Utilization Review Policy 297

POLICY: Oncology (Injectable) – Elahere Utilization Management Medical Policy
- Elahere™ (mirvetuximab soravtansine-gynx intravenous infusion – ImmunoGen)

EFFECTIVE DATE: 3/15/2023
LAST REVISION DATE: 06/04/2025

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW
Elahere, a folate receptor alpha (FRα)-directed antibody and microtubule inhibitor conjugate, is indicated for the treatment with FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, in adults who have received one to three prior systemic treatment regimens.[1]

Dosing Information
The recommended dose of Elahere is 6 mg/kg adjusted ideal body weight (AIBW) administered once every 3 weeks (21-day cycle) as an intravenous infusion until disease progression or unacceptable toxicity.[1] The total dose of Elahere is calculated based on each patient's AIBW using the following formula:
AIBW = Ideal body weight (IBW [kg]) + 0.4*(Actual weight [kg] – IBW [kg])
The formula to calculate female IBW is: Female IBW (kg) = 0.9*(height [cm]) – 92

Guidelines
The National Comprehensive Cancer Network (NCCN) ovarian cancer (including fallopian tube cancer and primary peritoneal cancer) clinical practice guidelines (version 2.2025 – May 23, 2025) recommend a variety of treatment options as recurrence therapy for platinum-resistant disease.[2] Single-agent Elahere is listed as a "preferred" targeted therapy for FRα-expressing tumors (≥ 75% positive tumor cells) [category 1] for platinum-resistant disease. Elahere + bevacizumab is listed under "useful in certain circumstances" for FRα-expressing tumors (≥ 25% positive tumor cells) [category 2A]. Elahere is also recommended for platinum-sensitive disease as "useful in certain circumstances" for FRα-expressing tumors (≥ 75% positive tumor cells) [category 2A] and FRα-expressing tumors (≥ 50% positive tumor cells) [category 2B].

POLICY STATEMENT
Prior Authorization is recommended for medical benefit coverage of Elahere. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Elahere as well as the monitoring required for adverse events and long-term efficacy, approval requires Elahere to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Elahere 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, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has folate receptor alpha positive disease; AND
   C) The medication will be prescribed by or in consultation with an oncologist.

   Dosing. Approve up to 6 mg/kg adjusted ideal body weight administered once every 3 weeks (21-day cycle).
   Note: To calculate adjusted ideal body weight (AIBW), use the following equation:
   AIBW = Ideal body weight (kg) + 0.4*(Actual weight [kg] – ideal body weight [kg]);
   To calculate female ideal body weight (kg) = 0.9*(height [cm]) – 92

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Elahere 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. Elahere® intravenous infusion [prescribing information]. Waltham, MA: ImmunoGen; March 2023.
2. The NCCN Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – 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
Annual Revision	No criteria changes.	11/15/2023
Update	**04/09/2024:** FDA labeled indication received a traditional approval so the following statement was removed from the overview section: This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.	--
Early Annual Revision	**Ovarian, Fallopian Tube, or Primary Peritoneal Cancer:** Additional criteria were added to the requirement of folate receptor positive disease, which are patient has to have either ≥ 75% folate receptor alpha positive tumor cells or patient is using this medication in combination with bevacizumab. The requirement that the patient has tried one systemic regimen and the note of examples of a systemic regimen were removed.	06/05/2024
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024
Annual Revision	**Ovarian, Fallopian Tube, or Primary Peritoneal Cancer:** The requirement that the patient has either ≥ 75% folate receptor alpha positive tumor cells or is using Elahere in combination with bevacizumab was removed. The requirement that the patient has platinum-resistant disease was removed.	06/04/2025
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/15/2025