CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 2931	**Date: April 15, 2014**
	Change Request 8418

Transmittal 2883, dated February 21, 2014, is being rescinded and replaced by Transmittal 2931, dated April 15, 2014, to revise the documents to delete HCPCS codes that have expired and provide appropriate updated codes, in the Pub. 100-04, Business Requirements, and Claims Processing 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	17/80.2/Oral Anti-Emetic Drugs Used as Full Replacement for Intravenous Anti-Emetic Drugs as Part of a Cancer Chemotherapeutic Regimen
R	17/80.2.1/HCPCS Codes for Oral Anti-Emetic Drugs
R	17/80.2.2/Claims Processing Jurisdiction for Oral Anti-Emetic Drugs
R	17/80/2.4/Billing and Payment Instructions for A/B MAC

III. FUNDING:

or 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. 100-04	Transmittal: 2931	Date: April 15, 2014	Change Request: 8418

Transmittal 2883, dated February 21, 2014, is being rescinded and replaced by Transmittal 2931, dated April 15, 2014, to revise the documents to delete HCPCS codes that have expired and provide appropriate updated codes, in the Pub.100-04, Business Requirements and Claims Processing Manual. All other information remains the same.

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 also the existing 9 anticancer chemotherapeutic agents that are listed below: Carmustine, Cisplatin, Cyclophosphamide, Dacarbazine, Mechlorethamine, Streptozocin, Doxorubicin, Epirubicin, and Lomustine. Claims for oral aprepitant (J8501) must also be accompanied with a diagnosis code of an encounter for antineoplastic chemotherapy (V58.11/Z51.11).

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.

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:

Q0181 - Unspecified oral dosage form, 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.

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

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	Shared-System Maintainers	Other

		A	B	HHH	MAC	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 (J8501) used in combination with an oral 5HT3 antagonist (Q0162, Q0166, Q0180) and oral dexamethasone (J8540) is eligible for coverage: • Alemtuzumab (J9010) • Azacitidine (J9025) • Bendamustine (J9033) • Carboplatin (J9045) • Clofarabine (J9027) • Cytarabine (J9098, J9100) • Daunorubicin (J9150, J9151) • Idarubicin (J9211) • Ifosfamide (J9208) • Irinotecan (J9206) • Oxaliplatin (J9263) 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 eleven new drugs listed above and the nine existing anticancer chemotherapeutic agents listed below: • Carmustine (J9050) • Cisplatin (J9060) • Cyclophosphamide (J8530, J9070) • Dacarbazine (J9130) • Mechlorethamine (J9230) • Streptozocin (J9320) • Doxorubicin (J9000, Q2049)	X			X					

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	• Epirubicin (J9178) • Lomustine (S0178)									
8418.1.1	Effective for claims with dates of service on and after May 29, 2013 Medicare Contractor shall deny the line for oral aprepitant (J8501), or the NOC code (Q0181), if an encounter for antineoplastic chemotherapy identified by ICD-9/10 codes (V58.11/Z51.11) is not present. Note: Please note that effective April 1, 2014 the following code Q0181 will be updated in the IOCE update.	X			X	X				IOCE
8418.1.2	Medicare Contractors shall deny lines as instructed in BR8418.1.1 using the following messages: • CARC 96: Non-covered charge(s). • 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 • 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. • MSN 14.9: Medicare cannot pay for this service for the diagnosis shown on the claim. Spanish Version- Este servicio fue denegado porque Medicare solamente lo cubre bajo ciertas circunstancias. Contractors shall use Group Code PR assigning financial liability to the beneficiary, if a claim is received with occurence code 32 indicating a signed	X			X					

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	ABN is on file, or occurrence code 32 is present with modifier GA. Contractors shall use Group Code CO assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.									
8418.2	Medicare Contractors shall determine coverage for an oral three-drug antiemesis regimen that includes any new FDA approved: • oral NK-1 antagonist, and • oral 5HT3 antagonist, and • oral dexamethasone for beneficiaries who are receiving an approved anticancer chemotherapeutic agent.	X			X					
8418.2.1	Medicare Contractors shall use NOC code Q0181 for any new FDA approved oral antiemesis drug as part of the three drug regimen until a specific code is assigned to the new drug. Note: Please note that effective April 1, 2014 the following code Q0181 will be updated in the IOCE update.	X			X					IOCE
8418.3	Medicare Contractors shall determine coverage for oral aprepitant with any FDA approved anticancer chemotherapeutic agents that are defined as highly or moderately emetogenic according to the NCD Manual Pub.100-03 chapter 1, section 110.18.	X			X					
8418.4	For claims with dates of service on or after May 29, 2013, contractors shall not search their files, but contractors will adjust claims brought to their attention.	X			X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
8418.5	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:

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

V. CONTACTS

Pre-Implementation Contact(s): Wendy Knarr, 410-786-0843 or wendy.knarr@cms.hhs.gov (DME Call relay #711 then have agent dial phone number), Bridgitte Davis-Hawkins, 410-786-4573 or bridgette.davis-hawkins@cms.hhs.gov (Part B), Cami DiGiacomo, 410-786-5888 or cami.digiacomo@cms.hhs.gov (Institutional Claims), Cheryl Gilbreath, 410-786-4919 or cheryl.gilbreath@cms.hhs.gov (Coverage) , 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)

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.

