

Elahere™ (mirvetuximab soravtansine-gynx) (Intravenous)

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Elahere 100 mg/20 mL single-dose vial: 6 vials every 21 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- 600 billable units (600 mg) every 21 days

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient at least 18 years of age; **AND**

Universal Criteria ¹

- Therapy will be used in combination with artificial tears and ophthalmic topical steroids; **AND**
- Patient has a baseline ophthalmological test (i.e., visual acuity and slit lamp exam) obtained prior to initiation of therapy and will continue to have follow-up ophthalmological examinations periodically thereafter (i.e., every other cycle for the first 8 cycles, and as clinically indicated); **AND**
- Patient does not have moderate to severe hepatic impairment (Child-Pugh Class B or C); **AND**
- Patient does not have any of the following:
 - a. Non-infectious interstitial lung disease or pneumonitis (Grade 3 or 4); **AND**
 - b. Peripheral neuropathy greater than Grade 1; **AND**
 - c. Active or chronic corneal disorders, history of corneal transplantation, or active ocular conditions requiring ongoing treatment/monitoring (e.g., uncontrolled glaucoma, wet age-related macular degeneration requiring intravitreal injections, active diabetic

retinopathy with macular edema, macular degeneration, presence of papilledema, and/or monocular vision); **AND**

Ovarian, Fallopian Tube, and Primary Peritoneal Cancer † ‡ Φ ¹⁻³

- Used as a single agent or in combination with bevacizumab; **AND**
- Patient has folate receptor alpha (FR α) expression positive disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Patient has platinum-resistant disease; **AND**
 - b. Patient has persistent or recurrent epithelial ovarian/fallopian tube/primary peritoneal cancer, carcinosarcoma (Malignant Mixed Müllerian Tumors), clear cell carcinoma of the ovary, mucinous carcinoma of the ovary, or grade 1 endometrioid carcinoma; **AND**
 - i. Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); **OR**
 - c. Patient has recurrent low-grade serous carcinoma

❖ *If confirmed using an immunotherapy assay-<http://www.fda.gov/companiondiagnostics>*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria ¹

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: persistent or recurrent pneumonitis/interstitial lung disease (ILD), severe peripheral neuropathy, severe ocular toxicities (i.e., visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis), etc.

V. Dosage/Administration ¹

Indication	Dose
Ovarian, Fallopian Tube, and Primary Peritoneal Cancer	Administer 6 mg/kg adjusted ideal body weight (AIBW) as an intravenous infusion every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity. <u>The total dose is calculated based on AIBW using the following formula:</u> $AIBW = Ideal\ Body\ Weight\ (IBW\ [kg]) + 0.4 * (Actual\ weight\ [kg] - IBW)$ – Female IBW (kg) = $0.9 * height(cm) - 92$

VI. Billing Code/Availability Information

HCPCS Code:

- J9063 – Injection, mirvetuximab soravtansine-gynx, 1 mg; 1 billable unit = 1 mg

NDC:

- Elahere 100 mg/20 mL (5 mg/mL) single-dose vial: 72903-0853-xx

VII. References

2. Elahere [package insert]. Waltham, MA; ImmunoGen, Inc; November 2022. Accessed January 2024.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) mirvetuximab soravtansine. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed January 2024.
4. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ovarian Cancer - Fallopian Tube Cancer and Primary Peritoneal Cancer 1.2024. National Comprehensive Cancer Network, 2024. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed January 2024.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.3	Malignant neoplasm of bilateral ovaries
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament

C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C57.9	Malignant neoplasm of female genital organ, unspecified
Z85.43	Personal history of malignant neoplasm of ovary

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
15	KY, OH	CGS Administrators, LLC