ELAHERE®
mirvetuximab soravtansine-gynx
injection 100 mg

Today's date: __/__/____

Ocular Assessment Form

This is an optional tool to help support eye care for patients prescribed ELAHERE

TO BE COMPLETED BY THE PRESCRIBING ONCOLOGIST OR PATIENT

ONCOLOGIST	
	Name
	Facility
	Phone
	Fax/email

PATIENT	
	Name
	Date of birth
	Patient ID

TO BE COMPLETED—AND SUBMITTED TO THE PRESCRIBING ONCOLOGIST—BY THE EYE CARE PROVIDER

Please select the appropriate option:

☐ Baseline exam ☐ Scheduled follow-up exam ☐ Follow-up due to patient-reported symptoms

Note: Premedication with ophthalmic topical steroids is recommended as part of treatment with ELAHERE, as outlined on page 2 of this form, Proactive Management of Ocular Events. Please coordinate prescription of eye drops with the treating oncologist.[1]

Symptom Assessment

☐ Patient reports the following new or ongoing ocular symptom(s): ☐ No symptoms reported

_____

Visual Acuity[1]	Baseline exam		Current exam	
	Right eye	Left eye	Right eye	Left eye
Best corrected distance visual acuity	20/	20/	20/	20/
Entering distance visual acuity Were corrective lenses worn during the assessment? ☐ Yes ☐ No	20/	20/	20/	20/

Ophthalmic Exam[1]

☐ No abnormal findings

Finding	Severity of finding[a]	Right eye	Left eye	Eye Care Provider Action	ELAHERE Prescriber Action: Recommended Dosage Modifications for Adverse Reactions[1]
Keratitis/ keratopathy	Nonconfluent superficial keratitis	☐ Yes	☐ Yes	Monitor	Monitor
	Confluent superficial keratitis	☐ Yes	☐ Yes	If yes for either eye, notify prescribing oncologist[b]	Withhold until improved or resolved, then maintain at same dose level or consider dose reduction.
	Cornea epithelial defect	☐ Yes	☐ Yes		
	3-line or more loss in best corrected visual acuity	☐ Yes	☐ Yes		
	Corneal ulcer	☐ Yes	☐ Yes		Withhold until improved or resolved, then reduce by one dose level.
	Stromal opacity	☐ Yes	☐ Yes		
	Best corrected distance visual acuity of 20/200 or worse	☐ Yes	☐ Yes		
	Corneal perforation	☐ Yes	☐ Yes		Permanently discontinue.
Uveitis	Grade 1/rare cell in anterior chamber	☐ Yes	☐ Yes	Monitor	Monitor
	Grade 2/1-2+ cell or flare in anterior chamber	☐ Yes	☐ Yes	If yes for either eye, notify prescribing oncologist[b]	Withhold until grade 1 or less, then maintain dose at same dose level
	Grade 3/3+ cell or flare in anterior chamber	☐ Yes	☐ Yes		Withhold until grade 1 or less, then reduce dose by 1 dose level
	Grade 4/hypopyon	☐ Yes	☐ Yes		Permanently discontinue

[a]Unless otherwise specified, National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 5.0.[1]
[b]Reporting exam findings to the treating oncologist can guide the need for dose modification of ELAHERE due to ocular adverse events.[1]

Additional Information	Eye Care Provider: *(Name and Contact Information)*

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Your patient is being referred by their oncologist for an ophthalmic exam as they have been prescribed ELAHERE treatment which has the potential to cause ocular side effects. ELAHERE is a therapy approved to treat certain patients with platinum-resistant ovarian cancer.[1]

INDICATION

ELAHERE is indicated for the treatment of adult patients with folate receptor-alpha (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.

SELECT IMPORTANT SAFETY INFORMATION

WARNING: 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.**

You can help manage these potential adverse events in your patients by

Conducting an ophthalmic exam[1]

- Prior to ELAHERE treatment initiation
- Every other cycle (approximately every 6 weeks) for the first 8 cycles (approximately 6 months), and as clinically indicated
- New or worsening patient-reported ocular signs or symptoms

Contacting the prescribing oncologist regarding[1]

- Adverse events listed under the Ophthalmic Exam section of this form
- Any additional adverse events

You can use this form to record findings from the patient's ophthalmic exam. After reviewing your findings, the oncologist may modify the patient's dose of ELAHERE to manage ocular adverse events.[1]

Proactive Management of Ocular Events

Patients should receive a baseline ophthalmic exam from an ophthalmologist or optometrist prior to treatment initiation and follow-up exams during every other cycle for the first 8 cycles, and as clinically indicated[1]

Tell patients to avoid use of contact lenses, unless they are medically necessary[1]

Use of preservative-free[a] lubricating eye drops at least 4 times daily and as needed is recommended during treatment with ELAHERE[1,2]

- Advise patients to wait at least 10 minutes after ophthalmic topical steroid administration before instilling lubricating eye drops

Use of ophthalmic topical corticosteroids is recommended[1]

- The initial prescription and renewals of any corticosteroid medication should be made only after examination with a slit lamp
- Patients should administer 1 drop of ophthalmic topical steroid in each eye 6 times daily starting the day prior to each infusion of ELAHERE until day 4
- Patients should administer 1 drop in each eye 4 times daily on days 5 to 8 of each cycle of ELAHERE

[a]Preservative-free is not a requirement for all patients. Lubricating eye drops without preservatives are recommended for patients with sensitive eyes.

