Reference number(s)
5671-A

Standard Medicare Part B Management Elahere

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over the counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Elahere	mirvetuximab soravtansine-gynx

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications

Elahere is indicated for the treatment of adult patients with folate receptor-alpha positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens.

Compendial Use

Persistent or recurrent folate receptor-alpha positive, platinum-sensitive epithelial ovarian, fallopian tube, or primary peritoneal cancer

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions:

Documentation of testing or laboratory results confirming folate receptor-alpha status, where applicable.

Coverage Criteria

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

Authorization of 12 months may be granted for treatment of folate receptor-alpha positive epithelial ovarian, fallopian tube, or primary peritoneal cancer when either of the following criteria are met:

- Member has platinum-resistant disease and all of the following criteria are met:
  - Member has received at least one prior systemic therapy
  - Requested medication will be used as a single agent or in combination with bevacizumab
- Member has persistent or recurrent platinum-sensitive disease, and the requested medication will be used in combination with bevacizumab

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat an indication listed in the coverage criteria
- The member is receiving benefit from therapy. Benefit is defined as:
  - No evidence of unacceptable toxicity while on the current regimen and
  - No evidence of disase progression while on the current regimen

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Elahere.
- The available compendium
  - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
  - Micromedex DrugDex

    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guidelines: Ovarian cancer including fallopian tube cancer and primary peritoneal cancer

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Elahere are covered in addition to using Elahere to treat and persistent or recurrent folate receptor-alpha positive, platinum-sensitive epithelial ovarian, fallopian tube, or primary peritoneal cancer.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Elahere to treat epithelial ovarian, fallopian tube, or primary peritoneal cancer with Elahere in combination with bevacizumab and persistent or recurrent folate receptor-alpha positive, platinum-sensitive epithelial ovarian, fallopian tube, or primary peritoneal cancer can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Elahere [package insert]. Waltham, MA: ImmunoGen, Inc.; March 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed August 21, 2024.