Utilization Review Policy 297

POLICY: Oncology (Injectable) – Elahere

- Elahere™ (mirvetuximab soravtansine-gynx intravenous infusion – ImmunoGen)

EFFECTIVE DATE: 3/15/2023
LAST REVISION DATE: 11/15/2023

COVERAGE CRITERIA FOR: All Aspirus Medicare 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, who have received one to three prior systemic treatment regimens in adults.[1]

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.[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 2.2023 – June 2, 2023) recommend a variety of treatment options as recurrence therapy for platinum-resistant disease. Single-agent Elahere is listed as a preferred targeted therapy for FRα-expressing tumors (category 2A). Other preferred agents include cytotoxic chemotherapy (e.g., oral cyclophosphamide + bevacizumab, docetaxel, etoposide, gemcitabine, or liposomal doxorubicin) [category 2A] and targeted therapy with single-agent bevacizumab (category 2A). Elahere + bevacizumab is listed under useful in certain circumstances for FRα-expressing tumors (category 2B).[2]

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, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has folate receptor alpha positive disease; AND
   - **C)** Patient has platinum-resistant disease; AND
   - **D)** Patient has tried at least one systemic regimen; AND
     Note: Examples of a systemic regimen include one or more of the following agents: bevacizumab, cyclophosphamide, docetaxel, etoposide, gemcitabine, paclitaxel, carboplatin, Lynparza (olaparib tablets), or Zejula (niraparib capsules).
   - **E)** 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; November 2022.
2. The NCCN Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – December 22, 2023). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 6, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	-	11/16/2022
Update	**01/06/2023**: The guidelines section was updated to reflect updated guideline recommendation for Elahere.	--
Annual Revision	No criteria changes.	11/15/2023