UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 1435-3
Program	Prior Authorization/Notification
Medication	Fruzaqla™ (fruquintinib)
P&T Approval Date	2/2024, 2/2025, 2/2026
Effective Date	5/1/2026

1. Background:

Fruzaqla™ (fruquintinib) is a kinase inhibitor 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-VEGF therapy, and, if RAS wild-type and medically appropriate, an anti-EGFR therapy.

The National Comprehensive Cancer Network (NCCN) also recommends use of Fruzaqla for advanced colorectal cancer and appendiceal neoplasms and cancers in patients who have progressed through all available regimens besides regorafenib or trifluridine/tipiracil with or without bevacizumab.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Fruzaqla** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Colorectal Cancer</u>

1. **<u>Initial Authorization</u>**

   a. **Fruzaqla** will be approved based on the following criteria:

      (1) Diagnosis of colorectal cancer

-AND-

(2) Disease is **one** of the following:

(a) Advanced
(b) Metastatic

-AND-

(3) Patient has been previously treated with **all** of the following:

(a) Fluoropyrimidine-based chemotherapy (e.g., capecitabine, 5-FU)
(b) Oxaliplatin-based chemotherapy (e.g., CAPEOX, FOLFOX)
(c) Irinotecan-based chemotherapy (e.g., FOLFIRI, FOLFIRINOX)
(d) Anti-VEGF therapy (e.g., aflibercept, bevacizumab, ramucirumab)

-AND-

(4) **One** of the following:

(a) **Both** of the following:

i. Disease is RAS wild-type

-AND-

ii. Patient has been previously treated with an anti-EGFR therapy (e.g., cetuximab, panitumumab)

-OR-

(b) Disease is not RAS wild-type

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Fruzaqla** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Fruzaqla therapy

Authorization will be issued for 12 months.

C. Appendiceal Neoplasms and Cancers

1. **Initial Authorization**

a. **Fruzaqla** will be approved based on the following criteria:

(1) **One** of the following diagnoses:

(a) Appendiceal adenocarcinoma (AA)

(b) Goblet cell adenocarcinoma (GCA)
(c) Undifferentiated carcinoma not otherwise specified (UC-NOS)

-AND-

(2) Patient has been previously treated with **all** of the following:

(a) Fluoropyrimidine-based chemotherapy (e.g., capecitabine, 5-FU)
(b) Oxaliplatin-based chemotherapy (e.g., CAPEOX, FOLFOX)
(c) Irinotecan-based chemotherapy (e.g., FOLFIRI, FOLFIRINOX)
(d) Anti-VEGF therapy (e.g., aflibercept, bevacizumab, ramucirumab)

-AND-

(3) **One** of the following:

(a) Both of the following:

i. Disease is RAS wild-type

-AND-

ii. Patient has been previously treated with an anti-EGFR therapy (e.g., cetuximab, panitumumab)

-OR-

(b) Disease is not RAS wild-type

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Fruzaqla** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Fruzaqla therapy

Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits and/or step therapy may be in place.

4. References:

1. Fruzaqla [package insert]. Cambridge, MA: Takeda Pharmaceuticals America, Inc.; February 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org. Accessed on December 16, 2025.

Program	Prior Authorization/Notification – Fruzaqla (fruquintinib)
Change Control	
2/2024	New program
2/2025	Annual review with no changes to coverage criteria. Updated references.
2/2026	Annual review. Added criteria for appendiceal neoplasms and cancers. Updated background and references.