**Oral Antiemetics for IV Replacement** **Policy Number:** M-0034

Payment will not be made for any use of these drugs outside of the criteria without prior authorization. The member may not be billed unless the member explicitly agrees in writing to be responsible for the charges in accordance with the contract/provider manual. Prior authorization will only be given if the provider demonstrates the intended use meets Medicare coverage guidelines.

**Coverage Guidelines:**

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary").

Oral Antiemetic Drugs are covered under the Oral Antiemetic Drug benefit (Social Security Act §1861(s)(2)(T). In order for a beneficiary's oral antiemetic drugs to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

For an item to be covered by Medicare, a written signed and dated order must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as non-covered.

An oral antiemetic drug billed with a HCPCS code listed in the Local Coverage Determination is covered if all of the following criteria are met:

- The drug has been approved by the Food and Drug Administration (FDA) for use as an antiemetic; and
- The drug has been ordered by the treating physician as part of a cancer chemotherapy regimen; and

- The drug is used as a full therapeutic replacement for an intravenous antiemetic drug that would otherwise have been administered at the time of the chemotherapy treatment; and
- Oral anti-emetic drugs administered with a particular chemotherapy treatment must be initiated within two hours of the administration of the chemotherapeutic agent and may be continued for a period not to exceed 48 hours from that time.

If all of the criteria are not met, the oral antiemetic drug will be denied as non-covered. Criterion 3 is not met when the chemotherapy drug is an oral drug or when the chemotherapy drug is administered intravenously in the home setting because the type and dosage of chemotherapy drugs administered in these situations do not require intravenous antiemetic drugs.

Aprepitant (J8501) and dexamethasone (J8540) are covered only if, in addition to the general criteria listed above, they are administered as part of an oral antiemetic 3-drug regimen which includes a 5-HT3 antagonist [i.e., granisetron (Q0166), ondansetron (Q0162), or dolasetron (Q0180)]. If aprepitant and/or dexamethasone are not used as part of this 3-drug regimen, they will be denied as noncovered.

If all of the above criteria are met, the quantity of oral antiemetic drugs covered for each episode of chemotherapy cannot exceed the initial loading dose plus 48 hours of therapy. However, for the drugs granisetron (Q0166) and dolasetron (Q0180), the quantity of drugs covered for each episode of chemotherapy is limited to the initial loading dose plus 24 hours of therapy. Quantities of drugs in excess of these amounts are non-covered.

More than one oral antiemetic drug may be covered for concurrent use if more than one oral drug is needed to fully replace the intravenous drugs that would otherwise have been given.

The quantity of oral antiemetic drugs that is dispensed should be limited to a 30-day supply. Orders may be refillable.

**Coding Guidelines:**

The following instructions apply to claims billed using J codes. When claims are billed in NCPDP format using NDC numbers, different instructions may apply. Refer to the NCPDP Companion Document available through the CMS web site.

Codes J8501, J8540, J8650 and Q0162-Q0181 may be billed only when the oral antiemetic drug is used in the situations described in Non-Medical Necessity Coverage and Payment Rules section. The quantity of drugs billed using codes Q0162-Q0181 must not exceed the 24 or 48 hours of therapy specified above.

Code Q0181 is a miscellaneous code, which may be used only when all the requirements of the policy are met, but the drug administered does not have a specific code (J8501, J8540, J8650 and Q0162-Q0180).

Refer to the Oral Anticancer Drugs policy for information on coding antiemetic drugs used in conjunction with oral anticancer drugs.

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

**Limitations:**

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following indications and limitations of coverage and/or medical necessity.

The statutory coverage criteria for oral antiemetics drugs addressed in this policy are specified in the related Policy Article.

Aprepitant (J8501) and dexamethasone (J8540) are 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:

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

If aprepitant and dexamethasone 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.

