

Fosaprepitant: Emend®; Focinvez™; Fosaprepitant; Navitrux™ (Intravenous)

Document Number: IC-0036

Last Review Date: 08/04/2026

Date of Origin: 12/01/2011

Dates Reviewed: 03/2012, 06/2012, 09/2012, 12/2012, 03/2013, 06/2013, 09/2013, 12/2013, 03/2014, 06/2014, 09/2014, 12/2014, 03/2015, 05/2015, 08/2015, 11/2015, 02/2016, 05/2016, 08/2016, 11/2016, 02/2017, 05/2017, 08/2017, 11/2017, 02/2018, 05/2018, 04/2019, 04/2020, 04/2021, 04/2022, 06/2022, 04/2023, 09/2023, 04/2024, 04/2025, 04/2026, 08/2026

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

Emend, Focinvez, & Fosaprepitant

- 1800 billable units per 28 days

Navitrux

- 1800 mg per 28 days

III. Initial Approval Criteria ^{1-3,8}

Prior authorization validity is provided in the following conditions:

- Member is at least 6 months of age; **AND**

Universal Criteria ¹⁻⁷

- Member is not taking pimozide concurrently; **AND**

Prevention of Chemotherapy-Induced Nausea and Vomiting (CINV) † ‡ ¹⁻⁸

- Member is receiving highly emetogenic anticancer chemotherapy (HEC)*; **AND**
 - Used in combination with a serotonin (5-HT₃) receptor antagonist (e.g., ondansetron, granisetron, palonosetron, etc.); **AND**
 - Used in combination with a corticosteroid such as dexamethasone (*Note: Only applicable to adult members*); **AND**
 - Used with or without olanzapine; **OR**
- Member is receiving moderately emetogenic anticancer chemotherapy (MEC)**; **AND**

- Used in combination with a 5-HT₃ receptor antagonist (e.g., ondansetron, granisetron, palonosetron, etc.); **AND**
 - Used in combination with a corticosteroid such as dexamethasone (*Note: Only applicable to adult members*); **OR**
- Used in combination with olanzapine, 5-HT₃ receptor antagonist, and dexamethasone as a component of a 4-drug regimen if not previously given; **AND**
 - Member has additional risk factors for anticancer agent-induced nausea/vomiting **¥**; **OR**
- Member experienced emesis during a previous cycle of anticancer chemotherapy with a 3-drug regimen (olanzapine or neurokinin-1 receptor antagonist (NK-1 RA)-containing regimen); **AND**
 - Used in combination with olanzapine, 5-HT₃ receptor antagonist, and dexamethasone as a component of a 4-drug regimen if not previously given

***Highly emetogenic chemotherapy (HEC):**

Highly Emetogenic Chemotherapy (HEC) ⁵			
Carboplatin	Carmustine	Cisplatin	Cyclophosphamide
Dacarbazine	Datopotamab deruxtecan-dlnk	Doxorubicin	Epirubicin
Fam-trastuzumab deruxtecan-nxki	Ifosfamide	Mechlorethamine	Melphalan ≥140 mg/m ²
Sacituzumab govitecan- hziy	Streptozocin	Zolbetuximab-clzb	
The following can be considered HEC in certain members ⁵			
Dactinomycin	Daunorubicin	Idarubicin	Irinotecan
Oxaliplatin	Trabectedin		
The following regimens can be considered HEC ⁵			
FOLFOX	FOLFIRI	FOLFIRINOX; FOLFOXIRI	AC (any anthracycline + cyclophosphamide)

****Moderately emetogenic chemotherapy (MEC):**

Moderately Emetogenic Chemotherapy (MEC) ⁵			
Aldesleukin >12–15 million IU/m ²	Amifostine >300 mg/m ²	Bendamustine	Busulfan
Clofarabine	Cytarabine >200 mg/m ²	Dinutuximab	Dual-drug liposomal encapsulation of cytarabine and daunorubicin

Irinotecan (liposomal)	Lurbinectedin	Melphalan <140 mg/m ²	Methotrexate > 250mg/m ²
Mirvetuximab soravtansine-gynx	Naxitamab-gqgk	Romidepsin	Temozolomide

¶ Member risk factors for anticancer agent-induced nausea/vomiting ⁵

- Younger age
- Female sex
- Previous history of anticancer agent-induced nausea and vomiting (chemotherapy-induced nausea and vomiting [CINV])
- Little or no previous alcohol use
- Prone to motion sickness
- History of morning sickness during pregnancy
- Anxiety/high pretreatment expectation of nausea
- Partial or complete bowel obstruction
- Vestibular dysfunction
- Brain metastases
- Electrolyte imbalance: hypercalcemia, hyperglycemia, or hyponatremia
- Uremia
- Concomitant drug treatments, including opioids
- Gastroparesis: tumor or chemotherapy (e.g., vincristine) induced or other causes (e.g., diabetes)
- Excessive secretions (e.g., seen in members with head and neck cancers)
- Malignant ascites
- Psychophysiologic: Anxiety or anticipatory nausea/vomiting
- Cannabinoid hyperemesis syndrome
- Rapid opioid withdrawal
- Pancreatitis
- Dysmotility
- Concomitant radiation therapy(RT)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ^{1-5,8}

Prior authorization validity can be renewed based upon the following criteria:

- Member continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Beneficial response as evidenced by reduction in nausea and vomiting; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity reactions (including anaphylaxis), severe infusion site reactions, etc.

V. Dosage/Administration ^{1-3,8}

Indication	Dose		
Prevention of Chemotherapy-Induced Nausea and Vomiting (CINV)	<u>Adult dosing:</u>		
	Administer 150 mg intravenously (IV) over 20 to 30 minutes on Day 1		
	<u>Pediatric dosing:</u>		
	Age	Single-Day Chemotherapy Regimen	Single or Multi-Day Chemotherapy Regimens (oral formulations may be given as an alternative on Days 2-3)
	12 to 17 years	150 mg IV on Day 1	115 mg IV on Day 1, then 80 mg IV/PO on Days 2-3
	2 to < 12 years	4 mg/kg (maximum dose 150 mg) IV on Day 1	3 mg/kg (maximum dose 115 mg) on Day 1, then 2 mg/kg (maximum dose 80 mg) IV/PO on Days 2-3
6 months to < 2 years (member ≥ 6 kg)	5 mg/kg (maximum dose 150 mg) IV on Day 1		
*Infusion should be completed 30 minutes prior to chemotherapy.			

VI. Billing Code/Availability Information

HCPCS Code(s):

- J1453 – Injection, fosaprepitant, 1 mg; 1 billable unit = 1 mg (*Emend Only*)
- J1456 – Injection, fosaprepitant (teva), not therapeutically equivalent to J1453, 1 mg; 1 billable unit = 1 mg **Ψ**
- J1434 – Injection, fosaprepitant (focinvez), 1 mg; 1 billable unit = 1 mg (*Focinvez Only*) **Ψ**
- J3490 – Unclassified drugs **§**
- C9399 – Unclassified drugs or biologicals (*Hospital Outpatient Use Only*) **§**

NDC(s):

- Emend* 150 mg powder for injection, single-dose vial: 00006-3061-xx
- Fosaprepitant 150 mg powder for injection, single-dose vial: 00591-4385-xx **Ψ**
- Focinvez 150 mg/50 mL (3 mg/mL) ready-to-use injection solution in a single-dose vial: 82449-0231-xx, 70121-2631-xx **Ψ**
- Navitrox 150 mg powder for injection, single-dose vial: 83831-0153-xx **Ψ**

– * Available as a multi-sourced generic.

- **Ψ** Designated products approved by the FDA as a 505(b)(2) NDA of the innovator product. These products may be available from several different manufacturers. For a complete list of all available products and NDCs please reference the FDA website at [National Drug Code Directory](#) for Fosaprepitant. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug Administration's (FDA) Orange Book and are therefore considered single source products based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Act. For a complete list of all approved 505(b)(2) NDA products please reference the latest edition of the Orange Book: [Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book | FDA](#)
- **§** Applies to Navitrox and any other intravenously administered Fosaprepitant products that have received NDA approval by FDA and have not been assigned a classified HCPCS Code.

VII. References

1. Emend [package insert]. Whitehouse Station, NJ; Merck & Co., Inc.; May 2022. Accessed March 2026.
2. Fosaprepitant [package insert]. Parsippany, NJ; Teva Pharmaceuticals; June 2022. Accessed March 2026.
3. Focinvez [package insert]. Karnataka, India; Steriscience Pte. Limited; December 2024. Accessed March 2026.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Fosaprepitant. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. March 2026.
5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Antiemesis. Version 2.2025. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2026.
6. Roila F, Molassiotis A, Herrstedt J, et al. MASCC and ESMO Consensus Guidelines for the Prevention of Chemotherapy and Radiotherapy-Induced Nausea and Vomiting: ESMO Clinical Practice Guidelines. *Ann Oncol* (2016) 27 (suppl 5): v119-v133.
7. Hesketh PJ, Kris MG, Basch E, et al. Antiemetics: American Society of Clinical Oncology Guideline Update. *J Clin Oncol*. 2020 Aug 20;38(24):2782-2797. doi: 10.1200/JCO.20.01296.
8. Navitrox [package insert]. New Jersey, USA; Avyxa Pharma, LLC; June 2026. Accessed July 2026.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
R11.0	Nausea
R11.10	Vomiting, unspecified
R11.11	Vomiting without nausea
R11.12	Projectile vomiting
R11.2	Nausea with vomiting, unspecified
T45.1X5A	Adverse effect of antineoplastic and immunosuppressive drugs, initial encounter
T45.1X5D	Adverse effect of antineoplastic and immunosuppressive drugs, subsequent encounter
T45.1X5S	Adverse effect of antineoplastic and immunosuppressive drugs, sequela
T45.95XA	Adverse effect of unspecified primarily systemic and hematological agent, initial encounter
T45.95XD	Adverse effect of unspecified primarily systemic and hematological agent, subsequent encounter
T45.95XS	Adverse effect of unspecified primarily systemic and hematological agent, sequela
T50.905A	Adverse effect of unspecified drugs, medicaments and biological substances, initial encounter
T50.905D	Adverse effect of unspecified drugs, medicaments and biological substances, subsequent encounter
T50.905S	Adverse effect of unspecified drugs, medicaments and biological substances, sequela
Z51.11	Encounter for antineoplastic chemotherapy

ICD-10	ICD-10 Description
Z51.12	Encounter for antineoplastic immunotherapy

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC