Medical Drug Clinical Criteria

Subject:	**Elahere (mirvetuximab)**		
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Overview

This document addresses the use of Elahere (mirvetuximab). 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.

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 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.

Clinical Criteria

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.

Elahere (mirvetuximab sorvtansine-gynx)

Requests for Elahere (mirvetuximab sorvtansine-gynx) may be approved if the following criteria are met:

I. **Individual has a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer; AND**
   - A. **Individual has received one to three prior systemic treatment regimens, including at least 1 line of therapy containing bevacizumab; AND**
   - B. **Individual is folate receptor-alpha (FRα) positive; AND**
   - C. **Individual is platinum-resistant.**

Requests for Elahere (mirvetuximab soravtansine-gynx) may not be approved for the following:

I. **Individual has moderate or severe hepatic impairment (Child-Pugh Class B or C or total bilirubin >1.5 ULN); OR**
II. **When the above criteria are not met and for all other indications.**

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J3590	**Unclassified biologics (when specified as [Elahere] (mirvetuximab sorvtansine-gynx)**
J9999	**Not otherwise classified, antineoplastic drugs (when specified as [Elahere] (mirvetuximab sorvtansine-gynx)**

ICD-10 Diagnosis

All diagnoses pend

Document History

New: 12/12/2022
Document History:

- **12/12/2022 – Select Review: Add new clinical criteria document for Elahere (mirvetuximab soravtansine-gynx). Coding Reviewed: Added HCPCS J3590, J9999. All diagnosis pend.**

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: December 2, 2022.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on December 2, 2022.