CVS Caremark®

|  |
| --- |
| Reference number(s) |
| 1667-A |

# Specialty Guideline Management Zaltrap

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Zaltrap | ziv-aflibercept |

## 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.

### FDA-approved Indications

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.

### Compendial Uses

* 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)
* 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.

## Coverage Criteria

### 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.

## Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

## References

1. Zaltrap [package insert]. Bridgewater, NJ: Sanofi-aventis U.S. LLC; December 2023.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 11, 2024.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma. Version 4.2024. https://www.nccn.org/professionals/physician\_gls/pdf/anal.pdf. Accessed July 11, 2024.