

LCD for Oral Anticancer Drugs (L5057)

Contractor Information

Contractor Name

[NHIC](#)

Contractor Number

16003

Contractor Type

DME MAC

LCD Information

LCD ID Number

L5057

LCD Title

Oral Anticancer Drugs

Contractor's Determination Number

OCAN20080401

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CMS National Coverage Policy

None

Primary Geographic Jurisdiction

Connecticut
District of Columbia
Delaware
Massachusetts
Maryland
Maine
New Hampshire
New Jersey
New York - Entire State
Pennsylvania
Rhode Island
Vermont

Oversight Region

Region III

DME Region LCD Covers

Jurisdiction A

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 04/01/2008

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 medical policy, the criteria for reasonable and necessary are defined by the following indications and limitations of coverage and/or medical necessity.

Statutory coverage criteria for oral anticancer drugs are specified in the related Policy Article. In addition, the drug must be reasonable and necessary for the individual patient.

If the statutory coverage criteria are met but the drug is not reasonable and necessary for the individual patient it will be denied as not medically necessary.

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 DME MAC for oral anticancer and oral antiemetic drugs. Physicians may bill the DME MAC 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 related supply fee will also be denied as not medically necessary.

Coverage Topic

Prescription Drugs

Coding Information

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

National Drug Codes (NDC):

The National Drug Code (NDC) is a number which uniquely identifies a manufacturer's product in terms of the strength of each tablet/capsule, quantity of tablets/capsules in a package, and other packaging details. Suppliers must use the NDC that matches the product dispensed.

The oral anticancer drugs that are addressed in this policy are:

Busulfan
Capecitabine
Cyclophosphamide
Etoposide
Melphalan
Methotrexate
Temozolomide
Topotecan

HCPCS Codes:

A9270 NON-COVERED ITEM OR SERVICE

J8498 ANTIEMETIC DRUG, RECTAL/SUPPOSITORY, NOT OTHERWISE SPECIFIED

J8597 ANTIEMETIC DRUG, ORAL, NOT OTHERWISE SPECIFIED

J8999 PRESCRIPTION DRUG, ORAL, CHEMOTHERAPEUTIC, NOS

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." 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 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 upon request. Items billed 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.

A new detailed written order is required whenever there is a change in dosage or in the directions for administering the drug.

The ICD-9 diagnosis code describing the condition for which the drug is used must be included on each claim.

Claims for codes J8498 or J8597 must identify the name of the drug, the manufacturer, and the dosage strength of each tablet/suppository/etc. Only quantities of these drugs which meet the coverage criteria listed in the related Policy Article may be billed using these codes. The claim must also indicate which oral anticancer drug is being used and the prescribed frequency of administration of the anticancer drug. This information should be entered in the narrative field of an electronic claim.

Claims using code J8999 must include the name of the drug, the manufacturer, the NDC number, and the number of tablets or capsules dispensed. This information must 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

OCAN006

Revision History Explanation

Revision Effective Date: 04/01/2008

HCPCS CODES AND MODIFIERS:

Added Topotecan.

3/1/2008- In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC NHIC (16003) LCD L5057 from DME PSC TriCenturion (77011) LCD L5057.

Revision Effective Date: 07/01/2007

INDICATIONS AND LIMITATIONS OF COVERAGE:

Removed DMERC references

DOCUMENTATION REQUIREMENTS:

Removed DMERC references

03/01/2006 - In accordance with Section 911 of the Medicare Modernization Act of 2003, this policy was transitioned to DME PSC TriCenturion (77011) from DMERC Tricenturion (77011).

Revision effective date: 01/01/2006

HCPCS CODES AND MODIFIERS:

Added Q0511, Q0512, J8498, J8597.

Deleted G0370, K0415, K0416.

DOCUMENTATION REQUIREMENTS:

Edited for code changes.

Revised J8498, J8597, J8999 instructions

Revision effective date: 04/01/2005

LMRP converted to LCD and Policy Article

HCPCS CODES AND MODIFIERS:

Added G0370, removed NDC numbers

INDICATIONS AND LIMITATIONS OF COVERAGE:

Added a statement about denial of supply fees.

Revision effective date: 04/01/2004

INDICATIONS AND LIMITATIONS OF COVERAGE:

Added standard language about who is authorized to dispense drugs and bill Medicare.

HCPCS CODES AND MODIFIERS:

Added NDC codes: 00004-1100-20,00004-1101-50

Deleted invalid NDC codes: 00004-1100-13, 00004-1100-22, 00004-1101-13, 00004-1105-51,

00054-8550-03, 00054-8550-05, 00054-8550-06, 00054-8550-07, 00054-8550-10, 00182-1539-01, 00182-1539-95, 00364-2499-01, 00364-2499-36, 00536-3998-01, 00536-3998-36, 00603-4499-21, 00677-1610-01, 00781-1076-01, 00781-1076-36, 00904-1749-73, 51285-0509-02, 59911-5874-01, 62701-0940-36, 62701-0940-99

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 date the revision was published and not necessarily the effective date for the revision.

