CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 185	**Date: April 15, 2014**
	Change Request 8418

Transmittal 180, dated February 21, 2014, is being rescinded and replaced by Transmittal 185, dated April 15, 2014, to provide a formatting change and provide correct reference for the NCD Manual. All other information remains the same.

SUBJECT: Aprepitant for Chemotherapy Induced Emesis

I. SUMMARY OF CHANGES: Effective for claims with dates of service May 29, 2013, and later, CMS extends coverage of the oral antiemetic three-drug regimen of oral aprepitant, an oral 5HT3 antagonist and oral dexamethasone to beneficiaries who are receiving one or more of the following anti-cancer chemotherapeutic agents.

This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries,contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

EFFECTIVE DATE: May 29, 2013
IMPLEMENTATION DATE: July 7, 2014

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	15/50.5.4/Oral Anti-Nausea (Anti-Emetic) Drugs

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction
**Unless otherwise specified, the effective date is the date of service.*

Business Requirements

Pub. 100-02	Transmittal: 185	Date: April 15, 2014	Change Request: 8418

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SUBJECT: Aprepitant for Chemotherapy Induced Emesis

EFFECTIVE DATE: May 29, 2013
IMPLEMENTATION DATE: July 7, 2014

I. GENERAL INFORMATION

A. Background: Chemotherapy induced emesis is the occurrence of nausea and vomiting (N&V) during or after anticancer treatment with chemotherapy agents. The Social Security 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 §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, the Centers for Medicare & Medicaid Services (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.

CMS recently received a formal written request to reconsider this NCD and to expand coverage for the use of aprepitant, a 5HT3 antagonist and dexamethasone in the patients receiving anticancer therapeutic agents currently considered moderately emetogenic.

On May 29, 2013 CMS announced an updated NCD, section 110.18, to cover the use of the oral antiemetic three-drug combination of oral aprepitant, an oral 5HT3 antagonist, and oral dexamethasone for patients receiving highly and moderately emetogenic chemotherapy.

B. Policy: 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

Please note the entire list includes the existing 9 anticancer chemotherapeutic agents that are listed below: Carmustine,Cisplatin,Cyclophosphamide,Dacarbazine,Mechlorethamine,Streptozocin, Doxorubicin, Epirubicin, Lomustine. Claims for oral aprepitant must also be accompanied with a diagnosis code of an encounter for antineoplastic chemotherapy .

CMS also permits the Medicare Administrative Contractors (MACs) to 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, or any other anticancer chemotherapeutic agents that are FDA approved and may in 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.

This coverage policy applies only to the oral forms of the three drug regimen as 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.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
8418.1	Contractors shall be advised that effective for claims with dates of service on or after May 29, 2013, the following list of anti-cancer chemotherapeutic agents has been added for which the oral antiemetic drug aprepitant used in combination with an oral 5HT3 antagonist and oral dexamethasone is eligible for coverage: • Alemtuzumab • Azacitidine • Bendamustine • Carboplatin	X			X					

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	• Clofarabine • Cytarabine • Daunorubicin • Idarubicin • Ifosfamide • Irinotecan • Oxaliplatin See NCD Manual Pub.100-03 chapter 1, section 110.18 for more information on coverage. Please also note that the entire list includes the 11 new codes listed above and the nine existing anticancer chemotherapeutic agents listed below: Carmustine, Cisplatin, Cyclophosphamide, Dacarbazine, Mechlorethamine, Streptozocin, Doxorubicin, Epirubicin, Lomustine.									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
8418.2	MLN Article : A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X			X	

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information: N/A

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Cheryl Gilbreath, 410-786-4919 or cheryl.gilbreath@cms.hhs.gov (Coverage) , Bridgitte Davis-Hawkins, 410-786-4573 or bridgitte.davis-hawkins@cms.hhs.gov (Part B) , Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage) , Patricia Brocato-Simons, 410-786-0261 or patricia.brocatosimons@cms.hhs.gov (Coverage) , Wendy Knarr, 410-786-0843 or wendy.knarr@cms.hhs.gov (DME Call relay #71 and then have agent dial phone number) , Cami DiGiacomo, 410-786-5888 or cami.digiacomo@cms.hhs.gov (Institutional Claims)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS do not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

50.5.4 - Oral Anti-Nausea (Anti-Emetic) Drugs

(Rev. 185, Issued: 04-15-14, Effective: 05-29-13, Implementation: 07-07-14)

Effective January 1, 1998, Medicare also covers self-administered anti-emetics, which are necessary for the administration and absorption of the anti-neoplastic chemotherapeutic agents when a high likelihood of vomiting exists. The anti-emetic drug is covered as a necessary means for administration of the anti-neoplastic chemotherapeutic agents. Oral drugs prescribed for use with the primary drug, which enhance the anti-neoplastic effect of the primary drug or permit the patient to tolerate the primary anti-neoplastic drug in higher doses for longer periods, are not covered. Self-administered anti-emetics to reduce the side effects of nausea and vomiting brought on by the primary drug are not included beyond the administration necessary to achieve drug absorption.

Section 1861(s)(2) of the *Social Security* Act extends coverage to oral anti-emetic drugs that are used as full replacement for intravenous dosage forms of a cancer regimen under the following conditions:

- Coverage is provided only for oral drugs approved by the Food and Drug Administration (FDA) for use as anti-emetics;

- The oral anti-emetic must either be administered by the treating physician or in accordance with a written order from the physician as part of a cancer chemotherapy regimen;

- Oral anti-emetic drugs administered with a particular chemotherapy treatment must be initiated within 2 hours of the administration of the chemotherapeutic agent and may be continued for a period not to exceed 48 hours from that time;

- The oral anti-emetic drugs provided must be used as a full therapeutic replacement for the intravenous anti-emetic drugs that would have otherwise been administered at the time of the chemotherapy treatment.

Only drugs pursuant to a physician's order at the time of the chemotherapy treatment qualify for this benefit. The dispensed number of dosage units may not exceed a loading dose administered within two hours of the treatment, plus a supply of additional dosage units not to exceed 48 hours of therapy.

Oral drugs that are not approved by the FDA for use as anti-emetics and which are used by treating physicians adjunctively in a manner incidental to cancer chemotherapy are not covered by this benefit and are not reimbursable within the scope of this benefit.

It is recognized that a limited number of patients will fail on oral anti-emetic drugs. Intravenous anti-emetics may be covered (subject to the rules of medical necessity) when furnished to patients who fail on oral anti-emetic therapy.

More than one oral anti emetic drug may be prescribed and may be covered for concurrent use if needed to fully replace the intravenous drugs that otherwise would be given. *See the Medicare National Coverage Determinations Manual, Publication 100-03, Chapter 1, Section 110.18, for detailed coverage criteria.*