

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Fruzaqla Prior Authorization Policy

- Fruzaqla™ (fruquintinib capsules – Takeda)

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

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.²⁻⁴ 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 ≥ 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.

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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.