Evolent Clinical Guideline 3075 for Elahere™ (mirvetuximab soravtansine-gynx)

Guideline Number:	Applicable Codes	
Evolent_CG_3075		
"Evolent" refers to Evolent Health LLC and Evolent Specialty Services, Inc.		
Original Date:	**Last Revised Date:**	**Implementation Date:**
January 2023	April 2025	April 2025

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STATEMENT

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.

INDICATIONS

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

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

Ovarian/Fallopian Tube/Primary Peritoneal Cancer

- 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
- The member has disease progression on no more than three prior systemic treatment regimens (prior therapies may not include maintenance therapies).

CONTRAINDICATIONS/WARNINGS

- Contraindications
  - None
- US Boxed Warning
  - Ocular toxicity
    - Mirvetuximab soravtansine 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 mirvetuximab soravtansine, every other cycle for the first 8 cycles, and as clinically indicated.
- Administer prophylactic artificial tears and ophthalmic topical steroids.
- Withhold mirvetuximab soravtansine for ocular toxicities until improvement and resume at the same or reduced dose.
- Discontinue mirvetuximab soravtansine for grade 4 ocular toxicities.

EXCLUSION CRITERIA

- Disease progression on or after treatment with Elahere (mirvetuximab soravtansine-gynx).
- Concurrent use with other anti-cancer therapies.
- The member does not have platinum resistant disease defined as disease progression within 6 months of the last dose of platinum-containing chemotherapy.
- The member has endometrioid, clear cell, mucinous, or sarcomatous histology, mixed tumors containing any of the above histologies, or low-grade ovarian cancer.
- 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**.
- Dosing exceeds single dose limit of Elahere (mirvetuximab soravtansine-gynx) 6 mg/kg.
- 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, and ophthalmic exams are reviewed every other cycle for the first 8 cycles for ocular adverse reactions.
- Dosing exceeds single dose limit of Elahere (mirvetuximab soravtansine-gynx) 6 mg/kg (using adjusted or ideal body weight).
- 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:
  - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
  - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
  - 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.

- 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).
- 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.
- That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
- 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.

CODING AND STANDARDS

Codes

- J9063 - Injection, mirvetuximab soravtansine-gynx, 1 mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
April 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1471 Elahere (mirvetuximab soravtansine-gynx) • Removed verbiage under indication section regarding disease progression on Avastin (bevacizumab/bevacizumab biosimilar) containing regimen as a requirement
January 2025	• Added Evolent disclaimer language

	• Added Coding Information section with HCPCS code • Added maximum single dose limit to exclusion criteria

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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 procedure 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.

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