



Coverage of any drug intervention discussed in a WellFirst Health prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and applicable state and/or federal laws.

☒ Commercial (Small & Large Group) ☒ ASO ☒ Exchange/ACA
☒ Medicare Advantage (MAPD)

**Elahere™ (mirvetuximab soravtansine-gynx)
(Intravenous)**

Document Number: IC-0686

Covered Service: Yes

**Prior Authorization
Required:** Yes

**Additional
Information:** None.

Medicare Policy: Prior authorization is not required for Medicare Cost products (Dean Care Gold) and Medicare Supplement (Select) when this drug is provided by participating providers. Prior authorization is required if a member has Medicare primary and the plan secondary coverage. This policy is not applicable to our Medicare Replacement products.

**Wisconsin
Medicaid Policy:** Coverage of prescription drug benefits is administered by the Wisconsin Medicaid program. Coverage of medical drug benefits is administered by the Wisconsin Medicaid fee-for-service program. Medical drugs not paid on a fee-for-service basis by the Wisconsin Medicaid program are covered by the plan with no PA required.

I. Length of Authorization

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

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II. Dosing Limits

- **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 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

- Patient will use therapy in combination with artificial tears and ophthalmic topical steroids; **AND**
- Patient has a baseline ophthalmological test (i.e., visual acuity, 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:
 - Non-infectious interstitial lung disease or pneumonitis (Grade 3 or 4); **AND**
 - Peripheral neuropathy greater than Grade 1; **AND**
 - Patients with 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 Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer † ¹⁻³

- Used as single agent therapy; **AND**
- Patient has folate receptor alpha (FRα)-positive expression as determined by an FDA-approved or CLIA-compliant test❖; **AND**

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- Patient has platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer; **AND**
 - Patients has received up to three prior lines of systemic therapy which must have included prior bevacizumab
 - ❖ *If confirmed using an immunotherapy assay-<http://www.fda.gov/companiondiagnostics>*
- † FDA approved indication(s); ‡ Compendia Recommended Indication(s); Ø Orphan Drug

IV. Renewal Criteria ¹

Coverage can be renewed based upon the following criteria:

- Patient continues to meet 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, 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 Cancer	<p>Administer 6 mg/kg adjusted ideal body weight (AIBW) administered as an intravenous infusion every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity.</p> <p><u>The total dose is calculated based on AIBW using the following formula:</u></p> $AIBW = \text{Ideal Body Weight (IBW [kg])} + 0.4 * (\text{Actual weight [kg]} - \text{IBW})$ $\text{Female IBW (kg)} = 0.9 * \text{height(cm)} - 92$

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VI. Billing Code/Availability Information

HCPCS Code:

- J9999 – Not otherwise classified, antineoplastic drug

NDC:

- Elahere 100 mg 5 mg/mL-20 mL solution in a single-dose vial: 72903-0853-xx

VII. References

- Elahere [package insert]. Waltham, MA; ImmunoGen, Inc; November 2022. Accessed November 2022.
- Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) mirvetuximab soravtansine. National Comprehensive Cancer Network, 2022. 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 November 2022.
- Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ovarian Cancer - Fallopian Tube Cancer and Primary Peritoneal Cancer 5.2022. National Comprehensive Cancer Network, 2022. 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 November 2022.

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

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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)

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.



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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)
15	KY, OH	CGS Administrators, LLC

Committee/Source

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