POLICY Document for ELOXATIN (oxaliplatin) oxaliplatin

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections 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

Medical Prior Authorization oxaliplatin

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
oxaliplatin (all brands)	oxaliplatin

Indications

FDA-approved Indications

Oxaliplatin, in combination with infusional fluorouracil and leucovorin, is indicated for:

- Adjuvant treatment of stage III colon cancer in patients who have undergone complete resection of the primary tumor.
- Treatment of advanced colorectal cancer.

Compendial Uses

Colon cancer
Rectal cancer

Esophageal or esophagogastric junction cancers
Gastric cancer
Hepatobiliary cancers
    Extrahepatic cholangiocarcinoma
    Intrahepatic cholangiocarcinoma
    Gallbladder cancer
Bladder cancer (including non-urothelial and urothelial cancer with variant histology)
Neuroendocrine and adrenal tumors
    - Neuroendocrine tumors of the gastrointestinal tract, lung, and thymus
    - Neuroendocrine tumors of the pancreas
    - Well differentiated grade 3 neuroendocrine tumors
    - Poorly differentiated/large or small cell disease/mixed neuroendocrine-non-neuroendocrine neoplasms

- Occult primary tumors (cancer of unknown primary)
- Ovarian cancer, fallopian tube cancer, and primary peritoneal cancer
    - Epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer
    - Carcinosarcoma (malignant mixed Müllerian tumors)
    - Clear cell carcinoma of the ovary
    - Mucinous carcinoma of the ovary
    - Grade 1 endometrioid carcinoma
    - Low-grade serous carcinoma/ovarian borderline epithelial tumors (low malignant potential)
    - Malignant germ cell tumors
- Pancreatic adenocarcinoma
- Testicular cancer
- Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL)
- Anal carcinoma
- B-Cell lymphomas
    - Histologic Transformation of Indolent Lymphomas to Diffuse Large B-Cell Lymphoma
    - Mantle Cell Lymphoma
    - Diffuse Large B-Cell Lymphoma
    - High-Grade B-Cell Lymphomas
    - Human immunodeficiency virus (HIV)-Related B-Cell Lymphomas
    - Post-Transplant Lymphoproliferative Disorders
- Primary cutaneous lymphomas
    - Mycosis fungoides/Sezary syndrome
    - Primary cutaneous CD30+ T-Cell lymphoproliferative disorders
- T-Cell lymphomas
    - Peripheral T-Cell lymphomas
    - Adult T-Cell leukemia/lymphoma
    - Extranodal natural killer (NK)/T-Cell lymphoma
    - Hepatosplenic T-Cell lymphoma
    - Breast Implant-Associated Anaplastic Large Cell Lymphoma (ALCL)
- Classic Hodgkin lymphoma
- Small bowel adenocarcinoma

- Ampullary adenocarcinoma
- Nasopharyngeal carcinoma

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Colorectal Cancer

Authorization of 6 months may be granted for treatment of colorectal cancer (including appendiceal adenocarcinoma, anal adenocarcinoma, and colon and rectal cancers).

Pancreatic Adenocarcinoma

Authorization of 6 months may be granted for treatment of pancreatic adenocarcinoma.

Esophageal and Esophagogastric Junction Cancers

Authorization of 6 months may be granted for treatment of esophageal and esophagogastric junction cancers.

Gastric Cancer

Authorization of 6 months may be granted for treatment of gastric cancer.

Biliary Tract Cancers

Authorization of 6 months may be granted for treatment of biliary tract cancers (including intrahepatic and extrahepatic cholangiocarcinoma and gallbladder cancer).

Neuroendocrine and Adrenal Tumors

Authorization of 6 months may be granted for treatment of neuroendocrine and adrenal tumors (including neuroendocrine tumors of the gastrointestinal tract, lung, and thymus, neuroendocrine tumors of the pancreas, well differentiated grade 3 neuroendocrine tumors and poorly differentiated/large or small cell carcinoma/mixed neuroendocrine-non-neuroendocrine neoplasms).

Occult Primary Tumors (cancer of unknown primary)

Authorization for 6 months may be granted for treatment of occult primary tumors.

Ovarian Cancer, Fallopian Tube Cancer, and Primary Peritoneal Cancer

Authorization of 6 months may be granted for treatment of epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Müllerian tumors), clear cell carcinoma of the ovary, mucinous carcinoma of the ovary, grade 1 endometrioid carcinoma, low-grade

serous carcinoma/ovarian borderline epithelial tumors (low malignant potential), and malignant germ cell tumor residual disease.

Testicular Cancer

Authorization of 6 months may be granted for treatment of testicular cancer.

Bladder Cancer

Authorization of 6 months may be granted for treatment of bladder cancer (including non-urothelial and urothelial cancer with variant histology).

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)

Authorization of 6 months may be granted for treatment of CLL/SLL.

Anal Carcinoma

Authorization of 6 months may be granted for treatment of metastatic anal cancer.

B-Cell Lymphomas

Authorization of 6 months may be granted for treatment of B-Cell lymphomas (including histologic transformation of indolent lymphomas to diffuse large B-Cell lymphoma, mantle cell lymphoma, diffuse large B-Cell lymphoma, high-grade B-Cell lymphomas, HIV-Related B-Cell lymphomas, and post-transplant lymphoproliferative disorders).

