Fosaprepitant:
Emend®; Fosaprepitant Ψ; Focinvez Ψ
(Intravenous)

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I. Length of Authorization

Coverage is provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- 150 mg single-dose vial: 3 vials per 7 days

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

- 450 billable units (450 mg) per 7 days

III. Initial Approval Criteria [1-3]

Coverage is provided in the following conditions:

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

Universal Criteria [1-7]

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

Prevention of Chemotherapy-Induced Nausea and Vomiting (CINV) † ‡ [1-5]

- Patient is receiving highly and/or moderately emetogenic anticancer chemotherapy (HEC*/MEC**); **AND**
  - Used in combination with a 5-HT_3 antagonist (e.g., ondansetron, granisetron, palonosetron, etc.); **AND**
  - Used in combination with a corticosteroid such as dexamethasone *(Note: Only applicable to adult patients);* **AND**
  - Used with or without olanzapine (*applies to HEC only*); **OR**

- Patient experienced emesis during a previous cycle of anticancer chemotherapy with a 3-drug regimen (olanzapine or NK-1 receptor antagonist-containing regimen); **AND**
    - Used in combination with olanzapine, 5HT3 antagonist and dexamethasone as a component of a 4-drug regimen if not previously given

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

Highly Emetogenic Chemotherapy (HEC) [3]			
Carboplatin	Carmustine	Cisplatin	Cyclophosphamide
Dacarbazine	Doxorubicin	Epirubicin	Fam-trastuzumab deruxtecan-nxki
Ifosfamide	Mechlorethamine	Melphalan ≥140 mg/m²	Sacituzumab govitecan-hziy
Streptozocin			
The following can be considered HEC in certain patients [3]			
Dactinomycin	Daunorubicin	Idarubicin	Irinotecan
Methotrexate ≥250mg/m²	Oxaliplatin	Trabectedin	
The following regimens can be considered HEC [3]			
FOLFOX	FOLFIRI	FOLFIRINOX; FOLFOXIRI	AC (any anthracycline + cyclophosphamide)

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

Moderately Emetogenic Chemotherapy (HEC) [3]			
Aldesleukin >12–15 million IU/m²	Amifostine >300 mg/m²	Bendamustine	Busulfan
Clofarabine	Cytarabine >200 mg/m²	Dinutuximab	Dual-drug liposomal encapsulation of cytarabine and daunorubicin
Irinotecan (liposomal)	Lurbinectedin	Melphalan <140 mg/m²	Mirvetuximab soravtansine-gynx
Naxitamab-gqgk	Romidepsin	Temozolomide	

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

IV. Renewal Criteria [1-5]

Coverage can be renewed based upon the following criteria:

- Patient 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]

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

VI. Billing Code/Availability Information

HCPCS Code:

- 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**
- J3490 – Unclassified drugs *(Focinvez Only)* **Ψ** *(Discontinue use on 04/01/2024)*
- J1434 – Injection, fosaprepitant (focinvez), 1 mg; 1 billable unit = 1 mg *(Focinvez Only)* **Ψ** *(Effective 04/01/2024)*

NDC:

- 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: 82243-1001-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 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

VII. References

1. Emend [package insert]. Whitehouse Station, NJ; Merck & Co., Inc.; May 2022. Accessed March 2024.
2. Fosaprepitant [package insert]. North Wales, PA; Teva Pharmaceuticals USA, Inc.; October 2023. Accessed March 2024.
3. Focinvez [package insert]. North Brunswick, NJ; Spes Pharm., Inc.; August 2023. Accessed March 2024.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Fosaprepitant. National Comprehensive Cancer Network, 2024. 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 2024.
5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Antiemesis. Version 1.2024. National Comprehensive Cancer Network, 2024. 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 2024.
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.

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
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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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