



Elahere
Ovarian / Fallopian tube / Peritoneal cancer
Elahere (Mirvetuximab Soravtansine-gynx) C9146
Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

<input type="checkbox"/>	Standard Request– (72 Hours)	<input type="checkbox"/>	Urgent Request (standard time frame could place the member's life, health or ability in serious jeopardy)
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Date Requested _____

Requestor _____ Clinic name: _____ Phone _____ / Fax _____

MEMBER INFORMATION

*Name: _____ *ID#: _____ *DOB: _____

PRESCRIBER INFORMATION

*Name: _____ MD FNP DO NP PA *Phone: _____

*Address: _____ *Fax: _____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: _____ Phone: _____

*Address: _____ Fax: _____

PROCEDURE / PRODUCT INFORMATION

HCP Code	Name of Drug	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known

Self-administered Provider-administered Home Infusion

Chart notes attached. **Other important information:** _____

Diagnosis: ICD10: _____ **Description:** _____

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

New Start or Initial Request: (Clinical documentation required for all requests)

- Member has folate receptor-alpha positive disease; and
- Member has platinum-resistant disease; and
- Member has received at least one prior systemic therapy.

If not, please provide **clinical rationale** for formulary exception: _____

Continuation Requests: (Clinical documentation required for all requests)

- Provider has reviewed the attached “Criteria for Continuation” and attests the member meets ALL required PA Continuation criteria.**
- Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:** ____ / ____ / ____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

THIS AUTHORIZATION DOES NOT GUARANTEE PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Ovarian / Fallopian tube / Peritoneal cancer PA

Drug Name(s):

ELAHERE

MIRVETUXIMAB SORAVTANSINE-GYNX

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Drug meets utilization management criteria:
3. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

- N/A

Prescriber Restrictions:

- N/A

Coverage Duration:

Initial Approval will be for 6 months. Continuation will be approved up to 12 months.

FDA Indications:

- Ovarian cancer, Fallopian tube, or primary peritoneal cancer, folate receptor-alpha positive, platinum-resistant, in patients treated with 1 to 3 prior systemic regimens

Off-Label Uses:

- N/A

Age Restrictions:

- Safety and effectiveness have not been established in pediatric patients

Other Clinical Consideration:

- **Black Box Warning (ocular toxicity)**
 - 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.**

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/4D44BD/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYN/C/19E873/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.DoIntegratedSearch?SearchTerm=Elahere&UserSearchTerm=Elahere&SearchFilter=filterNone&navitem=searchGlobal#