

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 3184-3
Program	Step Therapy
Medication	Fruzaqla™ (fruquintinib)
P&T Approval Date	5/2024, 5/2025, 2/2025
Effective Date	5/1/2026

1. Background:

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain. Some states mandate benefit coverage for off-label use of medications for some diagnoses or under therapeutic classes. This program requires a patient trial of or contraindication to Stivarga® (regorafenib) before providing coverage for Fruzaqla™ (fruquintinib).

Fruzaqla (fruquintinib) and Stivarga (regorafenib) are kinase inhibitors 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 the use of Fruzaqla (fruquintinib) and Stivarga (regorafenib) for advanced colorectal cancer and appendiceal neoplasms and cancers in patients who have progressed through all available regimens besides fruquintinib, regorafenib or trifluridine/tipiracil with or without bevacizumab.

Members currently on Fruzaqla therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

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,b}:

<p>A. <u>Patients less than 19 years of age</u></p> <p>1. Fruzaqla will be approved based on the following criterion:</p> <p>a. Patient is less than 19 years of age</p> <p style="text-align: center;">Authorization will be issued for 12 months.</p>
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B. Colorectal Cancer

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

a. Diagnosis of advanced or metastatic colorectal cancer

-AND-

b. **One** of the following:

(1) History of failure, contraindication, or intolerance to Stivarga (regorafenib)

-OR-

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

(a) As continuation of therapy

-AND-

(b) Patient has **not** received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Takda sponsored Takeda Oncology Here2Assist program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Fruzaqla*

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from Takeda sponsored Takeda Oncology Here2Assist program shall be required to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

C. Appendiceal Neoplasms and Cancers

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

a. **One** of the following diagnoses:

- (1) Appendiceal adenocarcinoma (AA)
- (2) Goblet cell adenocarcinoma (GCA)
- (3) Undifferentiated carcinoma not otherwise specified (UC-NOS)

-AND-

b. **One** of the following:

(1) History of failure, contraindication, or intolerance to Stivarga (regorafenib)

-OR-

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

(a) As continuation of therapy

-AND-

(b) Patient has **not** received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Takda sponsored Takeda Oncology Here2Assist program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Fruzaqla*

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from Takeda sponsored Takeda Oncology Here2Assist program shall be required to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

D. Other Indications

1. **Fruzaqla** will be approved

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.

^b Coverage of oncology medications may be approved based on state mandates.

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 Notification may be in place.
- Coverage of oncology medications may be approved based on state mandates.

4. References:

1. Fruzaqla [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; February 2025.
2. Stivarga [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; February 2025.
3. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at <https://www.nccn.org>. Accessed on December 16, 2025.

Program	Step Therapy – Fruzaqla (fruquintinib)
Change Control	
5/2024	New program.
5/2025	Annual review with no changes to step criteria. Updated background and references.
2/2026	Annual review. Added criteria for appendiceal neoplasms and cancers. Updated background and references.