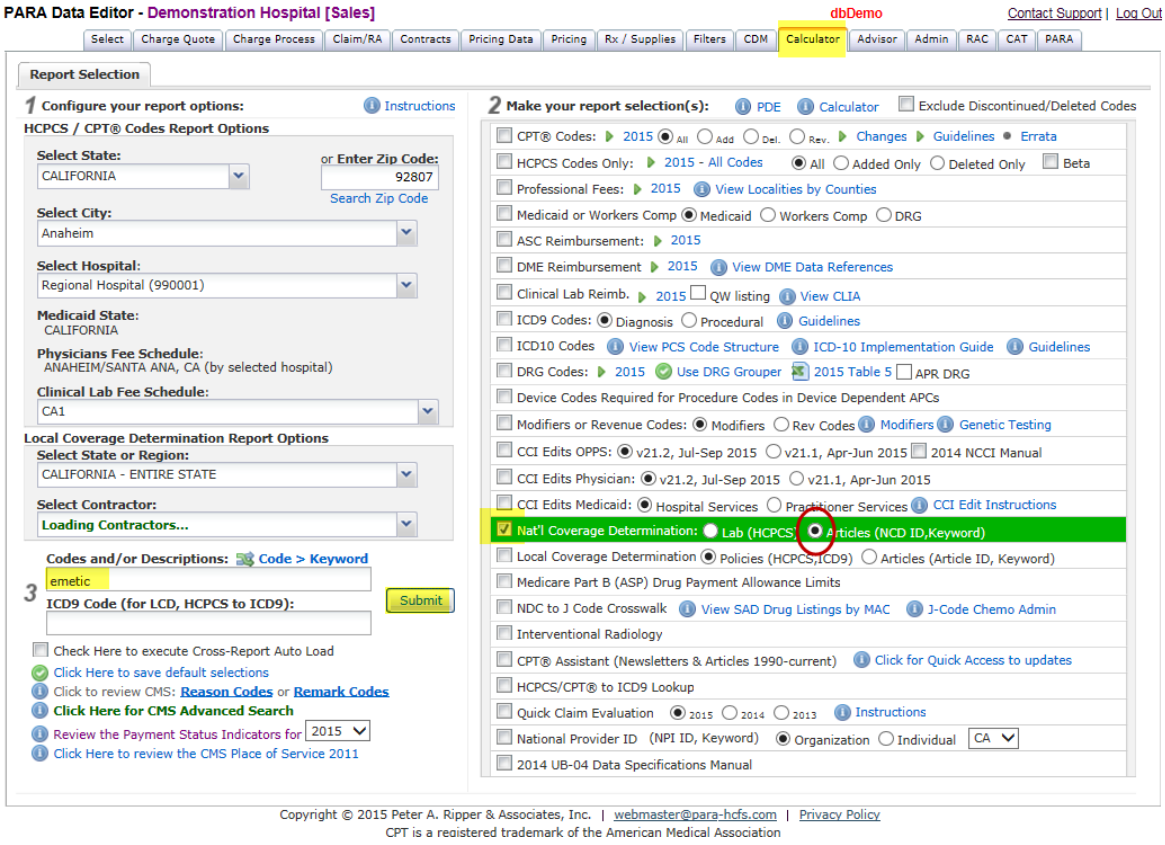
Medicare Coverage for Oral Anti-Emetic Drugs

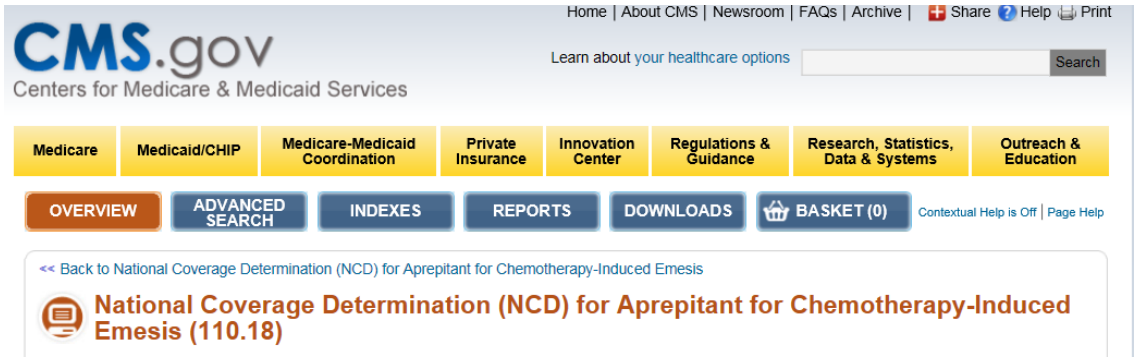
If special requirements are met, Medicare will cover certain oral anti-emetic drugs when provided to outpatient chemotherapy patients in the hospital setting. Medicare has published a National Coverage Determination for oral anti-emetics; it can be found on the **PARA Data Editor** Calculator tab by running the report as follows:



The report returned provides a hyperlink to the Medicare NCD:

Medicare Coverage for Oral Anti-Emetic Drugs

The National Coverage Determination is found upon executing the hyperlink returned on the **PARA Data Editor** report:



Description Information

Benefit Category
Oral Antiemetic Drugs

Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Item/Service Description

A. General

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 sex, 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 anti-emetic 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 anti-emetic 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 anti-emetics for a specified population of Medicare patients receiving highly emetogenic chemotherapy.

Indications and Limitations of Coverage

B. Nationally Covered Indications

Effective for services performed on or after April 4, 2005, 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 anti-emetic 3-drug combination of aprepitant (Emend®), a 5-HT3 antagonist, and dexamethasone is reasonable and necessary for a specified patient population. We have defined the patient population for which the use of the oral anti-emetic 3-drug combination of aprepitant (Emend®), a 5-HT3 antagonist, and 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
- Lomustine

C. Nationally Noncovered Indications

The evidence is adequate to conclude that aprepitant cannot function alone as a full replacement for intravenously administered anti-emetic agents for patients who are receiving highly emetogenic chemotherapy.

D. Other

N/A

Coverage does not necessarily convey additional reimbursement, although it affects patient liability which would otherwise be incurred for these oral medications if billed as non-covered self-administered drugs.

Most drugs furnished as an outpatient hospital service are packaged under OPPS. However, self-administered drugs are not covered and must be billed to the Medicare beneficiary as patient liability. In the case of anti-emetics which are reasonable and necessary supportive and adjunctive drugs used with chemotherapy, coverage may be available if the requirements are met and claims are submitted correctly.

Medicare's requirements for coverage of oral anti-emetic drugs are, in summary:

- The oral anti-emetics are used in lieu of IV anti-emetic therapy (per medical record); the use must be documented to reflect that the beneficiary is receiving the oral anti-emetic drug(s) as full therapeutic replacement for an intravenous anti-emetic drug as part of a cancer chemotherapeutic regimen.
- Claim diagnosis coding indicates that anti-emetics are part of a cancer chemotherapeutic regimen for antineoplastic chemotherapy (V58.11/Z51.11).
- The antineoplastic chemotherapy drug administered is among those listed in the Medicare Claims Processing Manual (a link and an excerpt are provided on the following pages.)
- The oral antiemetic treatment consists of a 3-drug combination of oral aprepitant, an oral 5HT3 antagonist and oral dexamethasone;
- When billed to the Part A MAC, all three drugs in the combination oral anti-emetic must be on the same claim. Covered HCPCS include J0185 for aprepitant and Q-codes representing the various forms of 5HT3 antagonist and dexamethasone. The Q-code HCPCS descriptions contain the phrase "… 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."

Medicare does not pay for an oral anti-emetic drug that is not administered for use immediately before, at, or within 48 hours after administration of a Medicare covered chemotherapy drug.

If the use of anti-emetics does not meet the criteria for coverage, these oral drugs should be billed under revenue code 0637 as non-covered Self-Administered Drugs.

In addition to the National Coverage Determination available on the **PARA Data Editor**, a link and the pertinent excerpt from the Medicare Claims Processing Manual is provided on the following pages.

Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals

http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf

Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals

80.2 - Oral Anti-Emetic Drugs Used as Full Replacement for Intravenous Anti-Emetic Drugs as Part of a Cancer Chemotherapeutic Regimen

(Rev. 2931, Issued: 04-15-14, Effective: 05-29-13, Implementation: 07-07-14)

See the Medicare Benefit Policy Manual, Chapter 15, and the National Coverage Determination (NCD) Manual, Section 110.18, for detailed coverage requirements.

Effective for dates of service on or after January 1, 1998, Medicare Part B (including (institutional claims processed by Part A Medicare Administrative Contractors (MACs) and physician/supplier claims processed by DME MACs) pays for oral anti-emetic drugs when used as full therapeutic replacement for intravenous dosage forms as part of a cancer chemotherapeutic regimen when the drug(s) is administered or prescribed by a physician for use immediately before, at, or within 48 hours after the time of administration of the chemotherapeutic agent.

