

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Fruzaqla Prior Authorization Policy

- Fruzaqla™ (fruquintinib capsules – Takeda)

**REVIEW DATE:** 01/15/2025

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### OVERVIEW

Fruzaqla, a kinase inhibitor of vascular endothelial growth factor receptors (VEGFR)-1, -2, and -3, is indicated for the treatment of **metastatic colorectal cancer** in adults 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.<sup>1</sup>

### Guidelines

The National Comprehensive Cancer Network colon (version 5.2024 – August 22, 2024) and rectal (version 4.2024 – August 22, 2024) cancer treatment guidelines recommend Fruzaqla for the subsequent treatment of advanced or metastatic colon, rectal, or appendiceal cancer as a single agent (category 2A).<sup>2-4</sup> Patients should have proficient mismatch repair/microsatellite-stable disease, or be ineligible for or progressed on checkpoint inhibitor therapy for deficient mismatch repair/microsatellite instability-high or polymerase epsilon/delta mutation positive disease. Patients should have progressed through all available regimens except Fruzaqla, Lonsurf® (trifluridine, tipiracil tablet), and Stivarga® (regorafenib tablet).

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Fruzaqla. All approvals are provided for the duration noted below.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

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

#### FDA-Approved Indication

- 1. Colon, Rectal, or Appendiceal Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
  - A)** Patient is  $\geq 18$  years of age; AND
  - B)** Patient has advanced or metastatic disease; AND
  - C)** Patient meets ONE of the following (i or ii):
    - i.** Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; OR
    - ii.** Patient is ineligible for or progressed on checkpoint inhibitor therapy and meets ONE of the following (a or b):

Note: Examples of checkpoint inhibitors include Keytruda (pembrolizumab intravenous infusion) and Opdivo (nivolumab intravenous infusion).

      - a)** Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease; OR
      - b)** Patient is polymerase epsilon/delta (POLE/POLD1) mutation positive; AND

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- D)** Patient has previously been treated with ALL of the following (i, ii, and iii)
- i.** Fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; AND  
Note: Examples of fluoropyrimidine agents include 5-fluorouracil (5-FU) and capecitabine.
  - ii.** An anti-vascular endothelial growth factor (VEGF) agent; AND  
Note: Examples of anti-VEGF agents include bevacizumab.
  - iii.** If the tumor is *RAS* wild-type (*KRAS* wild-type and *NRAS* wild-type) [that is, the tumor or metastases are *KRAS* and *NRAS* mutation negative], the patient meets ONE of the following (a or b):
    - a)** According to the prescriber, anti-epidermal growth factor receptor (EGFR) therapy is NOT medically appropriate; OR
    - b)** The patient has received an anti-EGFR therapy.  
Note: Examples of anti-EGFR therapy includes Erbitux (cetuximab intravenous infusion) and Vectibix (panitumumab intravenous infusion).

### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Fruzaqla 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. Fruzaqla capsules [prescribing information]. Lexington, MA: Takeda; November 2023.
2. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 9, 2025. Search term: fruquintinib.
3. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 5.2024 – August 22, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 9, 2025.
4. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 4.2024 – August 22, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 9, 2025.