**Coding Information:**

**CPT/HCPCS Code(s)**

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|---|---|
| J8501 | APREPITANT, ORAL, 5 MG |
| J8540 | DEXAMETHASONE, ORAL, 0.25 MG |
| J8650 | NABILONE, ORAL, 1 MG |
| 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-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 |
| Q0165 | PROCHLORPERAZINE MALEATE, 10 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI- |

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| | 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 |
| Q0167 | DRONABINOL, 2.5 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 |
| Q0168 | DRONABINOL, 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 |
| 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 |
| Q0170 | PROMETHAZINE HYDROCHLORIDE, 25 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 |
| Q0171 | CHLORPROMAZINE HYDROCHLORIDE, 10 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 |
| Q0172 | CHLORPROMAZINE HYDROCHLORIDE, 25 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 |
| Q0173 | TRIMETHOBENZAMIDE HYDROCHLORIDE, 250 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 |
| Q0174 | THIETHYLPERAZINE MALEATE, 10 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 |
| Q0175 | PERPHENAZINE, 4 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 |

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| Q0176 | PERPHENAZINE, 8MG, 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 |
| Q0177 | HYDROXYZINE PAMOATE, 25 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 |
| Q0178 | HYDROXYZINE PAMOATE, 50 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 |
| Q0181 | UNSPECIFIED ORAL DOSAGE FORM, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR A IV ANTI-EMETIC AT THE TIME OF CHEMOTHERAPY TREATMENT, NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN |
| Q0511 | PHARMACY SUPPLY FEE FOR ORAL ANTI-CANCER, ORAL ANTI-EMETIC OR IMMUNOSUPPRESSIVE DRUG(S); FOR THE FIRST PRESCRIPTION IN A 30-DAY PERIOD |
| Q0512 | PHARMACY SUPPLY FEE FOR ORAL ANTI-CANCER, ORAL ANTI-EMETIC OR IMMUNOSUPPRESSIVE DRUG(S); FOR A SUBSEQUENT PRESCRIPTION IN A 30-DAY PERIOD |

**ICD-9 Code(s):**

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|---|---|
| 140.0-209.36 | MALIGNANT NEOPLASM OF UPPER LIP VERMILION BORDER - MERKEL CELL CARCINOMA OF OTHER SITES |
| 209.70-209.79 | SECONDARY NEUROENDOCRINE TUMOR, UNSPECIFIED SITE - SECONDARY NEUROENDOCRINE TUMOR OF OTHER SITES |
| 230.0-239.9 | CARCINOMA IN SITU OF LIP ORAL CAVITY AND PHARYNX - NEOPLASM OF UNSPECIFIED NATURE SITE UNSPECIFIED |
| 273.3 | MACROGLOBULINEMIA |

| | |
|---|---|
| V58.11 | ENCOUNTER FOR ANTINEOPLASTIC CHEMOTHERAPY |

**Background:**

Cancer is the result of cells that rapidly over divide. Moreover, these cells can cause a simple benign tumor or they can result in a very serious life threatening disease. Anticancer drugs are designed to kill the rapidly proliferating cells and eliminate the disease. Oral anticancer medications allow the patient an alternative route of administration other than intravenous administration.

**Definitions:**

HCPCS Code—Healthcare Common Procedure Coding System - A system of letter and number codes assigned to procedures, medications, supplies and equipment used for pricing and billing.

ICD-9 Code—International Classification of Disease, 9th edition. A standardized classification of disease, injuries, and causes of death, by etiology and anatomic localization and codified into a 6-digit number, which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both US and internationally.

**References:**


1. Local Coverage Article for Oral antiemetic Drugs (Replacement for Intravenous Antiemetics) (A25511). Available at: http://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=25511&ver=45&ContrId=140&ContrVer=2&CntrctrSelected=140*2&Date=01%2f01%2f2012&DocID=A25511&bc=hAAAAAgAAAAA&. Accessed on 9/6/12.
2. Local Coverage Determination Oral Antiemetic Drugs (Replacement for Intravenous Antiemetics). (L11560). Available at : http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=11560&ContrId=140&ver=47&ContrVer=2&articleId=25511&CntrctrSelected=140*2&Date=01%2f01%2f2012&DocID=A25511&IsPopup=y&. Accessed on 9/6/12.
3. Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D Drugs and Formulary Requirements. Available at: http://vivawebserver.hs.uab.edu/employees/albums/userpics/10001/PDBMChap6_02.19.10.pdf. Accessed 11/14/12.

**Document History:**
Date Written: 09/6/2012
Effective Date: 1/1/13
Revised:
Reviewed: 11/17/12
External Review: 12/18/12