10/01/2002 - Updated list of National Drug Codes. Added codes A9270 and J8999 and instructions for their use.

06/01/2007 - In accordance with Section 911 of the Medicare Modernization Act of 2003, Virginia and West Virginia were transitioned from DME PSC TriCenturion (77011) to DME PSC TrustSolutions (77012).

Last Reviewed On Date

Related Documents

Article(s)

[A25227 - Oral Anticancer Drugs - Policy Article - Effective April 2008](#)

LCD Attachments

There are no attachments for this LCD

Article for Oral Anticancer Drugs - Policy Article - Effective April 2008 (A25227)

Contractor Information

Contractor Name

[NHIC](#)

Contractor Number

16003

Contractor Type

DME MAC

Article Information

Article ID Number

A25227

Article Type

Article

Key Article

Yes

Article Title

Oral Anticancer Drugs - Policy Article - Effective April 2008

Primary Geographic Jurisdiction

Connecticut
District of Columbia
Delaware
Massachusetts
Maryland
Maine
New Hampshire
New Jersey
New York - Entire State
Pennsylvania
Rhode Island
Vermont

DME Region Article Covers

Jurisdiction A

Original Article Effective Date

04/01/2005

Article Revision Effective Date

04/01/2008

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. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as non-covered.

Oral Anticancer Drugs

An oral anticancer drug is covered if all of the following criteria (1-4) are met:

- 1) It is a drug or biological that has been approved by the Food and Drug Administration (FDA), and
- 2) It has the same ingredients as a non-self-administrable anticancer chemotherapeutic drug or biological that is covered when furnished incident to a physician's service. The oral anticancer drug and the non-self-administrable drug must have the same chemical/generic name as indicated by the FDA's Approved Drug Products (Orange Book), Physician's Desk Reference (PDR), or an authoritative drug compendium, or it is a prodrug which, when ingested, is metabolized into the same active ingredient which is found in the non-self-administrable form of the drug, and
- 3) It is used for the same indications, including unlabeled uses, as the non-self-administrable form of the drug
 - a. For busulfan, capecitabine, cyclophosphamide, etoposide, melphalan, methotrexate, or temozolomide, it is prescribed for the treatment of cancer (ICD-9 codes 140.0-208.91, 230.0-239.9, 259.2, 273.3, V58.11);
 - b. For topotecan, it is prescribed for the treatment of relapsed small cell lung (ICD-9 codes 162.2-162.9); and
- 4) It is prescribed by a physician or other practitioner licensed under state law to prescribe such drugs as anticancer chemotherapeutic agents.

A drug that is not available in an injectable form does not meet criterion 2. If an oral anticancer drug is used for immunosuppression (rather than the treatment of cancer), criterion 3 is not met, and the drug cannot be covered under the oral anticancer drug benefit. (If the drug is used for immunosuppression following organ transplant, refer to the Immunosuppressive Drugs policy.)

If criteria 1-4 are not met, the drug will be denied as non-covered.

The quantity of oral anticancer drugs that is dispensed should be limited to a 30-day supply. Prescriptions may be refillable.

Antiemetic drugs used with oral anticancer drugs

A self-administered antiemetic drug billed with code J8498 or J8597 is covered if all of the following criteria are met:

- 1) It is used in conjunction with a covered oral anticancer drug, and
- 2) It is likely that administration of the covered oral anticancer drug will induce emesis if the antiemetic drug is not administered, and
- 3) The antiemetic drug is administered within 2 hours before the covered oral anticancer drug is administered.

Antiemetic drugs are covered under the oral anticancer drug benefit for the sole purpose of allowing

the absorption of the covered oral anticancer drug. Therefore, coverage is limited to doses of antiemetic drugs, which are administered during the two hours before administration of the covered oral anticancer drug. Doses of antiemetic drugs administered after the administration of the oral anticancer drug (e.g., to treat nausea or vomiting which is caused by the oral anticancer drug or other etiology) are non-covered.

If all of the criteria are not met, the antiemetic drug will be denied as non-covered.

For information on the coverage of oral antiemetic drugs when they are used as a full replacement for intravenous antiemetic drugs used in conjunction with intravenous cancer chemotherapeutic regimens, refer to the Oral Antiemetic Drugs (Replacement for Intravenous Antiemetics) policy.

Supply Fee

One unit of service of supply fee code Q0511 is covered for the first covered oral anticancer 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 anticancer 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 under this LCD. If the drug on the claim is denied as non-covered, the supply fee will be denied as non-covered.

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.

J8498 is not eligible for payment of a supply fee.

CODING GUIDELINES

For the instructions below that apply to 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.

The National Drug Code (NDC) is a number, which uniquely identifies a manufacturer's product in terms of the strength of each tablet/capsule, quantity of tablets/capsules in a package, and other packaging details. Suppliers must use the NDC that matches the product dispensed.

For all NDC numbers, 1 unit of service = 1 tablet or 1 capsule.

For codes J8498 and J8597, 1 unit of service = 1 mg.

National Drugs Codes (NDCs) may be billed only when the drug is used as an oral anticancer drug. If cyclophosphamide or methotrexate is prescribed as an oral immunosuppressive drug following an organ transplant, code J8530 or J8610 respectively must be used. (Refer to the Immunosuppressive Drugs policy for additional information.) If cyclophosphamide or methotrexate are prescribed as an oral immunosuppressive drug for other conditions (e.g., lupus, rheumatoid arthritis, etc.), a claim should not be submitted to Medicare (unless requested by the beneficiary) because there is no statutory benefit for oral immunosuppressive drugs in these conditions.

Code J8498 or J8597 may be billed only when the antiemetic drug is used in conjunction with a covered oral anticancer drug. Suppliers may bill only for quantities of antiemetic drugs that are to

be used within 2 hours before the covered oral anticancer drug. Refer to the Oral Antiemetic Drugs (Replacement for Intravenous Antiemetics) policy for information on billing oral antiemetics used in conjunction with intravenous cancer chemotherapeutic regimens.

A list of valid NDC numbers for covered oral anticancer drugs can be found on the SADMERC web site. Until a new NDC number is added to the list, suppliers must submit claims using code J8999.

Oral anticancer drugs which are not covered under the oral anticancer drug benefit (i.e., those that are not specifically listed in this policy) must be billed using code A9270 (noncovered item or service) if the supplier chooses to submit a claim.

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.

For Topotecan

Codes:

162.2-162.9

For Busulfan, Capecitabine, Cyclophosphamide, Etoposide, Melphalan, Methotrexate, and Temozolomide

[140.0 -](#) MALIGNANT NEOPLASM OF UPPER LIP VERMILION BORDER - UNSPECIFIED
[208.91](#) LEUKEMIA IN REMISSION

[230.0 -](#) CARCINOMA IN SITU OF LIP ORAL CAVITY AND PHARYNX - NEOPLASM OF
[239.9](#) UNSPECIFIED NATURE SITE UNSPECIFIED

259.2 CARCINOID SYNDROME

273.3 MACROGLOBULINEMIA

V58.11 ENCOUNTER FOR ANTINEOPLASTIC CHEMOTHERAPY

ICD-9 Codes that are Not Covered

All codes not listed in the previous section.

Other Information

Revision History Explanation

Revision Effective Date: 04/01/2008

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Expanded range of payable codes. Added V58.11

ICD-9 CODES THAT ARE COVERED

Removed V58.0-V58.10, V58.12.

Added 162.2-162.9 for Topotecan

3/1/2008- In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC NHIC (16003) Article A25227 from DME PSC TriCenturion (77011) Article A25227.

09/03/2007 - This article was updated by the ICD-9 2007-2008 Annual Update.

06/01/2007 - In accordance with Section 911 of the Medicare Modernization Act of 2003, Virginia and West Virginia were transitioned from DME PSC TriCenturion (77011) to DME PSC TrustSolutions (77012).

Revision Effective Date: 01/01/2007

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Specified that the quantity of drugs dispense should be limited to a one month supply.

Removed references to the DMERC.

CODING GUIDELINES:

Removed references to the DMERC.

ICD-9 CODES THAT ARE COVERED:

Expanded range of payable codes. Added V58.0 – V58.12.

09/04/2006 - This article was updated by the ICD-9 2006-2007 Annual Update.

03/01/2006 - In accordance with Section 911 of the Medicare Modernization Act of 2003, this article was transitioned to DME PSC TriCenturion (77011) from DMERC Tricenturion (77011).

Revision Effective Date: 01/01/2006

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Edited for Code changes

Revised instructions for Supply Fee

CODING GUIDELINES:

Added J8498, J8597

Deleted K0415, K0416

Revision Effective Date: 10/01/2005

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

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

Effective Date: 04/01/2005

LMRP converted to LCD and Policy Article

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Added G0370 and instructions

CODING GUIDELINES:

Added instructions about the use of NDC numbers.

ICD-9 CODES THAT ARE COVERED:

Expanded range of payable codes

Related Documents

LCD(s)

[L5057 - Oral Anticancer Drugs](#)