



Corporate Medical Policy

Chemotherapy for Malignant Disease

File Name: chemotherapy_for_malignant_disease
Policy Number: DRU4030
Origination: 6/1989
Last Review: 6/2009

Active policy, no longer scheduled for routine literature review.

Description of Procedure or Service

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. Chemotherapy may be used in the following ways:

- ◆ As a first line therapy for advanced malignant disease,
- ◆ As an [adjunct](#) to local treatment, i.e., following surgery to remove the malignancy,
- ◆ As a primary treatment for localized malignant disease,
- ◆ For direct instillation to the site affected by the malignant disease.

Please note that for the purpose of BCBSNC policy, the **Food and Drug Administration's (FDA)** approval means full, unrestricted market approval. Off-labeled indications (using a drug for a purpose other than what the FDA approved it for) may also be covered. **Please see "Policy" below for medical guidelines for when off-labeled use may be covered.**

Policy

BCBSNC covers Chemotherapeutic drugs when they are considered medically necessary because the criteria listed below have been met.

Benefits Application

Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

When Chemotherapy is covered

When both of the following criteria are met:

1. The drug *must be approved by the FDA*

Policy: Chemotherapy for Malignant Disease

2. The drug must have been proven effective and accepted for the treatment of the specific type of cancer for which the drug has been prescribed in any one of the following established reference compendia:

- a. The National Comprehensive Cancer Network Drugs & Biologics Compendium,
- b. The ThomsonMicromedex DrugDex,
- c. The Elsevier Gold Standard's Clinical Pharmacology, or
- d. Any other authoritative compendia as recognized periodically by the United States Secretary of Health and Human Services.

***Note:

Once a particular chemotherapeutic drug has received full and unrestricted FDA market approval, the Plan will provide benefits for additional indications ("off label use") when an additional indication is recognized by any one of the reference compendia listed above and has shown to be effective and accepted for treatment of the cancer for which it has been prescribed.

When Chemotherapy is not covered

1. when the appropriate FDA approval has not been granted (See Description of Service.)
2. when the chemotherapeutic drug is not listed in one of the above medical reference sources
3. when the chemotherapeutic drug has not proven to be an effective or accepted treatment for the diagnosis for which administration of the chemotherapeutic drug is anticipated.

Policy Guidelines

The NC state statute 58-51-59 states "coverage shall not be required for any experimental or investigational drugs or any drug that the federal Food and Drug Administration has determined to be contraindicated for treatment of the specific type of cancer for which the drug has been prescribed.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 96401, 96402, 96405, 96406, 96409, 96411, 96413, 96415, 96416, 96417, 96420, 96422, 96423, 96425, 96440, 96445, 96450, 96542, 96549.

BCBSNC 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.

Policy: Chemotherapy for Malignant Disease

Medical Term Definitions

Adjunct

a supplement to the primary treatment.

Scientific Background and Reference Sources

Senior Director, Medical Affairs

Certificate provisions defining investigational.

North Carolina General Statutes: 58-51-59

Devita, Vincent T., Jr., et al. Cancer Principles and Practice of Oncology.

5th ed. Lippincott-Raven, Philadelphia, 1997. pp 333, 375, 383.

Specialty Matched Consultant Advisory Panel 11/1999

Medical Policy Advisory Group 12/2/1999

Specialty Matched Consultant Advisory Panel - 11/2001

Specialty Matched Consultant Advisory Panel - 10/2003

Specialty Matched Consultant Advisory Panel - 9-2005

North Carolina General Statutes: 58-51-59, House Bill 896, Session 2009.

Senior Medical Director 6/2009

Policy Implementation/Update Information

- 2/96 Revised: Clarification of policy guidelines
- 10/96 Revised: Added General Statutes identification number
- 1/98 Revised: Removed statements regarding review of medical literature by Medical Director when additional indications for use are not found in the 3 compendia. Added statement from the NC general statutes regarding indications not found to be safe and effective or that have been contraindicated by the FDA.
- 11/98 Revised: Removed statement "Plan Pharmacist is to refer the case to Medical Affairs for review by the Medical Director." Replaced with "the case should be referred back to the referring Medical Director for denial.
- 6/99 Reformatted, "Description of Procedure or Service" revised, Medical Term Definitions added.
- 12/99 Reaffirmed, Medical Policy Advisory Panel
- 7/00 System coding changes.
- 11/01 Specialty Matched Consultant Advisory Panel. No changes. Typos corrected.
- 11/03 Specialty Matched Consultant Advisory Panel review. Updated Benefit Application and Billing and Coding sections of the policy. No change to criteria.
- 10/8/05 Specialty Matched Consultant Advisory Panel review 9/19/2005. No changes to criteria. Policy status changed to "Active policy, no longer scheduled for routine review." References added.

Policy: Chemotherapy for Malignant Disease

- 1/5/06 Added new 2006 CPT codes 96401, 96402, 96409, 96411, 96413, 96415, 96416, 96417, and 96420 to the "Billing/Coding" section. Removed deleted CPT codes 96400, 96408, 96410, 96412, and 96414.
- 8/3/09 Updated #2 under the "When Covered" section. Removed "a. The American Medical Association Drug Evaluation; b. The American Hospital Formulary Service Drug Information; c. The United States Pharmacopeia Drug Information." Replaced with "a. The National Comprehensive Cancer Network Drugs & Biologics Compendium; or b. The ThomsonMicromedex DrugDex; or c. The Elsevier Gold Standard's Clinical Pharmacology; or d. Any other authoritative compendia as recognized periodically by the United States Secretary of Health and Human Services." as mandated by the North Carolina General Assembly, Session 2009, House Bill 896. References added. (btw)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.