Aprepitant for Chemotherapy-Induced Emesis (NCD 110.18)

<table>
<thead>
<tr>
<th>Policy Number</th>
<th>Approved By</th>
<th>Current Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>110.18</td>
<td>UnitedHealthcare Medicare Reimbursement Policy Committee</td>
<td>10/08/2014</td>
</tr>
</tbody>
</table>

IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY

This policy is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided. UnitedHealthcare reimbursement policies use Current Procedural Terminology (CPT®*), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT or other sources are for definitional purposes only and do not imply any right to reimbursement.

This reimbursement policy applies to all health care services billed on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450). Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design and other factors are considered in developing reimbursement policy. This information is intended to serve only as a general resource regarding UnitedHealthcare’s reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare enrollees. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to: legislative mandates, the physician or other provider contracts, and/or the enrollee’s benefit coverage documents. Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare due to programming or other constraints; however, UnitedHealthcare strives to minimize these variations.

UnitedHealthcare may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.

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Application

This reimbursement policy applies to services reported using the Health Insurance Claim Form CMS-1500 or its electronic equivalent or its successor form, and services reported using facility claim form CMS-1450 or its electronic equivalent or its successor form. This policy applies to all products, all network and non-network physicians, and other health care professionals.
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The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing UnitedHealthcare. It is not enough to link the procedure code to a correct, payable ICD-9-CM diagnosis code. The diagnosis must be present for the procedure to be paid. Compliance with the provisions in this policy is subject to monitoring by pre-payment review and/or post-payment data analysis and subsequent medical review. The effective date of changes/additions/deletions to this policy is the committee meeting date unless otherwise indicated. CPT codes and descriptions are copyright 2010 American Medical Association (or such other date of publication of CPT). All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS restrictions apply to Government use. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Current Dental Terminology (CDT), including procedure codes, nomenclature, descriptors, and other data contained therein, is copyright by the American Dental Association, 2002, 2004. All rights reserved. CDT is a registered trademark of the American Dental Association. Applicable FARS/DFARS apply.

Summary

Overview
Chemotherapy-induced nausea and vomiting (CINV) can range from mild to severe, with the most severe cases resulting in dehydration, malnutrition, metabolic imbalances, and potential withdrawal from future chemotherapy treatments. The incidence and severity of CINV are influenced by the specific chemotherapeutic agent(s) used; dosage, schedule and route of administration; and drug combinations. Patient specific risk factors such as gender, age, history of motion sickness, and prior exposure to chemotherapeutic agents can also have an effect on CINV incidence and severity. Progress has been made in reducing CINV, although it can still be hard to control symptoms that occur more than a day after chemotherapy, during repeat cycles of chemotherapy, and when chemotherapy is given on more than one day or in very high doses. No single antiemetic agent is completely effective in all patients. As noted above, many factors influence the incidence and severity of CINV, with the specific chemotherapeutic agent as the primary factor to consider when deciding which antiemetic to administer. Aprepitant (Emend®) is the first Food and Drug Administration-approved drug of its type. Aprepitant has been proposed to function in combination with other oral antiemetics for a specified population of Medicare patients receiving highly emetogenic chemotherapy and/or moderately emetogenic chemotherapy.

CMS is defining highly emetogenic chemotherapy and moderately emetogenic chemotherapy as those anticancer agents so designated in at least two of three guidelines published by the National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO), and European Society of Medical Oncology (ESMO)/Multinational Association of Supportive Care in Cancer (MASCC). The inclusive examples are: NCCN plus ASCO, NCCN plus ESMO/MASCC, or ASCO plus ESMO/MASCC.

Reimbursement Guidelines
Effective for services performed between April 4, 2005, and May 28, 2013, the Centers for Medicare & Medicaid Services makes the following determinations regarding the use of aprepitant in the treatment of reducing chemotherapy-induced emesis:

The evidence is adequate to conclude that the use of the oral antiemetic three-drug combination of oral aprepitant (Emend®), an oral 5HT3 antagonist, and oral dexamethasone is reasonable and necessary for a specified patient population. We have defined the patient population for which the use of the oral antiemetic three-drug combination of oral aprepitant (Emend®), an oral 5HT3 antagonist, and oral dexamethasone is reasonable and necessary as only those patients who are receiving one or more of the following anti-cancer chemotherapeutic agents:

- Carmustine
- Cisplatin
- Cyclophosphamide
- Dacarbazine
- Mechlorethamine
- Streptozocin
- Doxorubicin
- Epirubicin
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- Lomustine

Effective for services performed on or after May 29, 2013, the oral three-drug regimen of oral aprepitant, an oral 5HT3 antagonist and oral dexamethasone is reasonable and necessary for beneficiaries receiving, either singularly or in combination with other drugs the following anticancer chemotherapeutic agents:

- Alemtuzumab
- Azacitidine
- Bendamustine
- Carboplatin
- Carmustine
- Cisplatin
- Clofarabine
- Cyclophosphamide
- Cytarabine
- Daclizumab
- Daunorubicin
- Doxorubicin
- Epirubicin
- Idarubicin
- Ifosfamide
- Irinotecan
- Lomustine
- Mechlorethamine
- Oxaliplatin
- Streptozocin

The oral three drug regimen must be administered immediately before and within 48 hours after the administration of these chemotherapeutic agents.

