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: As part of their treatment with ELAHERE, your patient is being prescribed ophthalmic topical steroids that may elevate intraocular pressure.[1-4]

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	Right eye	Left eye	Action
Keratitis/ keratopathy	Nonconfluent superficial keratitis	☐ Yes	☐ Yes	Monitor
	Confluent superficial keratitis	☐ Yes	☐ Yes	If yes for either eye, notify prescribing oncologist[a]
	Cornea epithelial defect	☐ Yes	☐ Yes	
	3-line or more loss in best corrected visual acuity	☐ Yes	☐ Yes	
	Corneal ulcer	☐ Yes	☐ Yes	
	Stromal opacity	☐ Yes	☐ Yes	
	Best corrected distance visual acuity of 20/200 or worse	☐ Yes	☐ Yes	
	Corneal perforation	☐ Yes	☐ Yes	
Uveitis	Grade 1/rare cell in anterior chamber	☐ Yes	☐ Yes	Monitor
	Grade 2/1-2+ cell or flare in anterior chamber	☐ Yes	☐ Yes	If yes for either eye, notify prescribing oncologist[a]
	Grade 3/3+ cell or flare in anterior chamber	☐ Yes	☐ Yes	
	Grade 4/hypopyon	☐ Yes	☐ Yes	

[a]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]

INDICATIONS AND USAGE

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.

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

SELECT IMPORTANT SAFETY INFORMATION

BOXED 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[1,5-7]

- 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.

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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 61% of patients with ovarian cancer treated with ELAHERE. Nine percent (9%) of patients experienced Grade 3 ocular adverse reactions, including visual impairment, keratopathy/keratitis (corneal disorders), dry eye, photophobia, and eye pain; and one patient (0.2%) experienced Grade 4 keratopathy. The most common (≥5%) ocular adverse reactions were visual impairment (49%), keratopathy (36%), dry eye (26%), cataract (15%), photophobia (13%), and eye pain (12%).

The median time to onset for first ocular adverse reaction was 1.2 months (range: 0.03 to 12.9). Of the patients who experienced ocular events, 49% had complete resolution and 39% 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 0.6% 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 0.8% with Grade 3 events, and 1 patient (0.2%) with a Grade 4 event. One patient (0.2%) died due to respiratory failure in the setting of pneumonitis and lung metastases.

Monitor patients for pulmonary signs and symptoms of pneumonitis. Infectious, neoplastic, and other causes for 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)

PN occurred in 36% of patients with ovarian cancer treated with ELAHERE across clinical trials; 2% of patients experienced Grade 3 PN. PN adverse reactions included peripheral neuropathy (19%), peripheral sensory neuropathy (9%), paraesthesia (6%), neurotoxicity (3%), hypoaesthesia (2%), peripheral motor neuropathy (1%), neuralgia (0.4%), polyneuropathy (0.2%) and oral hypoesthesia (0.2%).

Monitor patients for signs and symptoms of neuropathy. 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.

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Important Safety Information (continued)

ADVERSE REACTIONS

Serious adverse reactions occurred in 31% of patients. The most common (≥2%) serious adverse reactions were intestinal obstruction (8%), ascites (4%), infection (3%), and pleural effusion (3%). Fatal adverse reactions occurred in 2% of patients, including small intestinal obstruction (1%) and pneumonitis (1%).

Permanent discontinuation of ELAHERE due to adverse reactions occurred in 11% of patients. The most common (≥2%) adverse reactions leading to permanent discontinuation were intestinal obstruction (2%) and thrombocytopenia (2%). One patient (0.9%) permanently discontinued ELAHERE due to visual impairment (unilateral decrease to BCVA ≤20/200 that resolved to baseline after discontinuation).

Dosage delays of ELAHERE due to an adverse reaction occurred in 39% of patients. Adverse reactions which required dosage delays in ≥3% of patients included visual impairment (15%), keratopathy (11%), neutropenia (6%), dry eye (5%), cataracts (3%) and increased gamma-glutamyltransferase (3%).

Dose reductions of ELAHERE due to an adverse reaction occurred in 20% of patients. Adverse reactions which required dose reductions in ≥3% of patients included visual impairment (9%) and keratopathy (7%).

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

DRUG INTERACTIONS

Strong CYP3A4 Inhibitors

DM4 is a CYP3A4 substrate. Concomitant use of ELAHERE with strong CYP3A4 inhibitors may increase unconjugated DM4 exposure, which may increase the risk of ELAHERE adverse reactions. 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 at least 1 month after the last dose.

Pediatric Use

Safety and effectiveness of ELAHERE have not been established in pediatric patients.

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.;2022. **2.** Matossian C, et al. *J Cataract Refract Surg*. 2021;47(1):53-64. **3.** Palacio-Pastrana C, et al. *Clin Ophthalmol*. 2020;14:1581-1589. **4.** Doughty MJ. In: *Ocular Pharmacology & Therapeutics: A Primary Care Guide*. BH/Optician; 2001:92-102. **5.** Data on file. ImmunoGen, Inc. **6.** Moore K, et al. Poster presented at: 2016 American Society of Clinical Oncology Annual Meeting; June 3-7, 2016; Chicago, IL. Poster 5567. **7.** Moore KN, et al. *J Clin Oncol*. 2017;35(10):1112-1118.

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