The allowable period of covered therapy includes day 1, the date of service of the chemotherapy drug (beginning at the time of treatment), plus a period not to exceed 2 additional calendar days, or a maximum period up to 48 hours. Some drugs are limited to 24 hours; some to 48 hours. The hour limit is included in the narrative description of the Health Care Common Procedure Coding System (HCPCS) code.

The oral, 3-drug combination is aprepitant, a 5HT3 antagonist, e.g. granisetron, ondansetron, or dolasetron, and dexamethasone, a corticosteroid.

The oral anti-emetic drug(s) should be prescribed only on a per chemotherapy treatment basis. For example, only enough of the oral anti-emetic(s) for one 24- or 48-hour dosage regimen (depending upon the drug) should be prescribed/supplied for each incidence of chemotherapy treatment. The 3-drug combination protocol requires the first dose to be administered before, during, or immediately after the anti-cancer chemotherapy administration. The second day is defined as “within 24 hours” and the third day is defined as “within 48 hours” of the chemotherapy administration. These drugs may be supplied by the physician in the office, by an inpatient or outpatient provider (e.g., hospital, critical access hospital (CAH), skilled nursing facility (SNF), or through a supplier (e.g., a pharmacy).

The physician must indicate on the prescription that the beneficiary is receiving the oral anti-emetic drug(s) as a full therapeutic replacement for an intravenous anti-emetic drug as part of a cancer chemotherapeutic regimen. Where the drug is provided by a facility, the beneficiary’s medical record maintained by the facility must be documented to reflect that the beneficiary is receiving the oral anti-emetic drug(s) as full therapeutic replacement for an intravenous anti-

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emetic drug as part of a cancer chemotherapeutic regimen. All other indications or combinations for the use of oral aprepitant that are not noted in the NCD Manual Pub. 100-03 chapter 1, section 110.18, are non-covered under Medicare Part B, but may be considered for payment under Medicare Part D.

Payment for drugs used as a full replacement for intravenous anti-emetic drugs is made under Part B. Beginning January 1, 2005, the payment allowance limit for these Part B drugs (the term "drugs" includes biologicals) will be based on the Average Sales Price (ASP) plus 6%. Hospital outpatient department providers may either:

(1) Bill all doses of the 3-drug oral regimen that will be given in a 3-day period, including the entire Tri-Pak (3 days of aprepitant, 57 units of J8501) as well as the oral dexamethasone and oral 5HT3 antagonist to the Part A MAC, or

(2) Bill the first day's supply of aprepitant along with an oral 5HT3 antagonist and oral dexamethasone to their local Part A MAC, and give a prescription for remaining doses of the regimen, for example the second and third days' supply of aprepitant and oral dexamethasone, which must be billed to the durable medical equipment (DME) MAC.

When billed to the Part A MAC, all three drugs in the combination oral anti-emetic must be on the same claim. Providers subject to the hospital outpatient PPS will be paid on the basis of an APC. If the hospital outpatient department dispenses the aprepitant for days two and three to the beneficiary and bills the DME MAC for the take home drugs, the hospital's billing department should review all instructions for billing oral anti-emetics. Follow this link to reach the local coverage determination (LCD) for oral anti-emetics:

http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=5058&lcd_version=27&show=all

In the case of IV Emend (HCPCS code J1453 - injection, fosaprepitant, 1 mg) provided on day 1, payment for days 2 and 3 would not be made under Part B.

Payment allowances for these drugs dispensed in physician offices will be based on the lower of the submitted charge or the ASP file price. These drugs continue to be priced based on the date of service. The drug payment allowance limit pricing file is distributed to contractors by the Centers for Medicare & Medicaid Services (CMS) on a quarterly basis.

The HCPCS codes shown in section 80.2.1 are used.

The common working file (CWF) edits claims with these codes to assure that the beneficiary is receiving the oral anti-emetic(s) as part of a cancer chemotherapeutic regimen by requiring a diagnosis code of an encounter for antineoplastic chemotherapy (V58.11/Z51.11).

Most drugs furnished as an outpatient hospital service are packaged under OPPS. However, chemotherapeutic agents and the supportive and adjunctive drugs used with them are paid separately.

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Effective for dates of service on or after April 4, 2005, coverage for the use of the oral anti-emetic 3-drug combination of aprepitant (Emend®), a 5-HT3 antagonist, and dexamethasone is considered reasonable and necessary for only those patients who are receiving one or more of the following anti-cancer chemotherapeutic agents:

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

Effective for services on or after May 29, 2013, the following anti-cancer chemotherapeutic agents have been added to the list of anticancer chemotherapeutic agents for which the use of the oral antiemetic 3-drug combination of oral aprepitant, an oral 5HT3 antagonist and oral dexamethasone is deemed reasonable and necessary:

- Alemtuzumab
- Azacitidine
- Bendamustine
- Carboplatin
- Clofarabine
- Cytarabine
- Daunorubicin
- Idarubicin
- Ifosfamide
- Irinotecan
- Oxaliplatin

MACs may determine coverage for other all-oral 3-drug anti-emesis regimens of aprepitant or any other Food and Drug Administration (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 anti-cancer chemotherapeutic agents that are FD- approved and are defined as highly or moderately emetogenic. See the Medicare NCD Manual, Section 110.18, for detailed coverage requirements.