**Nationally Noncovered Indications**

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.

**Other**

Medicare Administrative Contractors may determine coverage for other all-oral three-drug antiemesis regimens of aprepitant or any other FDA approved oral NK-1 antagonist in combination with an oral 5HT3 antagonist and oral dexamethasone with the chemotherapeutic agents listed above, or any other anticancer chemotherapeutic agents that are FDA approved and are defined as highly or moderately emetogenic.

**CPT/HCPCS Codes**

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J8501</td>
<td>Aprepitant, oral, 5 mg</td>
</tr>
<tr>
<td>J8540</td>
<td>Dexamethasone, oral, 0.25 mg</td>
</tr>
<tr>
<td>J8650</td>
<td>Nabilone, oral, 1 mg</td>
</tr>
<tr>
<td>Q0162</td>
<td>Ondansetron 1 mg, oral, FDA approved prescription antiemetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen</td>
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<tr>
<td>Q0166</td>
<td>Granisetron HCl, 1 mg, oral, FDA approved prescription antiemetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 24-hour dosage regimen</td>
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<tr>
<td>Q0180</td>
<td>Dolasetron mesylate, 100 mg, oral, FDA approved prescription antiemetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment,</td>
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- not to exceed a 24-hour dosage regimen

Q0181 Unspecified oral dosage form, FDA approved prescription antiemetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen

Modifiers

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<tr>
<th>Code</th>
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<tbody>
<tr>
<td>GA</td>
<td>Waiver of liability statement issued as required by payer policy, individual case</td>
</tr>
<tr>
<td>GZ</td>
<td>Item or service expected to be denied as not reasonable and necessary</td>
</tr>
<tr>
<td>KX</td>
<td>Requirements specified in the medical policy have been met</td>
</tr>
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References Included (but not limited to):

**CMS NCD**
NCD 110.18 Aprepitant for Chemotherapy-Induced Emesis

**CMS LCD(s)**
Numerous LCDs

**CMS Article(s)**
Numerous Articles

**CMS Benefit Policy Manual**
Chapter 15; § 50.5.4 Oral Anti-Nausea (Anti-Emetic) Drugs

**CMS Claims Processing Manual**
Chapter 17; § 80.2 Oral Anti-Emetic Drugs Used as Full Replacement for Intravenous Anti-Emetic Drugs as Part of a Cancer Chemotherapeutic Regimen, § 80.2.1 HCPCS Codes for Oral Anti-Emetic Drugs, § 80.2.4 Billing and Payment Instructions for Part A MACs

**CMS Transmittals**
Transmittal 590, Change Request 3831, Dated 06/24/2005 (Aprepitant for Chemotherapy-Induced Emesis)
Transmittal 2931, Change Request 8418, Dated 04/15/2014 (Aprepitant for Chemotherapy-Induced Emesis)

**UnitedHealthcare Medicare Advantage Coverage Summaries**
Chemotherapy, and Associated Drugs and Treatments

**MLN Matters**
Article MM8418, Aprepitant for Chemotherapy-Induced Emesis, Dated 05/29/2013

History

<table>
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<tr>
<th>Date</th>
<th>Revisions</th>
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<tbody>
<tr>
<td>10/08/2014</td>
<td>Annual Review; presented to MRPC for approval</td>
</tr>
<tr>
<td>06/25/2014</td>
<td>Administrative updates</td>
</tr>
<tr>
<td>04/07/2014</td>
<td>• NCD policy re-titled to “Oral Agents for Chemotherapy-Induced Emesis” from previous titled of “Aprepitant for Chemotherapy-Induced Emesis” effective May 29, 2013; see <a href="#">MLN8418</a> for additional instruction</td>
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<td>• Full re-review of policy scheduled for September 2014</td>
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<tr>
<td>09/25/2013</td>
<td>Re-review presented to MRPC for approval</td>
</tr>
<tr>
<td>09/12/2012</td>
<td>Administrative updates</td>
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<tr>
<td>09/12/2012</td>
<td>Re-review presented to MRPC for approval</td>
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<tr>
<td>11/17/2010</td>
<td>Re-review presented to MRPC for approval</td>
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