

Oral Anticancer Drugs

Tricenturion

Contractor Information

Contractor Name	Tricenturion
Contractor Number	77011
Contractor Type	DMERC

LMRP Information

A "Local Coverage Determination" (LCD), as established by Section 522 of the Benefits Improvement and Protection Act, is a decision by a fiscal intermediary or carrier whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with Section 1862(a)(1)(A) of the Social Security Act (i.e., a determination as to whether the service is reasonable and necessary). The difference between LMRPs and LCDs is that LCDs consist only of "reasonable and necessary" information, while LMRPs may also contain category or statutory provisions.

The final rule establishing LCDs was published November 11, 2003. Effective December 7, 2003, CMS's contractors will begin issuing LCDs instead of LMRPs. Over the next 2 years (until December 31, 2005) contractors will convert all existing LMRPs into LCDs and articles. Until the conversion is complete, for purposes of a 522 challenge, the term LCD will refer to both 1.) Reasonable and necessary provisions of an LMRP and, 2.) an LCD that contains only reasonable and necessary language. Any non-reasonable and necessary language a contractor wishes to communicate to providers must be done through an article.

LMRP Database ID Number	L5057
LMRP Title	Oral Anticancer Drugs
Original Policy Effective Date	For services performed on or after 01/01/1999
Original Policy Ending Date	
Revision Effective Date	For services performed on or after 04/01/2004
Revision Ending Date	
Contractor's Policy Number	OCAN20040401
AMA CPT / ADA CDT	CPT codes, descriptions and other data only are copyright 2004

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CMS National Coverage Policy None

Primary Geographic Jurisdiction CT
DE
MA
ME
NH
NJ
NY
PA
RI
VT

Oversight Region Region III

CMS Consortium Northeast

DMERC Region LMRP Covers Region A

LMRP Description Oral Anticancer Drugs

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.

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 anticancer drug is covered if all of the following criteria (1-6) 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, and

4. It is prescribed by a physician or other practitioner licensed under state law to prescribe such drugs as anticancer chemotherapeutic agents, and

5. It is prescribed for the treatment of cancer (ICD-9 codes 140.0-208.9, 236.1, 273.3), and

6. It is reasonable and necessary for the individual patient.

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 5 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, 2, 3, 4, or 5 are not met, the drug will be denied as noncovered. If criteria 1-5 are met but criterion 6 is not met, the drug 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 DMERC for oral anticancer and 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.

Antiemetic drugs used with oral anticancer drugs:

A self-administered antiemetic drug billed with code K0415 or K0416 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.

Oral antiemetics 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 noncovered.

If criterion 1 or 3 is not met, the antiemetic drug will be denied as noncovered.

If criteria 1 and 3 are met but criterion 2 is not met, the antiemetic drug will be denied as not medically necessary.

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

CPT/HCPCS Section	Oral Chemotherapy Drugs Administrative, Miscellaneous And Investigational Durable Medical Equipment Regional DMERCs
Benefit Category	Oral Anticancer Drugs
Coverage Topic	Prescription Drugs

Coding Information

CPT/HCPCS Codes	HCPCS MODIFIERS: EY - No physician or other licensed health care provider order for this item or service National Drug Codes (NDC): The appearance of a code in this section does not necessarily indicate coverage. 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.
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00173-0713-25 Busulfan, 2 mg, oral

00004-1100-20 Capecitabine, 150 mg, oral
00004-1100-51 Capecitabine, 150 mg, oral
00004-1101-16 Capecitabine, 500 mg, oral
00004-1101-50 Capecitabine, 500 mg, oral

00015-0504-01 Cyclophosphamide, 25 mg, oral
00054-4129-25 Cyclophosphamide, 25 mg, oral
00054-8089-25 Cyclophosphamide, 25 mg, oral
00015-0503-01 Cyclophosphamide, 50 mg, oral
00015-0503-02 Cyclophosphamide, 50 mg, oral
00054-4130-25 Cyclophosphamide, 50 mg, oral
00054-8130-25 Cyclophosphamide, 50 mg, oral

00378-3266-94 Etoposide, 50 mg, oral
00015-3091-45 Etoposide, 50 mg, oral
51079-0965-05 Etoposide, 50 mg, oral

