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) †

- Patient is receiving highly and/or moderately emetogenic chemotherapy (see HEC/MEC list below); **AND**
- Must be used in combination with a 5-HT_3 antagonist such as ondansetron, granisetron, palonosetron, etc.; **AND**
- Must be used in combination with a corticosteroid such as dexamethasone *(Note: Only applicable to adult patients)*

Highly Emetogenic Chemotherapy (HEC)			
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			
Dactinomycin	Daunorubicin	Idarubicin	Irinotecan
Methotrexate ≥250mg/m²	Oxaliplatin	Trabectedin	
Moderately Emetogenic Chemotherapy (MEC)			
Aldesleukin >12-15 million IU/m²	Amifostine >300mg/m²	Bendamustine	Busulfan
Clofarabine	Cytarabine >200mg/m²	Dinutuximab	Dual-drug liposomal encapsulation of cytarabine and daunorubicin
Irinotecan Liposomal	Lurbinectedin	Melphalan <140 mg/m²	Naxitamab-gqgk
Romidepsin	Temozolomide		
The following regimens can be considered HEC			
FOLFOX	FOLFIRI	FOLFIRINOX; FOLFOXIRI	AC (any anthracycline + cyclophosphamide)

† 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 universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity reactions, 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

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 2023.

2. Fosaprepitant [package insert]. North Wales, PA; Teva Pharmaceuticals USA, Inc.; September 2019. Accessed March 2023.
3. Focinvez [package insert]. North Brunswick, NJ; Spes Pharm., Inc.; August 2023. Accessed August 2023.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Fosaprepitant. National Comprehensive Cancer Network, 2023. 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 2023.
5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Antiemesis. Version 1.2023. National Comprehensive Cancer Network, 2023. 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 2023.
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

ICD-10	ICD-10 Description
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)

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 Determination (NCD), Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered 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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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

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PCHP:
Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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PreferredOne Insurance Company
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Minneapolis, MN 55459-0212
Phone: 1.800.940.5049 (TTY: 763.847.4013)
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customerservice@preferredone.com

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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