Primary Cutaneous Lymphomas

Authorization of 6 months may be granted for treatment of primary cutaneous lymphomas (including mycosis fungoides/Sezary syndrome and primary cutaneous CD30+ T-Cell lymphoproliferative disorders).

T-Cell Lymphomas

Authorization of 6 months may be granted for treatment of T-Cell lymphomas (including peripheral T-Cell lymphomas, adult T-Cell leukemia/lymphoma, hepatosplenic T-Cell lymphoma, extranodal NK/T-Cell lymphoma, and breast implant-associated ALCL).

Classic Hodgkin Lymphoma

Authorization of 6 months may be granted for treatment of classic Hodgkin lymphoma.

Small Bowel Adenocarcinoma

Authorization of 6 months may be granted for treatment of small bowel adenocarcinoma.

Ampullary Adenocarcinoma

Authorization of 6 months may be granted for treatment of ampullary adenocarcinoma.

Nasopharyngeal Carcinoma

Authorization of 6 months may be granted for treatment of nasopharyngeal carcinoma as concurrent chemoradiation for members with a contraindication to cisplatin.

Continuation of Therapy

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Section 2: Oncology Clinical Policy

PURPOSE

The purpose of this policy is to define the Novologix NCCN® Regimen Prior Authorization Program.

SCOPE

This policy applies to clients who have implemented the Novologix NCCN® Program as a part of their medical and/or pharmacy prior authorization solution.

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 Guidelines® and NCCN Compendium®. The NCCN Compendium lists the appropriate drugs and biologics as treatment options 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 Consensus[2]

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

POLICY

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.

PROCEDURE

This policy provides coverage of a regimen review when all of the following criteria are met:
1. Regimen prior authorization reviews, based on NCCN templates, are initiated through the provider portal.
   - If the 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.
2. The prior authorization review is requested for an oncology drug or biologic.
3. The member is eligible for regimen review.
4. The indication is for a cancer that is eligible for regimen review. Currently, the cancer types in scope for regimen review include the following:
   - Ampullary Adenocarcinoma
   - Anal Carcinoma
   - B-Cell Lymphomas
   - Basal Cell Skin Cancer
   - Biliary Tract Cancers
   - Bone Cancer
   - Breast Cancer
   - Bladder Cancer
   - Central Nervous System Cancers
   - Cervical Cancer
   - Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
   - Chronic Myeloid leukemia
   - Colon Cancer
   - Dermatofibrosarcoma Protuberans
   - Esophageal Cancer
   - Gastric Cancer
   - Gastrointestinal Stromal Tumors
   - Gestational Trophoblastic Neoplasms
   - Hairy Cell Leukemia
   - Head and Neck Cancers

- Histiocytic Neoplasms
- Hodgkin Lymphoma
- Hepatocellular Carcinoma
- Kaposi Sarcoma
- Kidney Cancer
- Melanoma: Cutaneous
- Melanoma: Uveal
- Merkel Cell Carcinoma
- Mesothelioma: Peritoneal
- Mesothelioma: Pleural
- Multiple Myeloma
- Myelodysplastic Syndromes
- Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions
- Myeloproliferative Neoplasms
- Neuroendocrine and Adrenal Tumors
- Non-Small Cell Lung Cancer
- Occult Primary
- Ovarian Cancer
- Pancreatic Cancer
- Penile Cancer
- Primary Cutaneous Lymphomas
- Prostate Cancer
- Rectal Cancer
- Small Bowl Adenocarcinoma
- Small Cell Lung Cancer
- Soft Tissue Sarcoma
- Squamous Cell Skin Cancer
- Systemic Mastocytosis
- Systemic Light Chain Amyloidosis
- T-Cell Lymphomas
- Testicular Cancer
- Thymomas and Thymic Carcinomas
- Thyroid Carcinoma
- Uterine Neoplasms
- Vaginal Cancer
- Vulvar Cancer
- Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma
- Wilms Tumor (Nephroblastoma)

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.

Further review may be indicated when the above criteria are not met.

Authorizations may be granted for 12 months or as medically required, based on the member's condition and provider's assessment.

Supportive Care: Myeloid Growth Factor Therapy
Granulocyte colony stimulating factors are recommended for primary prophylaxis based on the febrile neutropenia risk of the chemotherapy regimen. Febrile neutropenia risk levels vary by NCCN Chemotherapy Order template and are listed at the top of the template. Regimens associated with a high or intermediate risk of febrile neutropenia may include a granulocyte colony stimulating factor as part of the prior authorization.

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 evidence-based practice guidelines.

REFERENCES:

SECTION 1

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3. Lexicomp [database online]. Hudson, OH: Lexi-Comp, Inc. Available at: https://online.lexi.com/lco/action/home [available with subscription]. Accessed July 1, 2024.
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SECTION 2

1. National Comprehensive Cancer Network. About NCCN website. https://www.nccn.org/home/about, accessed September 9, 2024.
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3. National Comprehensive Cancer Network. NCCN Guidelines website. https://www.nccn.org/guidelines/category_1, accessed September 9, 2024. (Note: An account may be required.)
4. National Comprehensive Cancer Network. NCCN Drugs and Biologics Compendium website https://www.nccn.org/compendia-templates/compendia/drugs-and-biologics-compendia, accessed September 9, 2024. (Note: A subscription may be required.)
5. 5. National Comprehensive Cancer Network. NCCN Chemotherapy Order Templates (NCCN Templates)

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