PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Zaltrap Prior Authorization Policy
- Zaltrap® (ziv-aflibercept intravenous infusion – Regeneron/Sanofi-Aventis)

REVIEW DATE: 10/19/2022

OVERVIEW

Zaltrap, a recombinant fusion protein, in combination with FOLFIRI (5-fluorouracil [5-FU], leucovorin, and irinotecan), is indicated for patients with **metastatic colorectal cancer** that is resistant to or has progressed following an oxaliplatin-containing regimen.[1]

Guidelines

The National Comprehensive Cancer Network (NCCN) **colon cancer** guidelines (version 1.2022 – February 25, 2022)[2] and **rectal cancer** guidelines (version 2.2022 – September 20, 2022)[3] recommend Zaltrap as 1) primary treatment for patients with unresectable metachronous metastases and previous adjuvant FOLFOX (5-FU, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) regimens within the past 12 months in combination with irinotecan OR with FOLFIRI, or 2) subsequent therapy after first progression of unresectable advanced or metastatic disease in combination with irinotecan or with FOLFIRI for disease not previously treated with an irinotecan-based regimen.[2-4] Both of these uses have a category 2A recommendation. In patients with advanced or metastatic disease, Zaltrap is not listed as an option for initial therapy. Zaltrap has a category 2B recommendation for use as adjuvant therapy, in combination with FOLFIRI or irinotecan, for unresectable metachronous metastases that convert to resectable disease after primary treatment.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Zaltrap. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Zaltrap as well as the monitoring required for adverse events and long-term efficacy, approval requires Zaltrap to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Zaltrap is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Colon and Rectal Cancer.** Approve for 1 year if the patient meets the following criteria (A, B, C, D, E, and F):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has advanced or metastatic disease; AND
   - **C)** Patient has been previously treated with an oxaliplatin- or fluoropyrimidine-containing regimen; AND
     Note: Fluoropyrimidines include 5-fluorouracil (5-FU) and capecitabine.
   - **D)** Patient has not previously been treated with FOLFIRI; AND

Note: FOLFIRI includes 5-fluorouracil (5-FU), leucovorin, and irinotecan.

E) Zaltrap will be used in combination with 5-fluorouracil (5-FU) or capecitabine, and/or irinotecan; AND

F) The medication is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Zaltrap is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Zaltrap® intravenous infusion [prescribing information]. Bridgewater, NJ: Regeneron/Sanofi-Aventis; June 2020.
2. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 1.2022 – February 25, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 12, 2022.
3. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – September 20, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 121, 2022.
4. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 12, 2022. Search term: ziv-aflibercept.