Clinical Policy: Mirvetuximab ~~soravatansine~~Soravatansine-gynx (Elahere)

Reference Number: LA.PHAR.617
Effective Date: 05.10.24
Last Review Date: 05.14.25~~11.21.24~~ Coding Implications
Line of Business: Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

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.

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 Louisiana Healthcare Connections® 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 all ~~of~~ the following parameters (a, b, and c) (*see Appendix D*):
   a. FRα positive ovarian cancer determined by the Ventana FOLR1 (Folate Receptor 1/Folate Receptor Alpha) Assay;
   b. Platinum-resistant or platinum-sensitive ovarian cancer;
   c. 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~~6 mg/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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

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B. Other diagnoses/indications (must meet 1 or 2)**:**
   a. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy ~~for the relevant line of business:~~ LA.PMN.53 ~~for Medicaid~~.

II. Continued Therapy

A. Ovarian Cancer (must meet all)**:**
1. Currently receiving medication via Louisiana Healthcare Connections benefit or documentation supports that member is currently receiving Elahere for a covered indication and has received this medication for at least 30 days ~~.~~ ;
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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

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B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255 for Medicaid.
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion ~~2~~1 above does not apply, refer to the off-label use ~~policy for the relevant line of business:~~ LA.PMN.53 ~~for Medicaid~~.

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 – LA.PMN.53 ~~for Medicaid or evidence of coverage documents~~.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AIBW: adjusted ideal body weight FDA: Food and Drug Administration

FOLR1: folate receptor 1
FRα: 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
melphalan (Alkeran®)	Various	Varies
Zirabev™, Mvasi®, Alymsys®, Vegzelma™, Avzivi®, 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~~is defined as~~:~~

- ~~o~~ ~~Members who have only had 1 line~~ one 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.~~ the following:
  - ~~Members who have received 2~~Progression on primary, maintenance or ~~3 lines of platinum~~recurrence therapy ~~must have progressed on~~
  - Stable or ~~within~~persistent disease (if not on maintenance therapy)
  - Complete remission and relapse ≤ 6 months after ~~the date of the last dose of platinum-based therapy.~~completing chemotherapy
- Platinum-sensitive disease is defined as complete remission and relapse ≥ 6 months after completing chemotherapy.
- 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~~6 mg/kg IV based on ~~adjusted ideal body weight (~~AIBW~~)~~ on day 1 of every 3-week cycle	~~6mg~~6 mg/kg

VI. Product Availability

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

VII. References

1. Elahere Prescribing Information: Waltham, MA: ImmunoGen, Inc.; ~~November 2022.~~October 2024. Available at: https://www.rxabbvie.com/pdf/elahere~~.com/~~._pi.pdf. Accessed ~~March 28~~October 31, 2024.
2. National Comprehensive Cancer Network. Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer, Version ~~1~~3.2024. Available at:

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https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed ~~March 31~~November 12, 2024.
3. Mirvetuximab In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed ~~March 31, 2024~~January 29, 2025.
4. ClinicalTrials.gov. A Study of ~~Mirvetuximab Soravtansine~~mirvetuximab soravtansine in ~~Platinum-Resistant, Advanced High-Grade Epithelial Ovarian, Primary Peritoneal~~platinum-resistant, advanced high-grade epithelial ovarian, primary peritoneal, or ~~Fallopian Tube Cancers With High Folate Receptor-Alpha Expression~~fallopian tube cancers with high folate receptor-alpha expression (SORAYA). Available at: https://clinicaltrials.gov/ct2/show/NCT04296890. Accessed March 31, 2024.
5. Clinical Pharmacology [database online]. ~~Tampa, FL~~Philadelphia, PA: Elsevier~~; 2023. URL: . Updated periodically. Available at: http://~~www.~~clinicalkeys~~clinicalkey.com/pharmacology. Accessed November 12, 2024.
6. Moore KN, Angelergues A, Konecny GE, et al. Mirvetuximab Soravtansine in FRα-Positive, Platinum-Resistant Ovarian Cancer. December 6, 2023. N Engl J Med 2023; 389: 2162-2174.

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	LDH Approval Date
Policy created	05.01.23	08.28.23
Added updated HCPCS code [J9063]	02.10.24	05.10.24
No significant changes; in Appendix B, updated formatting and removed commercially unavailable products per Clinical Pharmacology; removed limitation of use language due to accelerated approval per updated labeling; references reviewed and updated.	11.21.24	01.27.25
Annual review: added platinum-sensitive ovarian cancer option to platinum-resistant cancer criterion per NCCN; Appendix D updated with definitions of platinum-resistant and sensitive cancer per NCCN; references reviewed and updated. Per NCCN Compendium and phase 3 confirmatory trial, removed requirement that at least one prior line of therapy contained bevacizumab.	05.14.25	

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CLINICAL POLICY

Mirvetuximab ~~soravtasnine~~Soravtasnine-gynx

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

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