

Emend® (fosaprepitant dimeglumine) (Intravenous)

Document Number: IC-0036

Last Review Date: 04/01/2020

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

I. Length of Authorization

Coverage is provided for six months and may be renewed.

II. Dosing Limits

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

- Emend 150 mg powder for injection: 1 vial per 7 days

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

- 150 billable units per 7 days

III. Initial Approval Criteria^{1,2,3,4,5}

Coverage is provided in the following conditions:

- Patient aged 6 months or older; **AND**

Universal Criteria

Patient is not taking pimozone 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-HT₃ antagonist such as ondansetron, granisetron, palonosetron, etc.; **AND**
- Must be used in combination with a corticosteroid such as dexamethasone

Highly Emetogenic Chemotherapy (HEC)			
Carboplatin	Carmustine	Cisplatin	Cyclophosphamide
Dacarbazine	Doxorubicin	Epirubicin	Ifosfamide
Mechlorethamine	Streptozocin		

Moderately Emetogenic Chemotherapy (MEC)			
Aldesleukin	Amifostine	Enfortumab vedotin	Azacitidine
Bendamustine	Busulfan	Clofarabine	Cytarabine
Dactinomycin	Daunorubicin	Dinutuximab	Idarubicin
Interferon alfa	Irinotecan	Melphalan	Methotrexate
Oxaliplatin	Temozolomide	Trabectedin	Daunorubicin Liposomal; Cytarabine Liposomal
Fam-trastuzumab deruxtecan			
The following regimens can be considered HEC:			
FOLFOX	FOLFIRI	FOLFIRINOX; FOLFOXIRI	AC (any anthracycline + cyclophosphamide)

† FDA-approved indication(s)

IV. Renewal Criteria^{1,2,3}

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; **AND**
- Disease response; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe hypersensitivity reactions, severe infusion site reactions, , etc.

V. Dosage/Administration

Indication	Dose											
Prevention of chemotherapy-induced nausea and vomiting	<u>Adult dosing:</u>											
	<ul style="list-style-type: none"> • 150 mg intravenously (IV) over 20 to 30 minutes Day 1 											
	<u>Pediatric dosing:</u>											
	<table border="1"> <thead> <tr> <th>Age</th> <th>Single-Day Chemotherapy Regimen</th> <th>Multi-Day Chemotherapy Regimen (oral given day 2-3)</th> </tr> </thead> <tbody> <tr> <td>12 to 17 years</td> <td>150 mg IV Day 1</td> <td>115 mg IV Day 1</td> </tr> <tr> <td>2 to < 12 years</td> <td>4 mg/kg (maximum dose 150 mg) IV Day 1</td> <td rowspan="2">3 mg/kg (maximum dose 115 mg) Day 1</td> </tr> <tr> <td>6 months to <2 years (Patient ≥ 6 kg)</td> <td>5 mg/kg (maximum dose 150 mg) IV Day 1</td> </tr> </tbody> </table>	Age	Single-Day Chemotherapy Regimen	Multi-Day Chemotherapy Regimen (oral given day 2-3)	12 to 17 years	150 mg IV Day 1	115 mg IV Day 1	2 to < 12 years	4 mg/kg (maximum dose 150 mg) IV Day 1	3 mg/kg (maximum dose 115 mg) Day 1	6 months to <2 years (Patient ≥ 6 kg)	5 mg/kg (maximum dose 150 mg) IV Day 1
	Age	Single-Day Chemotherapy Regimen	Multi-Day Chemotherapy Regimen (oral given day 2-3)									
12 to 17 years	150 mg IV Day 1	115 mg IV Day 1										
2 to < 12 years	4 mg/kg (maximum dose 150 mg) IV Day 1	3 mg/kg (maximum dose 115 mg) Day 1										
6 months to <2 years (Patient ≥ 6 kg)	5 mg/kg (maximum dose 150 mg) IV Day 1											
*Infusion should be completed 30 minutes prior to chemotherapy (single dose regimen)												

VI. Billing Code/Availability Information

HCPCS code:

J1453 –Injection, fosaprepitant, 1 mg; 1 billable unit = 1 mg

NDC:

- Emend 150 mg powder for injection, single-dose vial: 00006-3061-xx *
**Available generically from multiple manufacturers*

VII. References

1. Emend [package insert]. Whitehouse Station, NJ; Merck & Co., Inc.; November 2019. Accessed February 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Fosaprepitant. National Comprehensive Cancer Network, 2020. 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. February 2020.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Antiemesis. Version 1.2020. National Comprehensive Cancer Network, 2020. 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 February 2020.
4. 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.
5. Hesketh PJ, Kris MG, Basch E, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clin Oncol. 2017 Oct 1;35(28):3240-3261.

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
T45.1X5S	Adverse effect of antineoplastic and immunosuppressive drugs, sequela
T45.95XA	Adverse effect of unspecified primarily systemic and hematological agent, initial encounter

ICD-10	ICD-10 Description
T50.905A	Adverse effect of unspecified drugs, medicaments and biological substances, initial encounter
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: <http://www.cms.gov/medicare-coverage-database/search/advanced-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