

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



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MLN Matters® Number: MM8418 **Revised** Related Change Request (CR) #: CR 8418

Related CR Release Date: April 15, 2014 Effective Date: May 29, 2013

Related CR Transmittal #: R185BP, R2931CP, and R165NCD Implementation Date: July 7, 2014

Aprepitant for Chemotherapy-Induced Emesis

Note: This article was revised on April 16, 2014, to reflect the revised CR8418, issued on April 15. In the article, the CR release date, transmittal numbers, and the Web addresses for accessing the transmittals are revised. Also, we have deleted references to expired HCPCS codes. All other information remains the same.

Provider Types Affected

This MLN Matters® Article is intended for providers and suppliers submitting claims to Part A Medicare Administrative Contractors (A/MACs) and/or Durable Medical Equipment MACs (DME MACs) for services to Medicare beneficiaries.

Provider Action Needed

This article is based on Change Request (CR) 8418, which informs MACs that, effective for claims with dates of service on or after May 29, 2013, the Centers for Medicare & Medicaid Services (CMS) extends coverage of the oral antiemetic three-drug regimen of oral aprepitant, an oral 5HT3 antagonist, and oral dexamethasone to beneficiaries who are

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receiving certain anticancer chemotherapeutic agents. Make sure that your billing personnel are aware of these changes.

Background

Chemotherapy induced emesis is the occurrence of nausea and vomiting during or after anticancer treatment with chemotherapy agents. The Social Security Act (the Act) permits oral drugs to be paid under Part B in very limited circumstances, one of which is antiemetic therapy administered immediately before and within 48 hours after anticancer chemotherapy as described in section 1861(s)(2) of the Act. These drugs must fully replace the non-self-administered drug that would otherwise be covered.

On April 4, 2005, CMS announced a National Coverage Determination (NCD) for the use of the oral three-drug regimen of aprepitant, a 5HT3 antagonist, and dexamethasone for patients who are receiving certain highly emetogenic chemotherapeutic agents.

On May 29, 2013, CMS announced an update to that NCD, to cover the use of the oral antiemetic three-drug combination of oral aprepitant (J8501), an oral 5HT3 antagonist (Q0166, Q0179, Q0180), and oral dexamethasone (J8540) for patients receiving highly and moderately emetogenic chemotherapy. As a result, effective for services on or after May 29, 2013, the following anticancer 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 (J9010);
- Azacitidine (J9025);
- Bendamustine (J9033);
- Carboplatin (J9045);
- Clofarabine (J9027);
- Cytarabine (J9098, J9100);
- Daunorubicin (J9150, J9151);
- Idarubicin (J9211);
- Ifosfamide (J9208);
- Irinotecan (J9206); and
- Oxaliplatin (J9263).

Please note the entire list includes the 11 new codes listed above and the 9 existing anticancer chemotherapeutic agents listed below:

- Carmustine (J9050);
- Cisplatin (J9060);
- Cyclophosphamide (J8530, J9070);
- Dacarbazine (J9130);
- Mechlorethamine (J9230);

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- Streptozocin (J9320);
- Doxorubicin (J9000, Q2049);
- Epirubicin (J9178); and
- Lomustine (S0178).

CMS also permits the MACs to determine coverage for other all-oral three-drug antiemesis 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, or any other anticancer chemotherapeutic agents that are FDA-approved and may in the future be defined as highly or moderately emetogenic.

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.

Until a specific code is assigned to the new drug, any new FDA-approved oral antiemesis drug (oral NK-1 antagonist or oral 5HT3 antagonist) as part of the three-drug regimen must be billed with the following not-otherwise-classified (NOC) code effective April 1, 2014, in the IOCE update:

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

This NOC code must also be accompanied with a diagnosis code of an encounter for antineoplastic chemotherapy (ICD9/10 codes V58.11/Z51.11).

This coverage policy applies only to the oral forms of the three-drug regimen as a full replacement for their intravenous equivalents. All other indications or combinations for the use of oral aprepitant are non-covered under Medicare Part B, but may be considered under Medicare Part D.

For claims with dates of service on or after May 29, 2013, MACs will adjust claims processed before CR8418 was implemented if you bring those claims to the attention of your MAC.

Effective for claims with dates of service on or after May 29, 2013, MACS will deny lines for oral aprepitant (J8501), or NOC code Q0181 if an encounter for antineoplastic chemotherapy identified by ICD 9/10 codes V58.11/Z51.11 is not present. The denied lines will reflect the following messages on the remittance advice:

- Claim Adjustment Reason Code 96: Non-covered Charge(s)

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- Remittance Advice Remarks Code (RARC) M100: We do not pay for an oral anti-emetic drug that is not administered for use immediately before, at, or within 48 hours of administration of a covered chemotherapy; and
- RARC N386: This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Additional Information

The official instruction, CR8418, was issued to your MAC via three transmittals. The first updates the "Medicare Benefit Policy Manual" and that is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R185BP.pdf> on the CMS website. The second updates the " Medicare Claims Processing Manual" and is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2931CP.pdf> and the third updates the "Medicare National Coverage Determinations Manual" and it is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R165NCD.pdf> on the CMS website.

If you have any questions, please contact your MAC at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/> on the CMS website.

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