



Medicare Part C Medical Coverage Policy

Oral Anticancer Medications

Origination: June 17, 2009
Review Date: October 18, 2023
Next Review: October 2024

******This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services. ******

DESCRIPTION

Chemotherapy is a cancer treatment that uses chemical agents to kill cancer cells. The chemicals have a specific toxic effect upon cancer cells. They either destroy them or prevent the malignant cells from multiplying. The chemotherapy drugs may also have the same effect on normal cells. Administration of the drugs requires close monitoring for toxicity levels and for the patient's response to therapy.

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

- Busulfan (Myleran) – oral equivalent to intravenous busulfan
- Capecitabine (Xeloda) – an orally administered systemic prodrug of 5'-deoxy-5-fluorouridine (5'-DFUR)
- Cyclophosphamide (Cytoxan) – oral equivalent to intravenous cyclophosphamide
- Etoposide (Etopophos, VP-16) – water-soluble prodrug of etoposide phosphate
- Melphalan (Alkeran) – an oral equivalent to intravenous melphalan
- Methotrexate (Rheumatrex, Amethopterin) – oral equivalent to intravenous methotrexate
- Temozolomide (Temodar) – oral equivalent to intravenous Temodar
- Topotecan (Hycamtin) – oral equivalent to intravenous topotecan
- Oforta (Fludarabine Phosphate) oral equivalent to intravenous fludarabine phosphate

POLICY STATEMENT

Coverage will be provided for oral chemotherapy medications when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

BENEFIT APPLICATION

Please refer to the member's individual Evidence of Coverage (EOC) for benefit determination. Coverage will be approved according to the EOC limitations if the criteria are met.

Coverage decisions for will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCDs);
- General coverage guidelines included in Original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (EOC), the EOC always governs the determination of benefits.

INDICATIONS FOR COVERAGE

PART B COVERAGE CRITERIA:

A. Preauthorization by the Plan may be required;

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

- a) It is a drug or biological that has been approved by the Food and Drug Administration (FDA), **and**
- b) The drug 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**
- c) The drug is used for the same anticancer indications, including unlabeled uses as the non-self-administrable form of the drug, **and**
- d) The drug is prescribed by a physician or other practitioner licensed under state law to prescribe such drugs as anticancer chemotherapeutic agents.

The anticancer medications are used to treat multiple diagnoses. These diagnoses can be viewed in the Medicare Local Coverage Article for Oral Anticancer Drugs (A52479).

2. Antiemetic Drugs Used with Oral Anticancer (Chemotherapy) Drugs.

1. A self-administered drug (J8498 or J8597) is covered under Part B if **all** of the following criteria are met:
 - a. It is used in conjunction with a covered oral anti-cancer drug,

AND

- b. It is likely that administration of the covered oral anti-cancer drug will induce emesis if the antiemetic drug is not administered,

AND

- c. The antiemetic drug is administered within two (2) hours before the covered oral anti-cancer drug is administered.

Note: 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.

WHEN COVERAGE WILL NOT BE APPROVED UNDER PART B BENEFIT

1. If Part B criteria a-d is not met, the drug will be denied as non-covered under the Part B medical benefit.
2. 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 not covered.

PART D COVERAGE CRITERIA:**Preauthorization by the Plan is required;**

1. If the above criteria are not met for coverage under the Part B benefit, the medication may be covered under Part D if:
 - a. The medication is administered for an FDA approved use;
 - b. The medication is on a prescription from a physician;
 - c. The medication is used and sold in the United States
 - d. The medication is used for a medically accepted indication.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

Applicable Codes: J8498, J8510, J8520, J8521, J8530, J8560, J8562, J8597, J8600, J8610, J8700, J8705, J8999, Q0511, Q0512

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

SPECIAL NOTES

- An anticancer drug that is not available as a replacement for an injectable form does not meet the Part B criterion #1b. For example, those oral anticancer drugs that are not specifically listed in this policy, as indicated in LCD L33826. However, it could be covered under the Part D benefit.

- If an oral anticancer drug is used for immunosuppression (rather than the treatment of cancer), Part B criterion #1c is not met, and the drug cannot be covered under the oral anticancer Part B drug benefit.

References:

1. Medicare Local Coverage Determination for Oral Anti-cancer Drugs – CGS Administrators (L33826); Effective date: 10/01/2015; accessed via [LCD - Oral Anticancer Drugs \(L33826\) \(cms.gov\)](#) on 09/29/2023.
2. Medicare Local Coverage Article for Oral Anticancer Drugs for Oral Anti-cancer Drugs (A52479); Effective date: 10/01/2015; accessed via [Article - Oral Anticancer Drugs - Policy Article \(A52479\) \(cms.gov\)](#) on 09/29/2023.

Policy Implementation/Update Information:

Revision Date: New policy June 17, 2009; October 2012- minor edits

Revision Date: Annual Review; no CMS updates; updated reference section.

Revision Date: Staff clarification; Description of Procedure/Service – added references of IV equivalents to the oral drugs for confirmation to item #1b under Indications For Coverage, also added item #2 from the Oral Antiemetics medical policy per Medical Director recommendation for continuity with CMS guidance; When Coverage Will Not Be Approved, added item #2 from the Oral Antiemetics medical policy for continuity with CMS guidance; updated language under Special Notes to include example of oral anticancer drugs that do not meet criteria under Indications For Coverage – item #1b and item #2 as referenced in the Oral Anticancer LCD.

Revision Date: January 17, 2018; Annual Review; No CMS Updates. Minor Revisions Only.

Revision Date: January 15, 2020; Annual Review; No CMS Updates. Minor Revisions Only.

Revision Date: January 19, 2022; Annual Review; No CMS Updates. Minor Revisions Only.

Revision Date: October 18, 2023; Annual Review; No CMS Updates; Verbiage and HCPCs codes added to reflect LCD/LCA.

Approval Dates:

Medical Coverage Policy Committee: October 18, 2023

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