

MEDICAL PRIOR AUTHORIZATION

ELOXATIN (oxaliplatin) oxaliplatin

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.

A. FDA-Approved Indications

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

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

B. Compendial Uses

1. Colon cancer
2. Rectal cancer
3. Esophageal or esophagogastric junction cancers
4. Gastric cancer
5. Hepatobiliary cancers
 - a. Extrahepatic cholangiocarcinoma
 - b. Intrahepatic cholangiocarcinoma
 - c. Gallbladder cancer
6. Bladder cancer (including non-urothelial and urothelial cancer with variant histology)
7. Neuroendocrine and adrenal tumors
 - a. Neuroendocrine tumors of the gastrointestinal tract, lung, and thymus
 - b. Neuroendocrine tumors of the pancreas
 - c. Well differentiated grade 3 neuroendocrine tumors
 - d. Poorly differentiated/large or small cell disease/mixed neuroendocrine-non-neuroendocrine neoplasms
8. Occult primary tumors (cancer of unknown primary)
9. Ovarian cancer, fallopian tube cancer, and primary peritoneal cancer
 - a. Epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer
 - b. Carcinosarcoma (malignant mixed Müllerian tumors)
 - c. Clear cell carcinoma of the ovary
 - d. Mucinous carcinoma of the ovary
 - e. Grade 1 endometrioid carcinoma
 - f. Low-grade serous carcinoma/ovarian borderline epithelial tumors (low malignant potential)
 - g. Malignant germ cell tumors
10. Pancreatic adenocarcinoma
11. Testicular cancer
12. Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL)
13. Anal carcinoma
14. B-Cell lymphomas
 - a. Follicular lymphoma (grade 1-2)

- b. Histologic Transformation of Indolent Lymphomas to Diffuse Large B-Cell Lymphoma
- c. Mantle Cell Lymphoma
- d. Diffuse Large B-Cell Lymphoma
- e. High-Grade B-Cell Lymphomas
- f. Human immunodeficiency virus (HIV)-Related B-Cell Lymphomas
- g. Post-Transplant Lymphoproliferative Disorders
- 15. Primary cutaneous lymphomas
 - a. Mycosis fungoides/Sezary syndrome
 - b. Primary cutaneous CD30+ T-Cell lymphoproliferative disorders
- 16. T-Cell lymphomas
 - a. Peripheral T-Cell lymphomas
 - b. Adult T-Cell leukemia/lymphoma
 - c. Extranodal natural killer (NK)/T-Cell lymphoma
 - d. Hepatosplenic T-Cell lymphoma
 - e. Breast Implant-Associated Anaplastic Large Cell Lymphoma (ALCL)
- 17. Classic Hodgkin lymphoma
- 18. Small bowel adenocarcinoma
- 19. Ampullary adenocarcinoma

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

II. CRITERIA FOR INITIAL APPROVAL

A. Colorectal Cancer

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

B. Pancreatic Adenocarcinoma

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

C. Esophageal and Esophagogastric Junction Cancers

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

D. Gastric Cancer

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

E. Biliary Tract Cancers

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

F. 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).

G. Occult Primary Tumors (cancer of unknown primary)

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

H. Ovarian Cancer, Fallopian Tube Cancer, and Primary Peritoneal Cancer

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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.

I. Testicular Cancer

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

J. Bladder Cancer

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

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

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

L. Anal Carcinoma

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

M. B-Cell Lymphomas

Authorization of 6 months may be granted for treatment of B-Cell lymphomas (including follicular lymphoma [grade 1-2], 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).

N. 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).

O. 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).

P. Classic Hodgkin Lymphoma

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

Q. Small Bowel Adenocarcinoma

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

R. Ampullary Adenocarcinoma

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

III. CONTINUATION OF THERAPY

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

IV. REFERENCES

Reference number(s)
2041-A

1. Eloxatin [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; June 2023.
2. Oxaliplatin [package insert]. Lake Forest, IL: Hospira, Inc.; April 2021.
3. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. July 13, 2023.
4. Lexicomp [database online]. Hudson, OH: Lexi-Comp, Inc. Available at: <https://online.lexi.com/lco/action/home> [available with subscription]. Accessed July 13, 2023.