Clinical Policy: Mirvetuximab soravatansine-gynx (Elahere)

Reference Number: PA.CP.PHAR.617
Effective Date: 08/2023
Last Review Date: 01/2024

Description
Mirvetuximab soravtasnine-gynx (Elahere ™) is a folate receptor alpha (FRα)-directed antibody and microtubule inhibitor conjugate.

FDA Approved Indication(s)
Elahere is indicated for the treatment of adult patients with a FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patient for therapy based on an FDA-approved test.

This indication is approved under accelerated approval based on tumor response and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Elahere is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Ovarian Cancer (must meet all)**:**

1. Diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Member meets both of the following parameters (a and b) (*see Appendix D*):
   a. FRα positive ovarian cancer determined by the Ventana FOLR1 (Folate Receptor 1/Folate Receptor Alpha) Assay;
   b. Received at least 1 but no more than 3 prior systemic lines of anticancer therapy, including at least 1 line of therapy containing bevacizumab;
5. Documentation of current actual body weight in kg and height in cm;
6. Request meets one of the following (a or b):
   a. Dose does not exceed 6mg/kg dosed based on adjusted ideal body weight (*see Appendix D*) on day 1 of every 3-week cycle ;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Ovarian Cancer (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy.
3. Documentation of current actual body weight in kg;
4. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 6 mg/kg dosed based on adjusted ideal body weight (*see Appendix D*) on day 1 of every 3-week cycle;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AIBW: adjusted body weight
FDA: Food and Drug Administration
FOLR1: Folate Receptor 1/Folate Receptor Alpha
IBW: ideal body weight

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
carboplatin (Paraplatin®)	Various	Varies
cisplatin	Various	Varies
oxaliplatin	Various	Varies
docetaxel (Taxotere®)	Various	Varies
paclitaxel	Various	Varies
pemetrexed (Alimta®)	Various	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
melphalan (Alkeran®)	Various	Varies
Zirabev™, Mvasi®, Alymsys®, Vegzelma™, Avastin® (bevacizumab)	Various	Varies
cyclophosphamide	Various	Varies
doxorubicin (Adriamycin®)	Various	Varies
etoposide	Various	Varies
gemcitabine	Various	Varies
ifosfamide (Ifex®)	Various	Varies
irinotecan (Camptosar®)	Various	Varies
topotecan (Hycamtin®)	Various	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): ocular toxicity
  - Elahere 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 Elahere, every other cycle for the first 8 cycles, and as clinically indicated.
  - Administer prophylactic artificial tears and ophthalmic topical steroids.
  - Withhold Elahere for ocular toxicities until improvement and resume at the same or reduced dose.
  - Discontinue Elahere for Grade 4 ocular toxicities.

Appendix D: General Information

- Platinum-resistant disease was defined as:
  - Members who have only had 1 line of platinum-based therapy must have received at least 4 cycles of platinum therapies, must have had a response (complete response/remission or partial response/remission) and then progressed between > 3 months and ≤ 6 months after the date of the last dose of platinum-based therapy.
  - Members who have received 2 or 3 lines of platinum therapy must have progressed on or within 6 months after the date of the last dose of platinum-based therapy.
- Members must have received at least 1 but no more than 3 prior systemic lines of anticancer therapy. Examples include:
  - Adjuvant ± neoadjuvant considered 1 line of therapy
  - Maintenance therapy (e.g., bevacizumab, poly adenosine diphosphate-ribose polymerase (PARP) inhibitors) will be considered part of the preceding line of therapy (i.e., not counted independently).
  - Therapy changed due to toxicity in the absence of progression will be considered part of the same line (i.e., not counted independently).
  - Hormonal therapy will be counted as a separate line of therapy unless it was given as maintenance.

- The total dose of Elahere is calculated based on each patient's adjusted ideal body weight using the following formula:
  - AIBW = Ideal body weight (IBW [kg]) + 0.4*(Actual body weight [kg] – IBW)
  - Female IBW (kg) = 0.9*height(cm) – 92
- Information on FDA-approved tests for the measurement of FRα tumor expression is available at http://www.fda.gov/CompanionDiagnostics

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Ovarian, fallopian tube, or primary peritoneal cancer	6mg/kg IV based on adjusted ideal body weight (AIBW) on day 1 of every 3-week cycle	6mg/kg

VI. Product Availability

Single-dose vials for injection: 100 mg/20 mL (5 mg/mL)

VII. References

1. Elahere Prescribing Information: Waltham, MA: ImmunoGen, Inc. November 2022. Available at: https://www.elahere.com/. Accessed November 7, 2023.
2. National Comprehensive Cancer Network. Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer, Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed November 7, 2023.
3. Mirvetuximab In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed. November 7, 2023.
4. ClinicalTrials.gov. A Study of Mirvetuximab Soravtansine in Platinum-Resistant, Advanced High-Grade Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancers With High Folate Receptor-Alpha Expression (SORAYA). Available at: https://clinicaltrials.gov/ct2/show/NCT04296890. Accessed November 7, 2023.
5. Clinical Pharmacology [database online]. Tampa, FL: Elsevier; 2023. URL: www.clinicalkeys.com/pharmacology.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9063	Injection, mirvetuximab soravtansine-gynx, 1 mg

Reviews, Revisions, and Approvals	Date
Policy created	07/2023

Reviews, Revisions, and Approvals	Date
1Q 2024 annual review: in Appendix B, updated formatting and removed commercially unavailable products per Clinical Pharmacology; references reviewed and updated.	01/2024