

Specialty Guideline Management

Fruzaqla

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
Fruzaqla	fruquintinib

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 Indications¹

Fruzaqla is indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-vascular endothelial growth factor (VEGF) therapy, and, if RAS wild-type and medically appropriate, an anti-epidermal growth factor receptor (EGFR) therapy.

Compendial Uses²

- Advanced or metastatic colon cancer
- Advanced or metastatic rectal cancer

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

Coverage Criteria

Colorectal Cancer (CRC)¹⁻⁴

Authorization of 12 months may be granted for treatment of advanced or metastatic colorectal cancer, including appendiceal adenocarcinoma and anal adenocarcinoma, as a single agent when the member has progressed on previous treatment with all the following regimens unless the member has a contraindication or intolerance:

- Fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (with or without bevacizumab); and
- If RAS mutation status is negative (wild-type) and medically appropriate, an anti-epidermal growth factor receptor (EGFR) therapy

Continuation of Therapy

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

References

1. Fruzaqla [package insert]. Cambridge, MA: Takeda Pharmaceuticals America, Inc.; February 2025.
2. The NCCN Drugs & Biologics Compendium™ © 2025 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed July 10, 2025.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Anal Carcinoma. Version 4.2025. Accessed July 15, 2025. https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf
4. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Colon Cancer. Version 4.2025. Accessed July 10, 2025. https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf