

<p>Policy Name</p> <p>Oral antiemetic drugs: Aprepitant</p>	<p>Policy Number</p> <p>MP-RX-FP-07-23</p>	<p>Scope</p> <p><input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM Multihealth</p>								
<p>Service Category</p> <table border="0"> <tr> <td><input type="checkbox"/> Anesthesia</td> <td><input type="checkbox"/> Medicine Services and Procedures</td> </tr> <tr> <td><input type="checkbox"/> Surgery</td> <td><input type="checkbox"/> Evaluation and Management Services</td> </tr> <tr> <td><input type="checkbox"/> Radiology Procedures</td> <td><input type="checkbox"/> DME/Prosthetics or Supplies</td> </tr> <tr> <td><input type="checkbox"/> Pathology and Laboratory Procedures</td> <td><input checked="" type="checkbox"/> Part B Drugs</td> </tr> </table>			<input type="checkbox"/> Anesthesia	<input type="checkbox"/> Medicine Services and Procedures	<input type="checkbox"/> Surgery	<input type="checkbox"/> Evaluation and Management Services	<input type="checkbox"/> Radiology Procedures	<input type="checkbox"/> DME/Prosthetics or Supplies	<input type="checkbox"/> Pathology and Laboratory Procedures	<input checked="" type="checkbox"/> Part B Drugs
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<p>Service Description</p> <p>This document addresses the use of Antiemetics, a drug approved by the Food and Drug Administration (FDA) for the treatment of Postoperative nausea and vomiting; Prophylaxis and Chemotherapy-induced nausea and vomiting, Due to highly emetogenic chemotherapy, including high-dose cisplatin; Prophylaxis</p> <p>Background:</p> <p>Few side effects of cancer treatment are more feared by patients than nausea and vomiting. Although nausea and emesis (vomiting and/or retching) can result from surgery or radiation therapy, chemotherapy-induced nausea and vomiting (CINV) is potentially the most severe and most distressing. Significant progress has been made, but CINV remains an important adverse effect of treatment.</p> <p>Three distinct types of CINV have been defined, with important implications for both prevention and management:</p> <ul style="list-style-type: none"> • Acute emesis, which most commonly begins within one to two hours of chemotherapy and usually peaks in four to six hours • Delayed emesis, occurring more than 24 hours after chemotherapy • Anticipatory emesis, occurring prior to treatment as a conditioned response in patients who have developed significant nausea and vomiting during previous cycles of chemotherapy <p>The objective of antiemetic therapy is the complete prevention of CINV, and this should be achievable in the majority of patients receiving chemotherapy, even with highly emetic agents.</p> <p>The most important factor determining the likelihood of acute or delayed emesis developing during chemotherapy is the intrinsic emetogenicity of the particular agent. Although other factors may be important, such as patient age, sex, and history of alcohol consumption, these factors are not currently used to select the antiemetic strategy.</p> <p>The management of CINV has been greatly facilitated by the development of classification schemes that reflect the likelihood of emesis developing following treatment with particular agents. A 1997 classification scheme gained broad acceptance and was utilized as the basis for treatment recommendations by guideline panels. A modification of this schema was proposed at the 2004 Perugia Antiemetic Consensus Guideline meeting and is still relevant, although many more chemotherapy agents are now available. Chemotherapy</p>										

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agents were divided into four categories based upon the risk of emesis in the absence of antiemetic prophylaxis:

- Highly emetic – >90 percent risk of emesis
- Moderately emetic – >30 to 90 percent risk of emesis
- Low emetogenicity – 10 to 30 percent risk of emesis
- Minimally emetic – <10 percent risk of emesis

This drug classification schema is utilized in both the updated antiemetic guidelines of the Multinational Association of Supportive Care in Cancer (MASCC)/European Society for Medical Oncology (ESMO) and the American Society of Clinical Oncology (ASCO).

For combination regimens, the emetic level is determined by identifying the most emetic agent in the combination and then assessing the relative contribution of the other agents.