Questions:

For patient-specific questions, please reach out to the prescribing oncologist

For additional questions or to report adverse events call:
1-833-ELAHERE (1-833-352-4373)
Monday to Friday, 9AM to 8PM EST

Visit the eye care section of www.ELAHERE.com

Please see additional Important Safety Information on pages 3 and 4 and click to access full Prescribing Information, including BOXED WARNING and Medication Guide.

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Important Safety Information

WARNINGS and PRECAUTIONS
Ocular Disorders

ELAHERE can cause severe ocular adverse reactions, including visual impairment, keratopathy (corneal disorders), dry eye, photophobia, eye pain, and uveitis.

Ocular adverse reactions occurred in 59% of patients with ovarian cancer treated with ELAHERE. Eleven percent (11%) of patients experienced Grade 3 ocular adverse reactions, including blurred vision, keratopathy (corneal disorders), dry eye, cataract, photophobia, and eye pain; two patients (0.3%) experienced Grade 4 events (keratopathy and cataract). The most common (≥5%) ocular adverse reactions were blurred vision (48%), keratopathy (36%), dry eye (27%), cataract (16%), photophobia (14%), and eye pain (10%).

The median time to onset for first ocular adverse reaction was 5.1 weeks (range: 0.1 to 68.6). Of the patients who experienced ocular events, 53% had complete resolution; 38% had partial improvement (defined as a decrease in severity by one or more grades from the worst grade at last follow up). Ocular adverse reactions led to permanent discontinuation of ELAHERE in 1% of patients.

Premedication and use of lubricating and ophthalmic topical steroid eye drops during treatment with ELAHERE are recommended. Advise patients to avoid use of contact lenses during treatment with ELAHERE unless directed by a healthcare provider.

Refer patients to an eye care professional for an ophthalmic exam including visual acuity and slit lamp exam prior to treatment initiation, every other cycle for the first 8 cycles, and as clinically indicated. Promptly refer patients to an eye care professional for any new or worsening ocular signs and symptoms.

Monitor for ocular toxicity and withhold, reduce, or permanently discontinue ELAHERE based on severity and persistence of ocular adverse reactions.

Pneumonitis

Severe, life-threatening, or fatal interstitial lung disease (ILD), including pneumonitis, can occur in patients treated with ELAHERE.

Pneumonitis occurred in 10% of patients treated with ELAHERE, including 1% with Grade 3 events and 1 patient (0.1%) with a Grade 4 event. One patient (0.1%) died due to respiratory failure in the setting of pneumonitis and lung metastases. One patient (0.1%) died due to respiratory failure of unknown etiology. Pneumonitis led to permanent discontinuation of ELAHERE in 3% of patients.

Monitor patients for pulmonary signs and symptoms of pneumonitis, which may include hypoxia, cough, dyspnea, or interstitial infiltrates on radiologic exams. Infectious, neoplastic, and other causes for such symptoms should be excluded through appropriate investigations. Withhold ELAHERE for patients who develop persistent or recurrent Grade 2 pneumonitis until symptoms resolve to ≤ Grade 1 and consider dose reduction. Permanently discontinue ELAHERE in all patients with Grade 3 or 4 pneumonitis. Patients who are asymptomatic may continue dosing of ELAHERE with close monitoring.

Peripheral Neuropathy (PN)

Peripheral neuropathy occurred in 36% of patients with ovarian cancer treated with ELAHERE across clinical trials; 3% of patients experienced Grade 3 peripheral neuropathy. Peripheral neuropathy adverse reactions included peripheral neuropathy (20%), peripheral sensory neuropathy (9%), paraesthesia (6%), neurotoxicity (3%), hypoaesthesia (1%), peripheral motor neuropathy (0.9%), polyneuropathy (0.3%), and peripheral sensorimotor neuropathy (0.1%). Monitor patients for signs and symptoms of neuropathy, such as paresthesia, tingling or a burning sensation, neuropathic pain, muscle weakness, or dysesthesia. For patients experiencing new or worsening PN, withhold dosage, dose reduce, or permanently discontinue ELAHERE based on the severity of PN.

Embryo-Fetal Toxicity

Based on its mechanism of action, ELAHERE can cause embryo-fetal harm when administered to a pregnant woman because it contains a genotoxic compound (DM4) and affects actively dividing cells.
Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with ELAHERE and for 7 months after the last dose.

Please click to access full Prescribing Information, including BOXED WARNING and Medication Guide.

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Important Safety Information (continued)

ADVERSE REACTIONS

The most common (≥20 %) adverse reactions, including lab abnormalities, were increased aspartate aminotransferase, fatigue, increased alanine aminotransferase, blurred vision, nausea, increased alkaline phosphatase, diarrhea, abdominal pain, keratopathy, peripheral neuropathy, musculoskeletal pain, decreased lymphocytes, decreased platelets, decreased magnesium, decreased hemoglobin, dry eye, constipation, decreased leukocytes, vomiting, decreased albumin, decreased appetite, and decreased neutrophils.

DRUG INTERACTIONS

DM4 is a CYP3A4 substrate. Closely monitor patients for adverse reactions with ELAHERE when used concomitantly with strong CYP3A4 inhibitors.

USE IN SPECIAL POPULATIONS

Lactation

Advise women not to breastfeed during treatment with ELAHERE and for 1 month after the last dose.

Hepatic Impairment

Avoid use of ELAHERE in patients with moderate or severe hepatic impairment (total bilirubin >1.5 ULN).

Please see **full Prescribing Information**, including **BOXED WARNING.**

References: 1. ELAHERE. Package insert. ImmunoGen, Inc.; 2024. **2.** Moore KN, et al. *N Engl J Med.* 2023;389(23):2162-2174.

Please click to access full Prescribing Information, including BOXED WARNING and Medication Guide.