Drug Policy:

Elahere™ (mirvetuximab soravtansine-gynx)

POLICY NUMBER UM ONC_1471	SUBJECT Elahere™ (mirvetuximab soravtansine-gynx)		DEPT/PROGRAM UM Dept	PAGE 1 of 4
DATES COMMITTEE REVIEWED 01/11/23, 01/10/24, 01/08/25	APPROVAL DATE January 08, 2025	EFFECTIVE DATE January 31, 2025	COMMITTEE APPROVAL DATES 01/11/23, 01/10/24, 01/08/25	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Evolent Specialty Services Clinical Guideline Review Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses clinical guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this clinical guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their plan customer service representative for specific coverage information.

I. PURPOSE

To define and describe the accepted indications for Elahere (mirvetuximab soravtansine-gynx) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The requested medication was used within the last year, AND
2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

B. Ovarian /Fallopian Tube/Primary Peritoneal cancer

1. Elahere (mirvetuximab soravtansine-gynx) may be used as monotherapy in a member with a confirmed documentation of HIGH folate receptor alpha (FRα) positive (defined by the Ventana FOLR1 Assay or any FDA approved test, as greater than or equal to 75% tumor cells staining with 2+ intensity), platinum-resistant high grade serous epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer AND
2. The member has disease progression on Avastin (bevacizumab/bevacizumab biosimilar) containing regimen and no more than three prior systemic treatment regimens (prior therapies may not include maintenance therapies).

III. EXCLUSION CRITERIA

A. Disease progression on or after treatment with Elahere (mirvetuximab soravtansine-gynx).

B. Concurrent use with other anti-cancer therapies.

C. The member does not have platinum resistant disease defined as disease progression within 6 months of the last dose of platinum-containing chemotherapy.

D. The member has endometrioid, clear cell, mucinous, or sarcomatous histology, mixed tumors containing any of the above histologies, or low-grade ovarian cancer.

E. Lack of documentation to confirm the presence of folate receptor alpha (FRα) positivity by an FDA approved companion diagnostic test. A list for the FDA approved test is available at www.fda.gov/CompanionDiagnostics.

F. Dosing exceeds single dose limit of Elahere (mirvetuximab soravtansine-gynx) 6 mg/kg.

G. Use of Elahere (mirvetuximab soravtansine-gynx) in members with an active ocular disorder/condition that is not controlled with treatment. Prior to initiating Elahere (mirvetuximab soravtansine-gynx), the member has a baseline ophthalmic exam, ophthalmic exams are reviewed every other cycle for the first 8 cycles for ocular adverse reactions.

H. Dosing exceeds single dose limit of Elahere (mirvetuximab soravtansine-gynx) 6 mg/kg (using adjusted or ideal body weight).

I. Investigational use of Elahere (mirvetuximab soravtansine-gynx) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those

recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.

4. Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. CODING INFORMATION

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

V. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

VI. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VII. ATTACHMENTS

A. None

VIII. REFERENCES

A. Moore KN, 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 Jun;32(6):757-765.

B. Moore KN, et al. Integrated safety summary of single-agent mirvetuximab soravtansine in patients with folate receptor α (FRα)-positive recurrent ovarian cancer: Phase 1 and 3 clinical trials. J Clin Oncol 40, 2022 (suppl 16; abstr 5574) | DOI 10.1200/JCO.2022.40.16_suppl.5574.

C. Elahere prescribing information 2024. AbbVie Inc., North Chicago, IL

D. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs Bethesda, MD 2025.

E. Clinical Pharmacology Elsevier Gold Standard 2025.

F. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2025.

G. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2025.

H. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

I. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.