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	**APPROVAL DATE** January 11, 2023	**EFFECTIVE DATE** January 27, 2023	**COMMITTEE APPROVAL DATES** 01/11/23
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee	
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	**NCQA STANDARDS** UM 2	**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**	**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

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.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH 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. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR
2. When health plan Exchange coverage provisions-including any applicable PDLs (Preferred Drug Lists)-conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR

3. When Health Plans utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, and there is no Health Plan PDL applicable, the Preferred Drug Guidelines shall follow NCH recommended agents/regimens/preferred drugs AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When applicable, generic alternatives are preferred over brand-name drugs AND
6. When there is a documented drug shortage, disease progression, contraindication, or confirmed intolerance to a preferred drug/regimen, per NCH Policy and Pathway, the available alternative product may be used if deemed medically appropriate and the indication is listed in a standard reference compendia or accepted peer review literature. For a list of current drug shortages, please refer to FDA drug shortage website in the reference section.

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. 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 cycles for the first 8 cycles for ocular adverse reactions.

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

H. 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. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. 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. ImmunoGen, Inc. Waltham, MA 2023.

D. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs Bethesda, MD 2023.

E. Clinical Pharmacology Elsevier Gold Standard 2023.

F. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2023.

G. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.

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.

J. NCQA UM 2023 Standards and Elements.