UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1482-1
Program	Prior Authorization/Notification
Medication	Avmapki™ Fakzynja™ Co-Pack (avutometinib; defactinib)
P&T Approval Date	7/2025
Effective Date	10/1/2025

1. Background:

Avmapki Fakzynja Co-Pack a combination of avutometinib and defactinib, each kinase inhibitors, is indicated for the treatment of adult patients with KRAS-mutated recurrent low-grade serous ovarian cancer (LGSOC) who have received prior systemic therapy.

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

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. **Avmapki Fakzynja Co-Pack** 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>Ovarian Cancer</u>

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

   a. **Avmapki Fakzynja Co-Pack** will be approved based on **<u>all</u>** of the following criteria:

      (1) Diagnosis of recurrent low-grade serous ovarian cancer (LGSOC)

      -AND-

      (2) Tumor is *KRAS*-mutated

-AND-

(3) Patient has received prior systemic therapy

Authorization will be issued for 12 months.

2. **Reauthorization Criteria**

a. **Avmapki Fakzynja Co-Pack** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Avmapki Fakzynja Co-Pack therapy

Authorization will be issued for 12 months.

C. 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 may be in place.

4. References:

1. Avmapki Fakzynja Co-Pack [package insert]. Needham, MA: Verastem, Inc. May 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed May 27, 2025.

Program	Prior Authorization/Notification - Avmapki Fakzynja Co-Pack (avutometinib; defactinib)
Change Control	
7/2025	New program.