Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Mirvetuximab soravtansine-gynx (Elahere®)	MP-RX-FP-126-24	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of *Mirvetuximab soravtansine-gynx (Elahere®),* a folate receptor alpha (FRα)-directed antibody and microtubule inhibitor conjugate approved by the Food and Drug Administration (FDA) for the treatment of adult patients with FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.

Background Information

Elahere is a folate receptor alpha (FRα)-directed antibody and microtubule inhibitor conjugate 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.

NCCN provides a 2A recommendation as single agent use in ovarian cancer, including epithelial ovarian, fallopian tube, and primary peritoneal cancers for recurrence therapy in platinum-resistant disease when FR alpha expressing tumors are present.

NCCN provides a 2A recommendation for use in combination with bevacizumab in ovarian cancer, including epithelial ovarian, fallopian tube, or primary peritoneal cancers for recurrent, FRα-expressing tumor that is platinum-resistant persistent disease.

There is a black box warning for ocular toxicity. Elahere can cause severe ocular toxicities, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis.

Definitions and Measures

- Chemotherapy: Medical treatment of a disease, particularly cancer, with drugs or other chemicals.
- Disease Progression: Cancer that continues to grow or spread.
- ECOG or Eastern Cooperative Oncology Group Performance Status: A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may

Policy Name	Policy Number	Scope
Mirvetuximab soravtansine-gynx (Elahere®)	MP-RX-FP-126-24	☒ MMM MA ☒ MMM Multihealth

also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:

- 0 = Fully active, able to carry on all pre-disease performance without restriction
- 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
- 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
- 5 = Dead

- Line of Therapy:
  - First-line therapy: The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.
  - Second-line therapy: Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
  - Third-line therapy: Treatment given when both initial (first-line therapy) and subsequent treatment (second- line therapy) are not effective or there is disease progression.
- Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.
- Primary refractory disease: Cancer that does not respond at the beginning of treatment; may also be called resistant disease.
- Progressive Disease (PD): Cancer that is growing, spreading, or getting worse.
- Refractory Disease: Illness or disease that does not respond to treatment.
- Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.
- Stable disease: Cancer that is not decreasing or increasing in extent or severity.

Approved Indications

A. Treatment of adult patients with FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.

Other Uses

i. None.

Policy Name	Policy Number	Scope
Mirvetuximab soravtansine-gynx (Elahere®)	MP-RX-FP-126-24	☒ MMM MA ☒ MMM Multihealth

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J9063	Injection, mirvetuximab soravtansine-gynx, 1 mg [Elahere]

ICD-10	Description
C48.0-C48.8	Malignant neoplasm of retroperitoneum and peritoneum
C56.1-C56.9	Malignant neoplasm of ovary
C57.00-C57.9	Malignant neoplasm of unspecified fallopian tube

Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Mirvetuximab soravtansine-gynx (Elahere®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

i. Individual has a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer (Label, NCCN 2A); **AND**
   - A. Individual has received one to three prior systemic treatment regimens; **AND**
   - B. Individual is folate receptor-alpha (FRα) positive; **AND**
   - C. Individual is platinum-resistant; **AND**
   - D. Individual is using as a single agent.

OR

ii. Individual has a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer (NCCN 2A); **AND**

Policy Name	Policy Number	Scope
Mirvetuximab soravtansine-gynx (Elahere®)	MP-RX-FP-126-24	☒ MMM MA ☒ MMM Multihealth

A. Individual has recurrent or platinum-resistant disease; **AND**
B. Individual is using in combination with bevacizumab (or bevacizumab biosimilars); **AND**
C. Individual has a FRα positive tumor.

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Mirvetuximab soravtansine-gynx (Elahere®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen, and the maximum duration of therapy has not been exceeded. The following information should be submitted for reauthorization:
   A. A current oncology note documenting the patient's response to treatment showing no progression of disease.
   B. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results.

C. Authorization Duration

i. Initial Approval Duration: Up to 6 months
ii. Reauthorization Approval Duration: Up to 6 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Requests for Elahere (mirvetuximab soravtansine-gynx) may not be approved for the following:
   A. Individual has moderate or severe hepatic impairment (Child-Pugh Class B or C or total bilirubin >1.5 ULN); **OR**
   B. When the above criteria (Section A: Criteria for Initial Approval) are not met and for all other indications.

Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

Policy Name	Policy Number	Scope
Mirvetuximab soravtansine-gynx (Elahere®)	MP-RX-FP-126-24	☒ MMM MA ☒ MMM Multihealth

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Recommended Dosing Schedule
Mirvetuximab soravtansine-gynx (Elahere®) 100 mg/20 mL (5 mg/mL) SDV	- 6 mg/kg adjusted ideal body weight administered as an intravenous infusion every 3 weeks until disease progression or unacceptable toxicity.
Exceptions	
• The total dose of ELAHERE is calculated based on each patient's adjusted ideal body weight (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	

Reference Information

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website.
2. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: September 21, 2023
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. Matulonis UA, Lorusso D, Oaknin A, et al. Efficacy and Safety of Mirvetuximab Soravtansine in Patients With Platinum-Resistant Ovarian Cancer With High Folate Receptor Alpha Expression: Results From the SORAYA Study. J Clin Oncol. 2023;41(13):2436-2445. doi:10.1200/JCO.22.01900.
6. Moore KN, Oza AM, Colombo N, et al. Phase III, randomized trial of mirvetuximab soravtansine versus chemotherapy in patients with platinum-resistant ovarian cancer: primary analysis of FORWARD I. Ann Oncol. 2021;32(6):757-765. doi:10.1016/j.annonc.2021.02.017.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on September 21, 2023.
    a. Ovarian cancer. V2.2023. Revised June 2, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review 12/27/2024	Accelerated Approval Text Removed per FDA label. Added NCCN 2A criteria for use in ovarian cancer when used in combination with bevacizumab (or its biosimilars) in (FRα) positive tumors that are recurrent or platinum-resistant. Updated quantity limits table to add dosage form and strenght. Wording and formatting changes. Coding Reviewed: No changes.	3/20/2025	4/2/2025
Policy Inception 01/31/2024	New Medical Policy creation	4/18/2024	6/28/2024