00081-0045-35 Melphalan, 2 mg, oral
00173-0045-35 Melphalan, 2 mg, oral

00005-4507-04 Methotrexate, 2.5 mg, oral
00005-4507-05 Methotrexate, 2.5 mg, oral
00005-4507-07 Methotrexate, 2.5 mg, oral
00005-4507-09 Methotrexate, 2.5 mg, oral
00005-4507-23 Methotrexate, 2.5 mg, oral
00005-4507-91 Methotrexate, 2.5 mg, oral
00054-4550-15 Methotrexate, 2.5 mg, oral
00054-4550-25 Methotrexate, 2.5 mg, oral
00054-8550-25 Methotrexate, 2.5 mg, oral
00378-0014-01 Methotrexate, 2.5 mg, oral
00378-0014-50 Methotrexate, 2.5 mg, oral
00555-0572-02 Methotrexate, 2.5 mg, oral
00555-0572-35 Methotrexate, 2.5 mg, oral
00555-0572-45 Methotrexate, 2.5 mg, oral
00555-0572-46 Methotrexate, 2.5 mg, oral
00555-0572-47 Methotrexate, 2.5 mg, oral
00555-0572-48 Methotrexate, 2.5 mg, oral
00555-0572-49 Methotrexate, 2.5 mg, oral
00904-1749-60 Methotrexate, 2.5 mg, oral
51079-0670-05 Methotrexate, 2.5 mg, oral
00555-0927-01 Methotrexate, 5 mg, oral
00555-0928-01 Methotrexate, 7.5 mg, oral
00555-0929-01 Methotrexate, 10 mg, oral
00555-0945-01 Methotrexate, 15 mg, oral

00085-1248-01 Temozolomide, 5 mg, oral
00085-1248-02 Temozolomide, 5 mg, oral
00085-1244-01 Temozolomide, 20 mg, oral
00085-1244-02 Temozolomide, 20 mg, oral
00085-1259-01 Temozolomide, 100 mg, oral
00085-1259-02 Temozolomide, 100 mg, oral
00085-1252-01 Temozolomide, 250 mg, oral
00085-1252-02 Temozolomide, 250 mg, oral

HCPCS Codes:

A9270 NON-COVERED ITEM OR SERVICE

J8999 PRESCRIPTION DRUG, ORAL, CHEMOTHERAPEUTIC, NOS

K0415 PRESCRIPTION ANTIEMETIC DRUG, ORAL, PER 1 MG, FOR USE IN CONJUNCTION WITH ORAL ANTI-CANCER DRUG, NOT OTHERWISE SPECIFIED

K0416 PRESCRIPTION ANTIEMETIC DRUG, RECTAL, PER 1 MG, FOR USE IN CONJUNCTION WITH ORAL ANTI-CANCER DRUG, NOT OTHERWISE SPECIFIED

ICD-9 Codes that Support Medical Necessity

The presence of an ICD-9 code listed in this section is not sufficient by itself to assure coverage. Refer to the section on "Indications and Limitations of Coverage and/or Medical Necessity" for other coverage criteria and payment information.

[140.0 - 208.91](#)

236.1 NEOPLASM OF UNCERTAIN BEHAVIOR OF PLACENTA

273.3 MACROGLOBULINEMIA

Diagnoses that Support Medical Necessity

Refer to the previous section

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

Reasons for Denials

Items listed in this policy will be denied as not medically necessary when provided for conditions other than those listed in the "Indications and Limitations of Coverage and/or Medical Necessity" section unless it specifically states in that section that they will be denied as noncovered.

Non-covered ICD-9 Codes

Non-covered Diagnoses

All diagnoses that are not specified in the section ICD-9 Codes that Support Medical Necessity

Coding Guidelines

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

For codes K0415 and K0416, 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 are 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 K0415 or K0416 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.

As new NDC numbers for covered oral anticancer drugs are established, the DMERC will announce in its bulletin when those numbers can be accepted by the claim processing system. Until such time as a new NDC number can be accepted, suppliers must submit claims using code J8999.

Oral anticancer drugs which are not covered under the oral anticancer drug benefit (i.e., those which 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 to the DMERC.

Suppliers should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these items.

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.

A narrative diagnosis and/or ICD-9 diagnosis code describing the condition for which the drug is ordered must be entered on the order by the physician. 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 K0415 or K0416 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 Coverage and Payment Rules section 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 or attached to a hard copy claim.

Claims using code J8999 (see Coding Guidelines section), 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 HAO record of an electronic claim or attached to a hard copy claim.

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

Appendices

Footnotes

Utilization Guidelines

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

Other Comments

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** OCAN003

**Revision History
Explanation**

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.

**Last Reviewed on
Date**

**Disclaimer Specialty
Name**

LMRP Attachments There are no attachments for this LMRP