Generic Name: fruquintinib

Therapeutic Class or Brand Name: Fruzaqla

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 9/30/2024

Date Last Reviewed / Revised: 11/18/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. Documentation of the following diagnosis AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Metastatic colorectal cancer (mCRC) and criteria i and ii are met:

i. Documented treatment failure, intolerance, or contraindication to all the following 1 through 4:

1. Fluoropyrimidine-based chemotherapy
2. Oxaliplatin-based chemotherapy
3. Irinotecan-based chemotherapy
4. Anti-vascular endothelial growth factor (VEGF) therapy

ii. Documentation of RAS mutation status

1. If tumor is RAS wild type, criteria a or b are met:

a. Documentation of a trial of anti-epidermal growth factor receptor (EGFR) therapy.

b. Documentation by prescriber that anti-epidermal growth factor receptor (EGFR) therapy is not medically appropriate.

II. Minimum age requirement: 18 years old.

III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Pregnancy

- Severe hepatic impairment

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Fruzaqla (fruquintinib) 1 mg capsule: 84 capsules per 28 days
- Fruzaqla (fruquintinib) 5 mg capsule: 21 capsules per 28 days

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes documenting no evidence of unacceptable toxicity or disease progression while on the current regimen.

APPENDIX

N/A

REFERENCES

1. Fruzaqla. Prescribing information. Takeda Pharmaceuticals America, Inc: 2023. Accessed August 1, 2024. https://www.fruzaqlahcp.com/sites/default/files/resources/fruzaqla-prescribing-information.pdf
2. NCCN Clinical Practice Guidelines in Oncology. Colon Cancer. V.5.2025. Updated August 22, 2024. Accessed August 24, 2024. https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf
3. 3. NCCN Clinical Practice Guidelines in Oncology. Rectal Cancer. V.4.2024. Updated August 22, 2024. Accessed August 24, 2024. https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf