

## SPECIALTY GUIDELINE MANAGEMENT

### 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
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
  - d. Mucinous carcinoma
  - e. Grade 1 endometrioid carcinoma
  - f. Low-grade serous carcinoma/ovarian borderline epithelial tumors (low malignant potential) with invasive implants
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 nodal Marginal Zone Lymphoma to Diffuse Large B-Cell Lymphoma
- c. Mantle Cell Lymphoma
- d. Diffuse Large B-Cell Lymphoma
- e. High-Grade B-Cell Lymphomas
- f. AIDS-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 NK/T-Cell lymphoma, nasal type
  - d. Hepatosplenic T-Cell lymphoma
  - e. Breast Implant-Associated Anaplastic Large Cell Lymphoma (ALCL)
- 17. Classic Hodgkin lymphoma
- 18. Small bowel 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. Hepatobiliary Cancers

Authorization of 6 months may be granted for treatment of hepatobiliary 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 disease).

### 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

**1. Ovarian Cancer, Fallopian Tube Cancer, and Primary Peritoneal Cancer**

Authorization of 6 months may be granted for treatment of persistent or recurrent epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Müllerian tumors), clear cell carcinoma, grade 1 endometrioid carcinoma, and low-grade serous carcinoma/ovarian borderline epithelial tumors (low malignant potential) with invasive implants.

**2. Mucinous Carcinoma**

Authorization of 6 months may be granted for treatment of mucinous carcinoma.

**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 nodal marginal zone lymphoma to diffuse large B-Cell lymphoma, mantle cell lymphoma, diffuse large B-Cell lymphoma, high-grade B-Cell lymphomas, AIDS-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 NKT/T-Cell lymphoma (nasal type), 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, including advanced ampullary cancer.

**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.

Reference number(s)
2041-A

#### IV. REFERENCES

1. Eloxatin [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; April 2020.
2. Oxaliplatin [package insert]. Sunrise, FL: Cipla USA, Inc.; May 2020.
3. The NCCN Drugs & Biologics Compendium 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. July 14, 2021.
4. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; [http://online.lexi.com/lco/action/index/dataset/complete\\_ashp](http://online.lexi.com/lco/action/index/dataset/complete_ashp) [available with subscription]. Accessed July 14, 2021.
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7. Clinical Pharmacology [database online]. Tampa, FL: Elsevier; <https://www.clinicalkey.com/pharmacology> [available with subscription]. Accessed July 14, 2021.