Elahere® (mirvetuximab soravtansine-gynx)
(Intravenous)

-E-

Document Number: OHSU HEALTHSERVICES-0702

Date Reviewed: 09/2025
Date of Origin: 06/01/2023
Date Approved: 06/2023, 04/2024, 10/02/2025

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 6 months thereafter.

II. Dosing Limits

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

- 700 billable units every 21 days

III. Initial Approval Criteria [1]

Prior authorization validity 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 (total bilirubin >1.5 ULN); **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 [1-6, 5e-6e]

- Patient has folate receptor alpha (FRα) expression positive disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Patient has persistent, recurrent, progressive or relapsed disease; **AND**

b. Patient has low-grade serous carcinoma; **AND**

i. Patient has platinum-resistant disease; **AND**

1. Used as a single agent in FRα expression tumors [≥ 75% positive tumor cells]; **OR**
2. Used in combination with bevacizumab in FRα expression tumors [≥ 25% positive tumor cells]; **OR**

- Patient has platinum-sensitive disease treated with two prior lines of platinum-based therapy; **AND**

3. Used as a single agent in FRα expression tumors [≥ 75% positive tumor cells]; **OR**

c. Patient has epithelial ovarian/fallopian tube/primary peritoneal cancer, carcinosarcoma (malignant mixed Müllerian tumors), clear cell carcinoma of the ovary, mucinous neoplasms 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); **AND**

1. Patient has platinum-resistant disease; **AND**
   a. Used as a single agent in FRα expression tumors [≥ 75% positive tumor cells]; **OR**
   b. Used in combination with bevacizumab in FRα expression tumors [≥ 25% positive tumor cells]; **OR**
2. Patient has platinum-sensitive disease treated with two prior lines of platinum-based therapy; **AND**
   a. Used as a single agent in FRα expression tumors [≥ 75% positive tumor cells]

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

❖ *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]

Prior authorization validity 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 [1,4-6]

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. The total dose is calculated based on AIBW using the following formula: *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 (STANDARD)

2. Elahere [package insert]. North Chicago, IL; AbbVie, Inc; July 2025. Accessed August 2025.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) mirvetuximab soravtansine-gynx. National Comprehensive Cancer Network, 2025. 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 August 2025.

4. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ovarian Cancer - Fallopian Tube Cancer and Primary Peritoneal Cancer 3.2025. National Comprehensive Cancer Network, 2025. 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 August 2025.
5. Matulonis UA, Oaknin A, Pignata S, et al. Mirvetuximab soravtansine (MIRV) in patients with platinum-resistant ovarian cancer with high folate receptor alpha (FRα) expression: Characterization of antitumor activity in the SORAYA study. J Clin Oncol 2022;40:5512.
6. Secord AA, Lewin SN, Murphy CG, et al. The Efficacy and Safety of mirvetuximab soravtansine in FRalpha-Positive, Third-Line and Later, Recurrent Platinum-Sensitive Ovarian Cancer: The Single-Arm Phase 2 PICCOLO Trial. Ann Oncol. 2024:S0923-7534:04948-2.
7. Gilbert L, Oaknin A, Matulonia UA et al. Safety and efficacy of mirvetuximab soravtansine, a folate receptor alpha (FRα)-targeting antibody-drug conjugate (ADC), in combination with bevacizumab in patients with platinum-resistant ovarian cancer. Gynecol Oncol 2023;170:241-247.

VIII. References (ENHANCED)

1e. Matulonis UA, Oaknin A, Pignata S, et al. Mirvetuximab soravtansine (MIRV) in patients with platinum-resistant ovarian cancer with high folate receptor alpha (FRα) expression: Characterization of antitumor activity in the SORAYA study. J Clin Oncol 2022;40:5512.
2e. O'Malley DM, Matulonis UA, Birrer MJ, et al. Phase Ib study of mirvetuximab soravtansine, a folate receptor alpha (FRα)-targeting antibody-drug conjugate (ADC), in combination with bevacizumab in patients with platinum-resistant ovarian cancer. Gynecol Oncol 2020;157:379-385.
3e. Gilbert L, Oaknin A, Matulonis UA, et al. Safety and efficacy of mirvetuximab soravtansine, a folate receptor alpha (FRα)-targeting antibody-drug conjugate (ADC), in combination with bevacizumab in patients with platinum-resistant ovarian cancer. Gynecol Oncol 2023;170:241-247.
4e. Alvarez Secord, A. et al. The efficacy and safety of mirvetuximab soravtansine in FRα-positive, third-line and later, recurrent platinum-sensitive ovarian cancer: the single-arm phase II PICCOLO trial. Annals of Oncology, Volume 36, Issue 3, 321 – 330.
5e. Moore KN, Angelergues A, Konecny GE, et al. Mirvetuximab Soravtansine in Fra-Positive, Platinum-Resistance Ovarian Cancer. N Engl J Med 2023; 389:2162-2174.
6e. Prime Therapeutics Management. Elahere Clinical Literature Review Analysis. Last updated August 2025. Accessed August 2025.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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