Elahere (mirvetuximab soravtansine-gynx)
PAM – 062

Iowa Medicaid Program	Prior Authorization	**Effective Date**	04/01/2023
Revision Number	3	**Last Reviewed**	10/17/2025
Reviewed By	Medicaid Medical Director	**Next Review**	10/16/2026
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	10/20/2023

Overview

Medication: [1]	mirvetuximab soravtansine-gynx
Brand Name:	Elahere®
Pharmacologic Category:	Antineoplastic; 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. Select patients for treatment with Elahere® based on the presence of FRα tumor expression using an FDA-approved test.
How Supplied:	Single-dose vial, 100 mg/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 adjusted ideal body weight (AIBW) using the following formula: $\boldsymbol{AIBW} = Ideal\ Body\ Weight\ [IBW\ (kg)] + 0.4 \times [Actual\ weight\ (kg) - IBW]$ $\boldsymbol{Female\ IBW\ (kg)} = 0.9 \times [height(cm)] - 92$ Dosing based on AIBW reduces exposure variability for patients who are either under or overweight. See full prescribing information for dose reductions and modifications for adverse reactions.
Benefit Category:	Medical

BOXED 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]

Guidelines

The National Comprehensive Cancer Network (NCCN) publishes guidelines for the prevention, diagnosis, and management of malignancies across the continuum of care. The NCCN Guidelines® are a comprehensive set of guidelines detailing the sequential management decisions and interventions that currently apply to 97 percent of cancers affecting patients in the United States. The guidelines are developed and updated by 61 individual panels, comprising over 1,700 clinicians and oncology researchers from the 33 NCCN Member Institutions.

Guidelines are reviewed and updated on a continual basis to ensure that the recommendations take into account the most current evidence. 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.[3,4]

The information referenced at the time of this policy writing/revision is from the NCCN Guidelines® for (note version number and effective date):[5]

- Ovarian Cancer, including Fallopian Tube Cancer and Primary Peritoneal Cancer (v.3.2024 – July 15, 2024)

NCCN Guidelines® Recommendation(s)

Principles of Systemic Therapy – Acceptable Recurrent Therapies for Epithelial Ovarian (including LCOC) [a]/Fallopian Tube/ Primary Peritoneal Cancer [b]

(1) Recurrence Therapy for Platinum-Sensitive Disease [c]
  a. Targeted Therapy, Useful in Certain Circumstances
    i. FRα-expressing tumors – mirvetuximab soravtansine-gynx/ bevacizumab: Category 2B [d]

(2) Recurrence Therapy for Platinum-Resistant Disease
  a. Targeted Therapy (single agents), Preferred Regimens
    i. FRα-expressing tumors (≥ 75% positive tumor cells – mirvetuximab soravtansine-gynx: Category 1 [e]
  b. Targeted Therapy, Useful in Certain Circumstances
    i. FRα-expressing tumors – mirvetuximab soravtansine-gynx: Category 2A [d]

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

NCCN Guidelines® Recommendation(s)
[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] In general, the panel would recommend combination, platinum-based regimens for platinum-sensitive recurrent disease based on randomized trial data, especially in first relapses. [d] An FDA-approved biosimilar is an appropriate substitute for bevacizumab. [e] 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, HER2 status (by IHC), BRCA1/2, HRD status, MSI, MMR, TMB, BRAF, FRα (FOLR1), 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.

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 themselves, 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 to 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 housework, 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. 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**
3. Member is 18 years of age or older; **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* 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* 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.

* Dosing on adjusted ideal body weight (AIBW) reduces exposure variability for members who are either under or overweight. Calculations are as follows:

- AIBW = Ideal Body Weight (IBW [kg]) + 0.4*(actual weight [kg] – IBW)
- Female IBW [kg] = 0.9*height[cm] - 92

Approval Duration and Quantity Limits

	Initial Authorization	Subsequent Authorization(s)
Approval Duration	6 months	12 months
Quantity Limits	6 mg/kg based on AIBW 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 4-1-23 to 6-30-23)*
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 (Strength)	Labeler	Dosage	Pkg Size	Pkg Qty	Units/ Pkg
72903-0853-01 (100 mg/20 mL)	ImmunoGen, Inc. (72903)	1 mg	1	EA	100

Compliance

1. Should conflict exist between the 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 (07/2025). ImmunoGen, Inc.: Waltham, MA. Available online: www.elaherehcp.com. Accessed September 12, 2025.

[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 September 7, 2024.

[3] National Comprehensive Cancer Network (NCCN). Guidelines Process: About Clinical Practice Guidelines. Available online at www.nccn.org. Accessed July 29, 2024.

[4] National Comprehensive Cancer Network (NCCN). Guidelines Process: Development and Update of Guidelines. Available online at www.nccn.org. Accessed July 29, 2024.

[5] NCCN Clinical Practice Guidelines in Oncology. 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, go online to NCCN.org. NCCN Guidelines® referenced (note version number and effective date):

- Ovarian Cancer, including Fallopian Tube Cancer and Primary Peritoneal Cancer (v.3.2024 – July 15, 2024)

[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
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
10/17/2025	CAC	Annual review. No changes.	3
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
10/18/2024	CAC	Annual review. Overview table: removed accelerated approval statement, as Elahere® received regular FDA approval on 3/22/2024. Updated disease information in Descriptive Narrative. Reviewed and updated NCCN Guidelines®. Updated references, where applicable.	2
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee