Medical Policy:

Elahere (mirvetuximab soravtansine-gynx) intravenous infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.370	April 3, 2025	January 6, 2023

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Elahere, a folate receptor alpha (FRα)-directed antibody and microtubule inhibitor conjugate, is indicated for the treatment of FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer in adults who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.

Elahere is a first-in class antibody drug conjugate directed against FRα, which is cell-surface protein highly expressed in ovarian cancer. Elahere consists of a FRα-binding antibody, cleavable linker, and a potent tubulin-targeting agent. Upon binding to FRα, Elahere is internalized followed by intracellular release of the maytansine derivative (DM4), which causes cell death.

Length of Authorization

Coverage will be provided for 6 months and may be renewed

Dosing Limits [Medical Benefit]

Elahere is 6 mg/kg adjusted ideal body weight administered once every 3 weeks (21-day cycle) as an

intravenous (IV) infusion until disease progression or unacceptable toxicity.

Quantity Limit

- Elahere 100 mg/20 mL single-dose vial: 6 vials every 21 days
- Max Units (per dose and over time): 600mg every 21 days

Max Units (per dose and over time) [HCPCS Unit]:
600 billable units (600 mg) every 21 days

Guideline

I. INITIAL APPROVAL CRITERIA

1. **Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer –** Approve if the patient meets ALL of the following (A, B, C, D, E **AND** F):
    A. Patient is ≥ 18 years of age; **AND**
    B. Patient has folate receptor alpha positive disease and meets ONE of the following (i **OR** ii):
        i. Patient has ≥ 75% folate receptor alpha positive tumor cells; **OR**
        ii. Patient is using this medication in combination with bevacizumab; **AND**
    C. Patient has platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer; **AND**
    D. Medication must be prescribed by, or in consultation with, an oncologist

II. Renewal Criteria

1. Member is responding positively to therapy, as determined by the prescriber; **AND**
2. Member has not experienced unacceptable toxicity from the drug

Dosage/Administration

Indication	Dose
Ovarian Cancer	Administer 6 mg/kg adjusted ideal body weight (AIBW) administered as an intravenous infusion every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity. The total dose is calculated based on AIBW using the following formula: AIBW = Ideal Body Weight (IBW [kg]) + 0.4*(Actual weight [kg] – IBW) Female IBW (kg) = 0.9*height(cm) – 92

Applicable Procedure Codes

Code	Description
J9063	Injection, mirvetuximab soravtansine-gynx, 1 mg

Applicable NDCs

Code	Description
72903-0853-01	Elahere 5mg/1ml Solution containing 20 ml vial

ICD-10 Diagnoses

Code	Description
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum

C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.3	Malignant neoplasm of bilateral ovaries
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C57.9	Malignant neoplasm of female genital organ, unspecified
Z85.43	Personal history of malignant neoplasm of ovary

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	4/2/2025	Annual Review: 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. Removed from criteria: Used as single agent therapy. Removed Patients has received at least one prior line of systemic therapy; **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).*
EmblemHealth & ConnectiCare	3/19/2024	Annual Review: Updated dosing limits. Added C9146 and J9063, Removed J9999, Added C57.21-Z85.43
EmblemHealth & ConnectiCare	01/06/2023	New Policy

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 5.2022 – September 16, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 19, 2022.

3. Elahere IPD Analytics. Available at: http://secure.ipdanalytics.com. Accessed on December 19, 2022.
4. Elahere Micromedex (database online). Waltham, PA. Available at https://online.lexi.com. Accessed December 19, 2022.