

## PRIOR AUTHORIZATION POLICY

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

- Fruzaqla™ (fruquintinib capsules – Takeda)

**REVIEW DATE:** 11/15/2023; selected revision 12/13/2023

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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.

### Guidelines

The National Comprehensive Cancer Network colon (version 4.2023 – November 16, 2023) and rectal (version 6.2023 – November 16, 2023) cancer treatment guidelines recommend Fruzaqla for the subsequent treatment of advanced or metastatic colon, rectal, or appendiceal cancer as a single agent.<sup>2-4</sup> 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 the following (A, B, and C):
  - A)** Patient is  $\geq 18$  years of age; AND
  - B)** Patient has advanced or metastatic disease; AND
  - C)** Patient has previously been treated with 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. © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 5, 2023. Search term: fruquintinib.
3. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 4.2023 – November 16, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 5, 2023.
4. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 6.2023 – November 16, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 5, 2023.

**HISTORY**

Type of Revision	Summary of Changes	Review Date
New Policy	--	11/15/2023
Selected Revision	<b>Colon, Rectal, or Appendiceal Cancer:</b> Added Appendiceal to the condition of approval. Added “advanced” to the requirement that the patient has advanced or metastatic disease.	12/13/2023