

LCD for Oral Antiemetic Drugs (Replacement for Intravenous Antiemetics) (L11545)

Contractor Information

Contractor Number

00635

Contractor Type

DMERC

LCD Information

LCD ID Number

L11545

LCD Title

Oral Antiemetic Drugs (Replacement for Intravenous Antiemetics)

Contractor's Determination Number

OAED

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CMS National Coverage Policy

Pub 100-3, Medicare National Coverage Determinations Manual, Chapter 1, Section 110.18

Original Determination Effective Date

For services performed on or after 01/01/1999

Original Determination Ending Date**Revision Effective Date**

For services performed on or after 01/01/2006

Revision Ending Date**Indications and Limitations of Coverage and/or Medical Necessity**

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 regional medical review policy, the criteria for “reasonable and necessary” is defined by the following indications and limitations of coverage and/or medical necessity.

The statutory coverage criteria for the 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 patients who are receiving one or more of the following anticancer 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 medically necessary.

The supplier may dispense only a single course of oral antiemetic drugs at one time.

Drugs may be covered only if dispensed and billed to Medicare by the entity that actually dispenses the drug to the Medicare beneficiary, and that entity must be permitted under all applicable federal, state, and local laws and regulations to dispense drugs. Only entities licensed in the state where they are physically located may bill the DMERC for oral antiemetic drugs. Physicians may bill the DMERC for drugs if all of the following conditions are met: the physician is 1) enrolled as a DMEPOS supplier with the National Supplier Clearinghouse, and 2) dispensing the drug(s) to the Medicare beneficiary, and 3) authorized by the State to dispense drugs as part of the physician’s license. Claims submitted by entities not licensed to dispense drugs will be denied for lack of medical necessity.

If the drug on the claim is denied as not medically necessary, the supply fee will be denied as not medically necessary.

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

Coverage Topic

Prescription Drugs
Oral Antiemetic Drugs

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

CPT/HCPCS Codes

The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS:

EY No physician or other licensed health care provider order for this item or service
KX Specific required documentation on file

HCPCS CODES:

J8501 APREPITANT, ORAL, 5 MG

J8540 DEXAMETHASONE, ORAL, 0.25 MG

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-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
- 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
- Q0179 ONDANSETRON HYDROCHLORIDE 8 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 Codes that Support Medical Necessity

Not specified.

For ICD-9 codes relating to statutory coverage, see Policy Article.

Diagnoses that Support Medical Necessity

Not specified.

ICD-9 Codes that DO NOT Support Medical Necessity

Not specified.

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

Not specified.

General Information

Documentation Requirements

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. section 13951(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available to the DMERC upon request. Items billed to the DMERC before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.

The supplier must enter an ICD-9 diagnosis code corresponding to the patient's cancer diagnosis on each claim.

The oral antiemetic 3-drug combination of aprepitant (J8501), a 5-HT3 antagonist (Q0166, Q0179, Q0180), and dexamethasone (J8540) should be submitted on the same claim.

If aprepitant (J8501) is used in conjunction with one of the anticancer chemotherapeutic agents listed in the Indications and Limitations of Coverage section of this policy, a KX modifier should be added to the code.

Claims for code Q0181 must be accompanied by the name of the drug, the manufacturer, the dosage strength dispensed, the number of tablets and frequency of administration during the covered time period (24-48 hours) as specified on the order. This information should be entered in the narrative field of an electronic claim.

Refer to the Supplier Manual for more information on documentation requirements.

Appendices

Utilization Guidelines

Refer to Indications and Limitations of Coverage and/or Medical Necessity.

Sources of Information and Basis for Decision

Reserved for future use.

Advisory Committee Meeting Notes

Start Date of Comment Period

End Date of Comment Period

Start Date of Notice Period

09/01/1999

Revision History Number

006

Revision History Explanation

Revision Effective Date: 01/01/2006

INDICATIONS AND LIMITATIONS OF COVERAGE:

Added: J8540

Deleted: Q0181

HCPCS CODES AND MODIFIERS:

Added: J8540, Q0511, Q0512

Deleted: G0370

DOCUMENTATION REQUIREMENTS:

Added: J8540

Deleted: Q0181

Revised: Q0181 requirements

Revision Effective Date: 04/04/2005

INDICATIONS AND LIMITATIONS OF COVERAGE:

Added coverage criteria for aprepitant and dexamethasone

HCPCS CODES AND MODIFIERS:

Added: KX

DOCUMENTATION REQUIREMENTS:

Added KX modifier requirement and other claims submission requirements for aprepitant.

This revision corresponds to the effective date of the NCD change.

Revision Effective Date: 04/01/2005

LMRP converted to LCD and Policy Article

HCPCS CODES AND MODIFIERS:

Added: G0370, J8501

Revision effective date: 07/01/2003

INDICATIONS AND LIMITATIONS OF COVERAGE:

In paragraph on dispensing drugs, corrects reference to immunosuppressive drugs to say oral antiemetic drugs.

Revision effective date: 04/01/2003

HCPCS CODES AND MODIFIERS:

Added: EY modifier

INDICATIONS AND LIMITATIONS OF COVERAGE:

Adds standard language concerning coverage of items without an order

DOCUMENTATION REQUIREMENTS:

Adds standard language concerning use of EY modifier for items without an order

The revision date listed below is the approximate date the revision was published and not the effective date for the revision.

