

Reference number(s)
1667-A

## SPECIALTY GUIDELINE MANAGEMENT

### ZALTRAP (ziv-aflibercept)

#### 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 Indication

Zaltrap is indicated for use in combination with 5-fluorouracil, leucovorin, and irinotecan (FOLFIRI) in patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen.

###### B. Compendial Uses

1. Colorectal cancer with unresectable metachronous metastases and previous adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin) within the past 12 months, as initial treatment in combination with irinotecan or FOLFIRI (fluorouracil, leucovorin, and irinotecan)
2. Colorectal cancer (including anal adenocarcinoma and appendiceal adenocarcinoma), advanced or metastatic disease in combination with irinotecan or with FOLFIRI regimen not previously treated with irinotecan-based therapy, as subsequent therapy for disease progression

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

##### II. CRITERIA FOR INITIAL APPROVAL

###### **Colorectal cancer (CRC)**

Authorization of 12 months may be granted for treatment of advanced or metastatic CRC, including anal adenocarcinoma and appendiceal adenocarcinoma, in combination with 5-fluorouracil, leucovorin, and irinotecan (FOLFIRI) or in combination with irinotecan.

##### III. CONTINUATION OF THERAPY

Authorization of 12 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

1. Zaltrap [package insert]. Bridgewater, NJ: Sanofi-aventis U.S. LLC; December 2020.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed June 23, 2023.

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3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma. Version 2.2023. [https://www.nccn.org/professionals/physician\\_gls/pdf/anal.pdf](https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf). Accessed June 23, 2023.