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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	December 9, 2022
Subject:	Elahere	**Page:**	1 of 5

Last Review Date: March 8, 2024

Elahere

Description

Elahere (mirvetuximab soravtansine-gynx)

Background
Elahere (mirvetuximab soravtansine-gynx) is an antibody-drug conjugate (ADC). The antibody is a chimeric IgG1 directed against folate receptor alpha (FRα). The small molecule, DM4, is a microtubule inhibitor attached to the antibody via a cleavable linker. Upon binding to FRα, Elahere is internalized followed by intracellular release of DM4 via proteolytic cleavage. DM4 disrupts the microtubule network within the cell, resulting in cell cycle arrest and apoptotic cell death (1).

Regulatory Status
FDA-approved indication: Elahere is a folate receptor alpha (FRα)-directed antibody and microtubule inhibitor conjugate indicated for the treatment of adult patients with FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test (1).

Elahere has a boxed warning regarding the risk of ocular toxicity. Elahere can cause severe ocular toxicities, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis. An ophthalmic exam including visual acuity and slit lamp exam should be conducted prior to initiation of Elahere, every other cycle for the first 8 cycles, and as clinically indicated. Prophylactic artificial tears and ophthalmic topical steroids should be administered (1).

Elahere also contains warnings regarding the following: pneumonitis and peripheral neuropathy. Patients should be monitored for signs and symptoms of pneumonitis and neuropathy (1).

Elahere can cause embryo-fetal harm when administered to a pregnant woman. Female patients of reproductive potential should be advised to use effective contraception during treatment with Elahere and for 7 months after the last dose (1).

The safety and effectiveness of Elahere in pediatric patients less than 18 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Elahere may be considered **medically necessary** if the conditions indicated below are met.

Elahere may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Epithelial ovarian, fallopian tube, or primary peritoneal cancer
    a. Folate receptor-alpha (FRα) positive, as determined by an FDA-approved test
    b. Cancer is platinum-resistant
    c. Patient has received one to three prior systemic treatment regimens

AND ALL of the following:

1. Prescriber agrees to monitor for severe ocular toxicities

2. Patient will have an ophthalmic exam including visual acuity and slit lamp exam done prior to initiation of Elahere, every other cycle for the first 8 cycles, and as clinically indicated
3. Prescriber agrees to administer premedications as necessary, such as corticosteroid, antihistamine, antipyretic, antiemetic, ophthalmic topical steroids, and lubricating eye drops
4. Prescriber agrees to monitor for signs and symptoms of pneumonitis and neuropathy
5. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Elahere and for 7 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Epithelial ovarian, fallopian tube, or primary peritoneal cancer
    a. **NO** disease progression or unacceptable toxicity

AND ALL of the following:

1. Prescriber agrees to monitor for severe ocular toxicities
2. Patient will have an ophthalmic exam including visual acuity and slit lamp exam done as clinically indicated
3. Prescriber agrees to administer premedications as necessary, such as corticosteroid, antihistamine, antipyretic, antiemetic, ophthalmic topical steroids, and lubricating eye drops
4. Prescriber agrees to monitor for signs and symptoms of pneumonitis and neuropathy
5. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Elahere and for 7 months after the last dose

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits
Same as above

Rationale

Summary
Elahere (mirvetuximab soravtansine-gynx) is a folate receptor alpha (FRα)-directed antibody and microtubule inhibitor conjugate indicated for the treatment of adult patients with FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer. Elahere contains a boxed warning regarding severe ocular toxicities. The safety and effectiveness of Elahere in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Elahere while maintaining optimal therapeutic outcomes.

References
1. Elahere [package insert]. Waltham, MA: ImmunoGen, Inc.; November 2022.
2. NCCN Drugs & Biologics Compendium® Mirvetuximab soravtansine-gynx 2024. National Comprehensive Cancer Network, Inc. Accessed on January 30, 2024.

Policy History

Date	Action
December 2022	Addition to PA
March 2023	Annual review and reference update
December 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.