03/01/2001 - The revision language reflects a change in jurisdiction for claim submission by physicians who are also DMEPOS suppliers. In addition, the policy incorporates instructions from the Centers for Medicare & Medicaid Services (CMS), formerly the Health Care Financing Administration, regarding entities qualified to dispense and bill for Medicare-covered drugs.

Last Reviewed On Date**Related Documents****Article(s)**

A25265 - Oral Antiemetic Drugs (Replacement for Intravenous Antiemetics) - Policy Article - Effective January 2006

LCD Attachments

There are no attachments for this LCD

Other Versions

Updated on 08/24/2005 with effective dates 04/04/2005 - N/A

Updated on 02/28/2005 with effective dates 04/01/2005 - 04/03/2005

Updated on 03/31/2005 with effective dates 07/01/2003 - 03/31/2005

Updated on 02/18/2003 with effective dates 04/01/2003 - 06/30/2003

Article for Oral Antiemetic Drugs (Replacement for Intravenous Antiemetics) - Policy Article - Effective January 2006 (A25265)**Contractor Information****Contractor Number**

00635

Contractor Type

DMERC

Article Information**Article ID Number**

A25265

Article Type

Article

Key Article

Yes

Article Title

Oral Antiemetic Drugs (Replacement for Intravenous Antiemetics) - Policy Article - Effective January 2006

Original Article Effective Date

04/01/2005

Article Revision Effective Date

01/01/2006

Article Text

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

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 to the DMERC. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as noncovered.

An oral antiemetic drug billed with a HCPCS code listed in the Local Coverage Determination is covered if all of the following criteria (1-4) are met:

- 1) The drug has been approved by the Food and Drug Administration (FDA) for use as an antiemetic, and
- 2) The drug has been ordered by the treating physician as part of a cancer chemotherapy regimen, and
- 3) 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
- 4) The initial dose of the oral antiemetic drug is administered within 2 hours before or 48 hours after the administration of the chemotherapy drug.

If all of the criteria are not met, the oral antiemetic drug will be denied as noncovered. 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 (Q0179), 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 (1-4) 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 noncovered.

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.

SUPPLY FEE:

One unit of service of supply fee code Q0511 is covered for the first covered oral antiemetic drug that is dispensed in a 30-day period. If covered drugs are dispensed by more than one pharmacy during a 30 day period, one unit of Q0511 is covered for each pharmacy. One unit of service of supply fee code Q0512 is covered for each subsequent covered oral antiemetic drug that is dispensed in that 30-day period. If two dosage strengths of the same drug are dispensed on the same day, one unit of service of the appropriate supply fee is payable for each one. If more than one unit of service of code Q0511 is billed per 30 days by a single pharmacy, the excess units of service will be paid comparable to code Q0512. If the billed units of service of Q0511 or Q0512 exceed the number of drugs on the claim, the excess units will be denied as not separately payable.

Supply fees are eligible for coverage only for drugs that are covered by the DMERC under this LCD. If the drug on the claim is denied as noncovered, the supply fee will be denied as noncovered.

The supply fee code must be billed on the same claim as the drug(s). If it is not, the supply fee will be denied as incorrect billing.

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, and Q0163-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 Q0163-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, Q0163-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 Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these items.

Coverage Topic

Prescription Drugs

Coding Information

ICD-9 Codes that are Covered

The presence of an ICD-9 code listed in this section is not sufficient by itself to assure coverage. Refer to the Non-Medical Necessity Coverage and Payment Rules section for other coverage criteria and payment information.

140.0 - 208.91	MALIGNANT NEOPLASM OF UPPER LIP VERMILION BORDER - UNSPECIFIED LEUKEMIA IN REMISSION
230.0 - 239.9	CARCINOMA IN SITU OF LIP ORAL CAVITY AND PHARYNX - NEOPLASM OF UNSPECIFIED NATURE SITE UNSPECIFIED
273.3	MACROGLOBULINEMIA

ICD-9 Codes that are Not Covered

All ICD-9 codes not listed in the previous section.

Other Information

Revision History Explanation

Revision Effective Date: 01/01/2006

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Added: J8540, Q0511, Q0512

Revised Supply Fee instructions

Deleted: Q0181, G0370

CODING GUIDELINES:

Deleted dexamethasone example

Revision Effective Date: 04/04/2005

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Added additional coverage criterion for aprepitant and dexamethasone.

Revised supply fee coverage for multiple dosage forms of the same drug.

CODING GUIDELINES;

Added guidelines for dexamethasone.

Effective Date: 04/01/2005

LMRP converted to LCD and Policy Article

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Added statements about coverage of a supply fee.

ICD-9 CODES THAT ARE COVERED:

Expanded range of payable codes.

Related Documents

LCD(s)

L11545 - Oral Antiemetic Drugs (Replacement for Intravenous Antiemetics)

Other Versions

Updated on 08/24/2005 with effective dates 04/04/2005 - N/A

Updated on 02/28/2005 with effective dates N/A - N/A