VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Avmapki Fakzynja Co-Pack Prior Authorization Policy
- Avmapki™ Fakzynja™ Co-Pack (avutometinib capsules; defactinib tablets co-packaged – Verastem)

REVIEW DATE: 05/14/2025; selected revision 06/04/2025

OVERVIEW

Avmapki Fakzynja Co-Pack, a co-packaged product of two kinase inhibitors, is indicated for the treatment of Kirsten RAt Sarcoma (*KRAS)*-mutated recurrent low-grade serous ovarian cancer in adults who have received prior systemic therapy.[1]

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.

Guidelines

Avmapki Fakzynja Co-Pack is addressed in the National Comprehensive Cancer Network (NCCN) Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer guidelines (version 2.2025 – May 23, 2025). The following recurrence targeted therapies are recommended for epithelial ovarian (including less common ovarian cancers)/fallopian tube/primary peritoneal cancer as "Useful in Certain Circumstances" for both platinum-sensitive or platinum-resistant disease: Avmapki Fakzynja Co-Pack for low grade serous carcinoma for *KRAS*-mutated tumors (category 2A); Mekinist® (trametinib tablets and oral solution) [category 2A]; and Mektovi® (binimetinib tablets) [category 2B]. Primary "preferred" regimens for low-grade serous (stage IC) cancer include paclitaxel/carboplatin ± maintenance letrozole or other hormonal therapy (category 2B) or hormone therapy (aromatase inhibitors [AI]: anastrozole, letrozole, or exemestane) [category 2B].[2] Primary "preferred" regimens for low-grade serous ovarian cancer (stage II – stage IV disease) includes paclitaxel/carboplatin/bevacizumab + maintenance bevacizumab (category 2A); paclitaxel/carboplatin ± maintenance letrozole (category 2B) or other hormonal therapy (category 2B); or hormone therapy (AI: anastrozole, letrozole, or exemestane) [category 2B].

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Avmapki Fakzynja Co-Pack. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Avmapki Fakzynja Co-Pack is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Ovarian, Fallopian Tube, or Primary Peritoneal Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has recurrent low-grade serous cancer; AND
   - **C)** The cancer has a *KRAS* mutation; AND
   - **D)** Patient has tried at least one systemic therapy.
     Note: Examples of systemic therapy include one or more of the following medications: paclitaxel, carboplatin, bevacizumab, letrozole, anastrozole, or exemestane.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Avmapki Fakzynja Co-Pack 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. Avmapki™ Fakzynja™ Co-Pack [prescribing information]. Needham, MA: Verastem; May 2025.
2. The NCCN Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – May 23, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 29, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	05/14/2025
Selected Revision	**Ovarian, Fallopian Tube, or Primary Peritoneal Cancer**: This condition of approval was previously worded as "ovarian cancer". The word "ovarian" was removed from the requirement that the patient has recurrent low-grade cancer.	06/04/2025