12 years of age and older for the prevention of:

- acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin.
- nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).

#### **Limitations of Use**

Emend has not been studied for the treatment of established nausea and vomiting.

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• Chronic continuous administration of Emend is not recommended because it has not been studied, and because the drug interaction profile may change during chronic continuous use.

#### Emend (fosaprepitant) for injection

Emend for injection, in combination with other antiemetic agents, is indicated in adults and pediatric patients 6 months of age and older for the prevention of:

- acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin.
- delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).

#### Limitations of Use

• Emend has not been studied for the treatment of established nausea and vomiting.

#### Focinvez (fosaprepitant) injection

Focinvez, in combination with other antiemetic agents, is indicated in adults and pediatric patients 6 months of age and older for the prevention of:

- acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin.
- delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).

#### **Limitations of Use**

• Focinvez has not been studied for the treatment of established nausea and vomiting.

#### Varubi (rolapitant) tablets

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, highly emetogenic chemotherapy.

# **Coverage Criteria**

# Nausea and Vomiting Associated with Highly or Moderately Emetogenic Cancer Chemotherapy

Authorization may be granted when the requested drug is being prescribed for the prevention of nausea and vomiting associated with highly or moderately emetogenic cancer chemotherapy when ALL of the following criteria are met:

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- The request is NOT for Varubi (rolapitant).
- The requested drug will be used in combination with other antiemetic agents.

## Postoperative Nausea and Vomiting

Authorization may be granted for the requested drug when it is being prescribed for the prevention of postoperative nausea and vomiting when the following criteria is met:

• The request is for aprepitant capsules.

# **Quantity Limits Apply**

## **Post Limit Quantity**

The duration of 21 days is used for a 28-day fill period to allow time for refill processing.

These drugs are for short-term acute use; therefore, the intent is for prescriptions of the requested drug to be filled one month at a time; there should be no 3 month supplies filled.

Drug	4 Week Limit	12 Week Limit
Cinvanti (aprepitant) 130 mg Injection	4 vials (72 mL) / 21 days	Does Not Apply
(Single-Dose 130 mg / 18 mL Vial)		
Emend (aprepitant) 80 mg Capsule	16 capsules / 21 days	Does Not Apply
Emend (aprepitant) 125 mg Capsule	4 capsules / 21 days	Does Not Apply
Emend (aprepitant) 125 mg-80 mg Capsules	4 packs (12 capsules) / 21 days	Does Not Apply
(Tri-pack contains one 125 mg capsule and two 80 mg capsules)		
Emend (aprepitant) 125 mg Oral Suspension	12 vials / 21 days	Does Not Apply
(Single-Dose Kit contains 125 mg / 5 mL)		
Emend (fosaprepitant) 150 mg for Injection	12 vials / 21 days	Does Not Apply
(Single-Dose 150 mg Vial)		
Focinvez (fosaprepitant) 150 mg (3 mg / mL) Injection	12 vials / 21 days	Does Not Apply
(Single-Dose 150 mg / 50 mL Vial)		

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These drugs are for short-term acute use.

Drug	Limit
Aprepitant 40 mg Capsule	6 capsules / 6 months

# **Duration of Approval (DOA)**

• 79-J: DOA: 6 months

#### References

- 1. Aprepitant capsules [package insert]. Princeton, NJ: Sandoz Inc.; December 2020.
- 2. Cinvanti [package insert]. San Diego, CA: Heron Therapeutics, Inc.; March 2024.
- 3. Emend capsules and oral suspension [package insert]. Rahway, NJ: Merck Sharp & Dohme LLC; May 2022.
- 4. Emend for injection [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp., a subsidiary of Merck and Co., Inc.; May 2022.
- 5. Focinvez [package insert]. North Brunswick, NJ: Spes Pharmaceuticals Inc.; August 2023.
- 6. Varubi [package insert]. Deerfield, IL: TerSera Therapeutics LLC; August 2020.
- 7. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed December 11, 2024.
- 8. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 12/11/2024).
- 9. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Antiemesis. Version 2.2024. Available at: https://www.nccn.org/professionals/physician\_gls/pdf/antiemesis.pdf. Accessed November 29, 2024.
- 10. American Cancer Society. How is Chemotherapy Used to Treat Cancer? https://www.cancer.org/treatment/treatments-and-side-effects/treatmenttypes/chemotherapy/how-is-chemotherapy-used-to-treat-cancer.html. November 2019. Accessed November 29, 2024.