

Oxaliplatin (Eloxatin™)	
<input checked="" type="checkbox"/> Original	Original Committee Approval: 12/3/08
<input type="checkbox"/> Revised	Last Committee Approval: 12/3/08
	Last Review: October 2008

Background

Oxaliplatin (Eloxatin™, a trademark of Sanofi-Synthelab, Inc.) is a new 3rd-generation organoplatinum analog. It is used as an infusible cancer chemotherapeutic agent. Its putative mechanism of action is via the formation of reactive platinum complexes, which inhibit DNA synthesis by forming inter-strand and intra-strand cross-linking of DNA molecules. Such action is cytotoxic in disrupting DNA replication and transcription.

Oxaliplatin was initially approved by the FDA in August 2002, in combination with infusional 5-fluorouracil (5-FU) and leucovorin (LV), for the treatment of patients with metastatic (advanced) colorectal cancer whose disease had proved refractory to first-line therapy with other agents. Subsequent to this, it has received FDA approval and National Comprehensive Cancer Network (NCCN) recommendations for other indications as specified below.

Indications/Criteria

Oxaliplatin is considered medically necessary for the following indications:

Rectal or Colon Cancer

- In combination with infusional 5-fluorouracil/leucovorin for the initial treatment of advanced rectal or colon carcinoma (FOLFOX regimen).
- In combination with capecitabine for advanced or metastatic rectal or colon carcinoma (CapeOX regimen).
- As part of the FOLFOX regimen for the treatment of Stage IV disease with resectable liver metastases
- In combination with infusional 5-fluorouracil/leucovorin for adjuvant (post-operative) treatment of stage III colon cancer with previous complete resection of the primary tumor.

Gastric or Gastroesophageal Junction Adenocarcinoma

- When chemoradiation is not recommended, in combination with 5-FU or capecitabine for metastatic or locally advanced disease.

Oxaliplatin is considered experimental and investigational for the following conditions:

- Esophageal cancer
- Pancreatic adenocarcinoma
- Ovarian cancer

Special Considerations

Pulmonary Fibrosis

Pulmonary fibrosis can be a complication of Oxaliplatin therapy (<1% of study patients). This may be fatal. In case of unexplained respiratory signs and symptoms such as non-productive cough or pulmonary infiltrates on X-ray, this drug should be discontinued pending further investigation to exclude interstitial lung disease or pulmonary fibrosis.

Neuropathy

Oxaliplatin is associated with:

- An early onset, reversible, primarily peripheral, sensory neuropathy that occurs within hours or one to two days of dosing, resolves within one-two weeks, and frequently recurs with further dosing
- A persistent (>14 days), primarily peripheral, sensory neuropathy that is usually characterized by paresthesias and dysesthesias, but may also include proprioceptive deficits such as difficulty with writing and buttoning. 48% of the study patients receiving Oxaliplatin and 5-FU/LV experience some degree of this type of neuropathy. Symptom resolution may occur with some patients once the drug is discontinued.

Limitations/Exclusions

Healthy Options:	None; pre-authorization required.
Basic Health Plan:	None; pre-authorization required.
GAU:	None; pre-authorization required.
Medicare Advantage:	None; pre-authorization required.

Required Review and Approvals

Infusions require prior authorization by the CHP Medical Director or his/her designee. Each authorization period will be for six months.

All requests for this IV medication also require referral to CHP Case Management.

References

National Cancer Institute (www.cancer.gov)

Federal Drug Administration (www.fda.gov)

Facts and Comparisons 4.0 (<http://online.factsandcomparisons.com>)

Hayes, Inc. Online (www.hayesinc.com)

National Comprehensive Cancer Network, Clinical Practice Guidelines in Oncology™
(www.nccn.org)

UpToDate Online 16.2. (www.uptodate.com)

Aetna Clinical Policy Bulletin #0693 (rev. 7/18/08)