Medicare Claims Processing Manual

Chapter 17 - Drugs and Biologicals

Table of Contents

(Rev. 2931, Issued: 04-15-14)

Transmittals for Chapter 17

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 Benefits 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 *$5HT_3$* 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-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 $5HT_3$ antagonist* to the *Part A MAC*, or (2) Bill the first day's *supply of aprepitant along with an oral $5HT_3$ 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.

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-HT_3 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 5HT_3 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 $5HT_3$ 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.

80.2.1 - HCPCS Codes for Oral Anti-Emetic Drugs

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

The physician/supplier bills for these drugs on Form CMS-1500 or its electronic equivalent, *the 837P*. The facility bills for these drugs on Form CMS-1450 or its electronic equivalent, *the 837I*. The following HCPCS codes are assigned:

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 $5HT_3$ 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.

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 DRONABINOL 2.5mg, 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.

Q0169 PROMETHAZINE HYDROCHLORIDE 12.5mg, 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.

Q0173 TRIMETHOBENZAMIDE HYDROCHLORIDE 250mg, 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 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.

Q0175 PERPHENAZINE 4mg, 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 25mg, 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 100mg, 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 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.

80.2.2 - Claims Processing Jurisdiction for Oral Anti-Emetic Drugs

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

The following chart shows which drugs are billed to the *A/B MAC, or carrier* and which *drugs are billed* to the *DME MAC*.

Per the *Balanced Budget Act of 1997,* effective for claims with dates of service on or after January 1, 1998, the claims processing jurisdiction rules in Chart 1 apply. Effective July 1, 2006, claims from institutional (hospital) pharmacies are also billed as shown in this chart.

CHART 1

COMBINATION	JURISDICTION
Oral anti-cancer chemotherapy drug with oral anti-emetic drug	*DME MAC* maintains processing responsibility for the *National Drug Code (*NDC) oral anti-cancer chemotherapy drug and the K0415 oral anti-emetic drug code combinations. *DME MAC* processes the NDC oral anti-cancer chemotherapy drug and Q code oral anti-emetic drug(s) when provided in the physician's office. *Part A MAC processes the 3-drug combination anti-emetic (Aprepitant) in the form of a Tri-Pak when dispensed by a hospital.* *Part A MAC processes the initial days' supply of the 3-drug anti-emetic combination when a hospital dispenses it and writes a prescription for the second and third days' supply.* *DME MAC processes the second and third days' supply of the 3-drug anti-emetic combination.* *DME MAC* processes the NDC oral anti-cancer chemotherapy drug and/or Q code oral anti-emetic drug(s) when supplied by a pharmacy, including a hospital pharmacy.
Oral anti-cancer chemotherapy drug with rectal anti-emetic drug	*DME MAC* maintains responsibility for processing both the NDC oral anti-cancer chemotherapy drug and the K0416 rectal anti-emetic drug.
Oral anti-cancer chemotherapy drug with intravenous anti-emetic drug	*DME MAC* maintains responsibility for processing the NDC oral anti-cancer chemotherapy drug and the local carrier or Part A MAC for processing the intravenous anti-emetic J code drug(s).
Intravenous anti-cancer chemotherapy drug with oral anti-emetic drug	*A/B MAC or carrier* processes the intravenous J code anti-cancer chemotherapy drug. The oral anti-emetic Q code drug(s) is processed by the *DME MAC* when provided in the physician's office, hospital, or when provided by a supplier.
Intravenous anti-cancer chemotherapy drug with intravenous anti-emetic drug	*A/B MAC or carrier* processes both intravenous anti-cancer chemotherapy J code drug and intravenous anti-emetic J code drug(s).

Providers (HIPAA definition) that bill the *DME MAC* require a supplier number issued by the *National Supplier Clearinghouse (*NSC) in order to submit claims. Medicare Carriers and Part A MACs should instruct providers without a supplier number to contact the NSC service center at 1-866-238-9652 to request an enrollment package for a supplier number. Alternatively, providers may go to the CMS Web site, cms.hhs.gov/providers/enrollment/default.asp, and download the Form CMS-855-S in Adobe Acrobat format. The application can be completed hard copy and submitted to the NSC.

80.2.4 - Billing and Payment Instructions for *A/B MAC*

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

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* on the ASC 837I or on hard

copy Form CMS-1450 with the appropriate cancer diagnosis and HCPCS code or *Current Procedural Terminology (*CPT) code, and *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 Part A MAC*:

- 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.