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80.2.1 - HCPCS Codes for Oral Anti-Emetic Drugs

(Rev. 3085, Issued: 10-03-14, Effective: ICD-10: Upon Implementation of ICD-10; ASC X12: January 1, 2012, Implementation: ICD-10: Upon Implementation of ICD-10; ASC X12: November 4, 2014)

The physician/supplier bills for these drugs with the ASC X12 837 professional claim format, or if approved, with the paper form CMS-1500. The facility bills with the ASC X12 837 institutional claim format, or if approved, with the paper Form CMS-1450. The following HCPCS codes are assigned:

Code	Description
J8501	APREPITANT, oral, 5 mg (Note: HCPCS code is effective January 1, 2005, but coverage for aprepitant is effective April 4, 2005. Aprepitant is only covered in combination with a 5HT3 antagonist, and dexamethasone for beneficiaries who have received one or more of the specified anti-cancer chemotherapeutic agents.)
Q0161	CHLORPROMAZINE HYDROCHLORIDE 5mg, 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.
Q0162	ONDANSETRON 1mg, 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, 50mg, 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, 5mg, 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, 10mg, 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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Code	Description
Q0166	GRANISETRON HYDROCHLORIDE, 1mg, 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	DRONABINOL2.5mg, 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	RONABINO 5mg, 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.

NOTE: The 24-hour maximum drug supply limitation on dispensing, for HCPCS Codes Q0166 and Q0180, has been established to bring the Medicare benefit as it applies to these two therapeutic entities in conformity with the "Indications and Usage" section of currently FDA-approved product labeling for each affected drug product.

…

80.2.3 - MSN Denial /Claim Adjustment and Remark Messages for Anti-Emetic Drugs

(Rev. 3085, Issued: 10-03-14, Effective: ICD-10: Upon Implementation of ICD-10; ASC X12: January 1, 2012, Implementation: ICD-10: Upon Implementation of ICD-10; ASC X12: November 4, 2014)

If the claim for an anti-emetic drug is denied because FDA did not approve it or because the drug is not being used as part of an anticancer chemotherapeutic regimen, the contractor uses one of the following appropriate messages on the MSN:

6.2 - Drugs not specifically classified as effective by the Food and Drug Administration are not covered. (Claim Adjustment Reason Code 114)

6.4 - Medicare does not pay for an oral anti-emetic drug that is not administered for use immediately before, at, or within 48 hours after administration of a Medicare covered chemotherapy drug. (Group Code PR 96 with Remittance Advice Remark Code M100)

80.2.4 - Billing and Payment Instructions for A/B MACs (A)

(Rev. 3085, Issued: 10-03-14, Effective: ICD-10: Upon Implementation of ICD-10; ASC X12: January 1, 2012, Implementation: ICD-10: Upon Implementation of ICD-10; ASC X12: November 4, 2014)

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Claims for the oral anti-emetic drug aprepitant, either as a 3-day supply dispensed in a Tri-Pak or as the first day supply (not dispensed in a Tri-Pak), must be billed to the A/B MAC (A) on the ASC 837 institutional claim format or on hard copy Form CMS-1450 with the appropriate cancer diagnosis and HCPCS code or Current Procedural Terminology (CPT) code.

Claims for the second and third dose of the oral anti-emetic drug aprepitant not dispensed in a Tri-Pak must be billed to the DME MAC.

The following payment methodologies apply when hospital and SNF outpatient claims are processed by the A/B MAC (A):

- Based on APC for hospitals subject to the outpatient prospective payment system (OPPS);
- Under current payment methodologies for hospitals not subject to OPPS; or
- On a reasonable cost basis for SNFs.

Institutional providers bill for aprepitant under Revenue Code 0636 (Drugs requiring detailed coding).

NOTE: Inpatient claims submitted for oral anti-emetic drugs are processed under the current payment methodologies.

Medicare contractors shall pay claims submitted for services provided by a CAH as follows: Method I technical services are paid at 101% of reasonable cost; Method II technical services are paid at 101% of reasonable cost, and, Professional services are paid at 115% of the Medicare Physician Fee Schedule Data Base.