Medicare C/D Medical Coverage Policy

Oral Chemotherapy Medications

Origination: June 17, 2009
Review Date: March 15, 2010
Next Review: March 2012

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)
- Capecitabine (Xeloda)
- Cyclophosphamide (Cytoxan)
- Etoposide (Etopophos, VP-16)
- Melphalan (Alkeran)
- Methotrexate (Rheumatrex, Amethopterin)
- Temozolomide (Temodar)
- Topotecan (Hycamtion)

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 (E.O.C.) for benefit determination. Coverage will be approved according to the E.O.C. limitations if the criteria are met.

Coverage decisions for will be made in accordance with:
- The Centers for Medicare & Medicaid Services (CMS) national coverage decisions;
- General coverage guidelines included in original Medicare manuals unless superseded by operational policy letters or regulations; and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 (E.O.C.), the E.O.C. always governs the determination of benefits.

**CRITERIA REQUIRED FOR COVERAGE APPROVAL**

**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 indications, including unlabeled uses, as the non-self-administrable form of the drug
         - busulfan,
         - capecitabine,
         - cyclophosphamide,
         - etoposide,
         - melphalan,
         - methotrexate, or
         - temozolomide.
      2) Prescribed for the treatment of relapsed small cell lung (ICD-9 codes 162.2-162.9):
         - topotecan and

   d) The drug is prescribed by a physician or other practitioner licensed under state law to prescribe such drugs as anticancer chemotherapeutic agents.
WHEN COVERAGE WILL NOT BE APPROVED UNDER PART B BENEFIT
If Part B criteria a-d are not met, the drug will be denied as non-covered under the Part B medical benefit.

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: J8510, J8600, J8610, J8520, J8560, 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
• A drug that is not a replacement for an injectable form does not meet the Part B criterion #1b. 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 Chemotherapy Agents (ID#L23530); Effective date: 11/12/09; Accessed via Internet site www.cms.hhs.gov/mcd/viewlcd on 11/2/09.
2. Medicare Article for Oral Anticancer Drugs (ID#A25619); Effective date: 10/1/09; Accessed via Internet site www.cms.hhs.gov/mcd/viewarticle on 10/22/09.
3. Medicare Local Coverage Determination for Oral Anti-cancer Drugs (ID#L11559); Effective date: 4/1/08; Accessed via Internet site www.cms.hhs.gov/mcd/viewlcd on 11/2/09.

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