Approved Indications

- Postoperative nausea and vomiting; Prophylaxis and Chemotherapy-induced nausea and vomiting
- Chemotherapy-induced nausea and vomiting, Due to highly emetogenic chemotherapy, including high-dose cisplatin; Prophylaxis

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J8501	APREPITANT, ORAL, 5 MG
J8540	DEXAMETHASONE, ORAL, 0.25 MG
J8655	NETUPITANT 300 MG AND PALONOSETRON 0.5 MG, ORAL
Q0162	ONDANSETRON 1 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN
Q0163	DIPHENHYDRAMINE HYDROCHLORIDE, 50 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-

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	EMETIC AT TIME OF CHEMOTHERAPY TREATMENT NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN	
Q0164	PROCHLORPERAZINE MALEATE, 5 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN	
Q0166	GRANISETRON HYDROCHLORIDE, 1 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 24 HOUR DOSAGE REGIMEN	
Q0169	PROMETHAZINE HYDROCHLORIDE, 12.5 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN	
Q0180	DOLASETRON MESYLATE, 100 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 24 HOUR DOSAGE REGIMEN	

Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Clinical Criteria:

B vs D Criteria: Drugs included in this PA are subject to B vs D evaluation.

EMEND

Contraindicated in concomitant use with pimizide.

EMEND for oral suspension is indicated:

- In combination with other antiemetic agents for pediatric patients 6 months to less than 12 years of age or patients unable to swallow capsules
- Recommended dose: check the package insert for the weight-based regimen for the pediatric population (up to a maximum of 125mg on day 1 and 80mg on days 2-3).

EMEND capsules is indicated:

- In combination with other antiemetic agents for adults and pediatric patients 12 years of age and older.
- Recommended dose: 125mg on day 1 and 80mg on days 2-3

****Covered by part B, according to regulation and LCD***:**

- 1) MD has to indicate that it is being used as a complete replacement for IV antiemetics as part of chemotherapy regimen (can be written on prescription and/or documented in MedHOK after interventions by phone or RFI fax response)
- 2) It is to be administered within 48 hours of cancer treatment
- 3) Combination of 3 oral antiemetic drugs: an FDA-approved oral NK-1 antagonist + oral 5HT3 antagonist (ondansetron, palonosetron, granisetron, dolasetron) + dexamethasone
- 4) One or more of the cancer chemotherapeutic agents listed BELOW

*****Covered for part D if NOT prescribed for: Dx not related to cancer OR will be administered after 48 hours of chemotherapy*****

LCD: The use of the oral anti-emetic 3-drug combination of an FDA approved oral NK-1 antagonist in combination with an oral 5HT3 antagonist and dexamethasone (J8540) is covered if, in addition to meeting the statutory coverage criteria specified in the related Policy Article, they are administered to beneficiaries who are receiving one or more of the following anti-cancer chemotherapeutic agents:

- Alemtuzumab
- Azacitidine
- Bendamustin
- Carboplatin
- Carmustine
- Cisplatin

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<ul style="list-style-type: none"> • Clofarabine • Cyclophosphamide • Cytarabine • Dacarbazine • Daunorubicin • Doxorubicin • Epirubicin • Idarubicin • Ifosfamide • Irinotecan • Lomustine • Mechlorethamine • Oxaliplatin • Streptozocin <p>If the NK-1 antagonist, 5HT3 antagonist and dexamethasone 3-drug combination meet the statutory coverage criteria but are not used with one of the preceding chemotherapeutic agents, they will be denied as not reasonable and necessary.</p> <p>Nationally Noncovered Indications:</p> <ul style="list-style-type: none"> •The evidence is adequate to conclude that aprepitant cannot function alone as a full replacement for intravenously administered antiemetic agents for patients who are receiving highly emetogenic chemotherapy and/or moderately emetogenic chemotherapy. Medicare does not cover under Part B for oral antiemetic drugs in antiemetic drug combination regimens that are administered in part, via an oral route and in part, via an intravenous route. Medicare does not cover under Part B aprepitant when it is used alone for anticancer chemotherapy related nausea and vomiting. 		

Medical Policy

Healthcare Services Department

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Reference Information			
<ol style="list-style-type: none"> Oral antiemetic drugs (replacement for intravenous antiemetics-L33827) CMS.gov Centers for Medicare & Medicaid Services. October 1, 2015. Accessed August 23, 2023. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33827&ver=45&keyword=antiemetics&keywordType=starts&areald=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP&contractOption=all&sortBy=relevance&bc=1. 			
Policy History			
Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023

Revised: 9/27/2023