POLICY Document for Gemzar (gemcitabine) gemcitabine (generic)

The overall objective of this policy is to support the appropriate and cost effective use of the medication. This document provides specific information to each section of the overall policy.

Section 1: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 2: Oncology Clinical Policy

- Policy information specific to regimen review per NCCN Guidelines.

Section 1: Clinical Criteria

SPECIALTY GUIDELINE MANAGEMENT
Gemzar (gemcitabine) gemcitabine (generic)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. In combination with carboplatin for the treatment of patients with advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy

2. In combination with paclitaxel for the first-line treatment of patients with metastatic breast cancer after failure of prior anthracycline-containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated

3. In combination with cisplatin for the first-line treatment of patients with inoperable, locally advanced (Stage IIIA or IIIB), or metastatic (Stage IV) non-small cell lung cancer

4. As first-line treatment for patients with locally advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) adenocarcinoma of the pancreas. Gemcitabine is indicated for patients previously treated with 5-FU.

Compendial Uses

1. Bladder cancer, primary carcinoma of the urethra, upper genitourinary tract tumors, urothelial carcinoma of the prostate, non-urothelial and urothelial cancer with variant histology
2. Bone cancer
   o Ewing’s sarcoma family of tumors
   o osteosarcoma
3. Breast cancer
4. Head and neck cancers
   • nasopharyngeal cancer
5. Hepatobiliary cancers
   • extrahepatic cholangiocarcinoma
   • gallbladder cancer
   • intrahepatic cholangiocarcinoma
6. Hodgkin lymphoma
7. Kidney cancer
8. Malignant pleural mesothelioma
10. Non-small cell lung cancer (NSCLC)
11. Occult primary
12. Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer
13. Pancreatic adenocarcinoma
14. Small cell lung cancer (SCLC)
15. Soft tissue sarcoma (STS)
16. Testicular cancer
17. Thymomas/thymic carcinomas
18. Uterine sarcoma
19. AIDS-Related Kaposi Sarcoma

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Pancreatic Adenocarcinoma
   Authorization of 12 months may be granted for the treatment of pancreatic adenocarcinoma.

B. Breast Cancer
   Authorization of 12 months may be granted for the treatment of recurrent or metastatic breast cancer.

C. Intrahepatic and Extrahepatic Cholangiocarcinoma and Gallbladder Cancer
   Authorization of 12 months may be granted for the treatment of intrahepatic and extrahepatic cholangiocarcinoma and gallbladder cancer.

D. Epithelial Ovarian Cancer, Fallopian Tube Cancer, Primary Peritoneal Cancer
   Authorization of 12 months may be granted for the treatment of epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer.

E. Non-Small Cell Lung Cancer (NSCLC)
   Authorization of 12 months may be granted for the treatment of NSCLC.

F. Bladder Cancer, Primary Carcinoma of the Urethra, Upper Genitourinary Tract Tumors, Urothelial Carcinoma of the Prostate, Non-Urothelial and Urothelial cancer with Variant Histology
Authorization of 12 months may be granted for the treatment of bladder cancer, primary carcinoma of the urethra, upper genitourinary tract tumors, urothelial carcinoma of the prostate, and non-urothelial and urothelial cancer with variant histology.

G. Small Cell Lung Cancer (SCLC)
Authorization of 12 months may be granted for the treatment of SCLC.

H. Soft Tissue Sarcoma
Authorization of 12 months may be granted for the treatment of soft tissue sarcoma.

I. Bone Cancer
Authorization of 12 months may be granted for the treatment of Ewing's sarcoma and osteosarcoma.

J. Nasopharyngeal Cancer
Authorization of 12 months may be granted for the treatment of nasopharyngeal cancer.

K. Hodgkin Lymphoma
Authorization of 12 months may be granted for the treatment of Hodgkin lymphoma.

L. Kidney Cancer
Authorization of 12 months may be granted for the treatment of kidney cancer.

M. Malignant Pleural Mesothelioma
Authorization of 12 months may be granted for the treatment of malignant pleural mesothelioma.

N. Non-Hodgkin’s Lymphoma (NHL)
Authorization of 12 months may be granted for the treatment of NHL.

O. Occult Primary Tumors (cancer of unknown primary)
Authorization of 12 months may be granted for the treatment of occult primary tumors.

P. Testicular Cancer
Authorization of 12 months may be granted for the treatment of testicular cancer.

Q. Thymomas and Thymic Carcinomas
Authorization of 12 months may be granted for the treatment of thymomas and thymic carcinomas.

R. Uterine Sarcoma
Authorization of 12 months may be granted for the treatment of uterine sarcoma.

S. AIDS-Related Kaposi Sarcoma
Authorization of 12 months may be granted for the treatment of AIDS-Related Kaposi Sarcoma.

III. CONTINUATION OF THERAPY
All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

Section 2: Oncology Clinical Policy
Oncology Clinical Policy

Program Description
The National Comprehensive Care Network® (NCCN®) is an alliance of leading cancer centers devoted to patient care, research and education dedicated to improving the quality, effectiveness and efficiency of cancer care so patients can live better lives.¹ It is comprised of oncology experts who convene regularly to establish the best treatments for patients. NCCN develops various resources for use by stakeholders in the health care delivery system. These resources include, but are not limited to, the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), the NCCN Drugs & Biologics Compendium (NCCN Compendium®) and the NCCN Chemotherapy Order Templates (NCCN Templates®).

NCCN templates are based on NCCN Clinical Practice Guidelines and NCCN Compendium. The NCCN Compendium lists the appropriate drugs and biologics for specific cancers using U.S. Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category.

NCCN Categories of Evidence and Consensus²
- Category 1: Based on high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2A: Based on lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2B: Based on lower-level evidence, there is NCCN consensus that the intervention is appropriate.
- Category 3: Based on any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

Policy for Regimen Prior Authorization
A regimen prior authorization allows submission of a single prior authorization request for all oncology drugs or biologics within an NCCN template that require prior authorization.

This policy provides coverage of a regimen review when all of the following criteria are met:
- Regimen prior authorization reviews, based on NCCN templates, are initiated through the provider portal: https://provider.carefirst.com/providers/home.page
- The regimen prior authorization request is submitted via phone or fax, each drug or biologic will need to be submitted and reviewed as a separate prior authorization request for review with drug-specific criteria.
- The prior authorization review is requested for an oncology drug or biologic that requires prior authorization on the medical benefit.
- The indication is for a cancer that is eligible for regimen review. Currently, the cancer types in scope for regimen review include breast, lung, colon and rectal cancer.
- The member is eligible for regimen review.

In addition, the following criteria must be met for approval:
1. The requested regimen for the drug(s) or biologic(s) and indication is consistent with an NCCN recommendation with a level of evidence category of 1 or 2A.
2. The NCCN template must be accepted by the provider without modification.

Authorizations may be granted for 12 months.
Further review may be indicated where the above criteria are not met.

Continuation of Therapy
To submit a request for continuation of therapy, a new regimen prior authorization review must be requested. Upon template selection, the template must be modified to include the appropriate therapies being used for maintenance treatment. The regimen request will be submitted for further review.

Dosage and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia and/or evidence-based practice guidelines.

REFERENCES:

SECTION 1


SECTION 2