STATE OF IOWA DEPARTMENT OF
Health AND Human
SERVICES

Elahere (mirvetuximab soravtansine-gynx)
PAM–062

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	04/01/2023
Revision Number:	1	**Last Rev Date:**	10/20/2023
Reviewed By:	Medicaid Medical Director	**Next Rev Date:**	10/18/2024
Approved By:	Medicaid Clinical Advisory Committee	**Approved Date:**	10/20/2023

Overview

Medication:[1]	mirvetuximab soravtansine-gynx
Brand Name:	Elahere®
Pharmacologic Category:	Folate receptor alpha (FRα)-directed antibody and microtubule inhibitor conjugate
FDA-Approved Indication(s):	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. ➢ 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. **Patient Selection**: Select patients for the treatment of platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer with Elahere® based on the presence of FRα tumor expression using an FDA-approved test. ➢ Information on FDA-approved tests for the measurement of FRα tumor expression is available at www.fda.gov/CompanionDiagnostics.
How Supplied:	Single-dose vial containing 100 mg in 20 mL (5 mg/mL)
Dosage and Administration:	The recommended dose of Elahere® is 6 mg/kg adjusted ideal body weight (AIBW) administered once every 3 weeks (21-day cycle) as an intravenous infusion until disease progression or unacceptable toxicity. The total dose is calculated based on each patient's AIBW using the following formula: $AIBW = Ideal\ Body\ Weight\ [IBW\ (kg)] + 0.4 \times [Actual\ weight\ (kg) - IBW]$ $Female\ IBW\ (kg) = 0.9 \times [height(cm)] - 92$ See full prescribing information for dose reductions and modifications for adverse reactions.
Benefit Category:	Medical

Black Box Warning – Ocular Toxicity
• Elahere® can cause severe ocular toxicities, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis. • Conduct an ophthalmic exam including visual acuity and slit lamp exam prior to initiation of Elahere®, every other cycle for the first 8 cycles, and as clinically indicated. • Administer prophylactic artificial tears and ophthalmic topical steroids. • Withhold Elahere® for ocular toxicities until improvement and resume at the same or reduced dose. • Discontinue Elahere® for Grade 4 ocular toxicities.

Descriptive Narrative

Epithelial carcinoma is the most common histologic type of cancer of the ovary, fallopian tube, and peritoneum, accounting for 90 percent of all cancers at these sites. Ovarian carcinoma is traditionally referred to as a single entity, but it consists of a heterogeneous group of neoplasms with multiple histologic subtypes. Management of these neoplasms is largely dependent on factors such as tumor grade and stage.[2]

Epithelial ovarian cancer is the leading cause of death from gynecologic cancer in the United States and is the country's fifth most common cause of cancer mortality in females. In 2022 it is estimated that 19,880 new diagnoses and 12,810 deaths from this malignancy will occur in the United States. Five-year survival is about 49 percent, although survival is longer for select patients with early-stage disease and certain histological subtypes. Approximately half of patients present with distant disease; however, certain uncommon subtypes, such as clear cell and endometrioid cancer, are more likely to be diagnosed at earlier stages.[3]

Guidelines

As new and emerging therapies are rapidly coming to market, oncology treatment recommendations and guidelines are constantly changing. To keep up with these changes, the National Comprehensive Cancer Network (NCCN) publishes guidelines which are developed and updated by 60 individual panels, comprising over 1,660 clinicians and oncology researchers from the 31 NCCN Member Institutions.[4]

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

The information referenced at the time of this policy writing/revision is from:

- NCCN Guidelines® for Ovarian Cancer, including Fallopian Tube Cancer and Primary Peritoneal Cancer (v.2.2023 – June 2, 2023)[5]

NCCN Guidelines® Recommendation(s) for mirvetuximab soravtansine-gynx (Elahere®) – Acceptable Recurrence Therapies for Platinum-Resistant Epithelial Ovarian [including Less Common Ovarian Cancers (LCOC)[a]/Fallopian Tube/Primary Peritoneal Cancer] [b]
(1) Preferred Regimens – Targeted Therapy (single agents) A. Mirvetuximab soravtansine-gynx (for FRα-expressing tumors): Category 2A [c] (2) Useful in Certain Circumstances – Targeted Therapy A. Mirvetuximab soravtansine-gynx/bevacizumab (for FRα-expressing tumors): Category 2B [c,d]

[a] Chemotherapy has not been shown to be beneficial in ovarian borderline epithelial tumors (LMP).

[b] Patients who progress on two consecutive regimens without evidence of clinical benefits have diminished likelihood of benefitting from additional therapy. Decisions to offer clinical trials, supportive care, or additional therapy should be made on a highly individual basis.

[c] Validated molecular testing should be performed in a CLIA-approved facility using the most recent available tumor tissue. Tumor molecular analysis is recommended to include, at a minimum, tests to identify potential benefit from targeted therapeutics that have tumor-specific or tumor-agnostic benefit including, but not limited to, *BRCA1/2*, HRD status, MSI, MMR, TMB, *BRAF*, *FRα*, *RET*, and *NTRK* if prior testing did not include these markers. More comprehensive testing may be particularly important in LCOC with limited approved therapeutic options.

[d] An FDA-approved biosimilar is an appropriate substitute for bevacizumab.

NCCN Categories of Evidence and Consensus (all recommendations are category 2A unless otherwise indicated)	
Category 1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

NCCN Categories of Preference (all recommendations are considered appropriate)	
Preferred intervention	Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.
Other recommended intervention	Other interventions that may be somewhat less efficacious, more toxic, or based on less mature data; or significantly less affordable for similar outcomes.
Useful in certain circumstances	Other interventions that may be used for select patient populations (defined with recommendation).

Eastern Cooperative Oncology Group (ECOG) Performance Status Scale[6]

Developed by the Eastern Cooperative Oncology Group (ECOG), now part of the ECOG-ACRIN Cancer Research Group, and published in 1982, the ECOG Performance Status Scale describes a patient's level of functioning in terms of their ability to care for themself, daily activity, and physical ability (walking, working, etc.). It is used by doctors and researchers to assess how a patient's disease is progressing, how the disease affects the daily living abilities of the patient and determine appropriate treatment and prognosis.

GRADE	ECOG PERFORMANCE STATUS [Synonyms: WHO/Zubrod score]
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, e.g., 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.

Criteria

Prior authorization is required.

Elahere® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer; **AND**
2. Member is 18 years of age or older; **AND**
3. Disease meets **ALL** of the following (a, b, and c):
    a. Folate receptor-alpha (FR α) positive (based on an FDA-approved test); **AND**
    b. Platinum-resistant; **AND**
    c. Previous therapy includes at least 1 but no more than 3 prior systemic lines of anticancer therapy, including at least 1 line containing bevacizumab; **AND**
4. Member does not have moderate to severe hepatic impairment (Child-Pugh Class B or C or total bilirubin >1.5 ULN); **AND**
5. Prescribed by, or in consultation with, an oncologist; **AND**
6. Request meets one of the following (a or b):
    a. Regimen prescribed does not exceed 6 mg/kg dosed based on adjusted ideal body weight (see Overview table) on day 1 of every 3-week cycle; or
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Elahere® is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Documentation of positive clinical response to therapy, as demonstrated by tumor response or lack of disease progression, and an acceptable toxicity profile; **AND**
3. Prescribed by, or in consultation with, an oncologist; **AND**
4. Request meets one of the following (a or b):
    a. Regimen prescribed does not exceed 6 mg/kg dosed based on adjusted ideal body weight (see Overview table) on day 1 of every 3-week cycle; or
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Approval Duration and Quantity Limits

	Initial Authorization	Subsequent Authorization(s)
Approval Duration	6 months	12 months or until disease progression or unacceptable toxicity
Quantity Limits	6 mg/kg dosed based on adjusted ideal body weight on day 1 of every 3-week cycle	

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
~~C9146~~	~~Injection, mirvetuximab soravtansine-gynx, 1 mg~~ *(effective 4-1-2023 to 6-30-2023)*
J9063	Injection, mirvetuximab soravtansine-gynx, 1 mg *(effective 7-1-2023)*

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

NDC	Labeler	Dosage	Pkg Size	Pkg Qty	Units/Pkg
72903-0853-01	ImmunoGen, Inc. (72903)	1 mg	EA	1	100

Compliance

1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Elahere® prescribing information (11/2022). ImmunoGen, Inc.: Waltham, MA. Available online at: www.elaherehcp.com. Accessed August 22, 2023.

[2] Rendi MH. Epithelial carcinoma of the ovary, fallopian tube, and peritoneum: Histopathology. Chakrabarti A, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed October 7, 2023.

[3] Referenced from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ovarian Cancer, including Fallopian Tube Cancer and Primary Peritoneal Cancer (v.2.2023 – June 2, 2023). Accessed October 7, 2023. The NCCN Guidelines® are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version of the guidelines, go online to NCCN.org.

[4] National Comprehensive Cancer Network (NCCN). Development and Update of Guidelines. Available online at www.nccn.org. Accessed October 11, 2023.

[5] Referenced from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ovarian Cancer, including Fallopian Tube Cancer and Primary Peritoneal Cancer (v.2.2023 – June 2, 2023). Accessed October 7, 2023. The NCCN Guidelines® are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version of the guidelines, go online to NCCN.org.

[6] Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5:649-655. PMID 7165009.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
10/20/2023	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee