PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Elahere Prior Authorization Policy
- Elahere™ (mirvetuximab soravtansine-gynx intravenous infusion – ImmunoGen)

REVIEW DATE: 11/16/2022

OVERVIEW

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

Guidelines

The National Comprehensive Cancer Network (NCCN) ovarian cancer (including fallopian tube cancer and primary peritoneal cancer) clinical practice guidelines (version 1.2023 – December 22, 2022) 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 (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 prescription benefit coverage of Elahere. 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.

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, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 6, 2023.