



BILLING AND CODING GUIDE

ELAHERE Support Services (ESS) is committed to helping appropriate patients **start on ELAHERE** by offering **access** and **reimbursement** support, **affordability** assistance, and dedicated **nursing support** for patient questions based on Prescribing Information.

For more information, call the ELAHERE Support Services Program at 1-833-ELAHERE (1-833-352-4373) Monday to Friday, 8:00 AM to 8:00 PM ET

Support resources for your practice and your patients at [ELAHEREhcp.com](https://www.elaHEREhcp.com)

PERMANENT ELAHERE HCPCS CODE

Effective July 1, 2023

J9063

Injection, mirvetuximab soravtansine-gynx, 1 mg

INDICATION

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

FDA=US Food and Drug Administration; HCPCS=Healthcare Common Procedure Coding System.

Please see additional Important Safety Information for ELAHERE, including Boxed Warning on pages 11-12, and click to access [full Prescribing Information](#).

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BILLING AND CODING INFORMATION MAY HELP SUPPORT SUCCESSFUL CLAIMS PROCESSING



Accuracy in billing and coding can help enhance claims processing and facilitate timely reimbursement. AbbVie provides this informational guide as a reference for billing and coding for ELAHERE® (Injection, mirvetuximab soravtansine-gynx, 100 mg/20 ml).

Claims that include the following information may help support more successful processing:

- ✓ Accurate codes (eg, CPT, J-code, ICD-10-CM)
- ✓ Accurate product information (ie, dose, route, units given, units wasted)
- ✓ Accurate and complete NDC, prior authorization number, and National Provider Identifier
- ✓ Accurate beneficiary information (eg, insurance identification number, date of birth)
- ✓ Completion of all payer-specific requirements
- ✓ Consistency between the Prior Authorization and the filed claim

Note: AbbVie makes every effort to ensure this guide is accurate and current at the time of dissemination. As there may be instances where there are delays in updates to the guide, ensure you determine the accurate coding prior to submission.

CPT®=Current Procedural Terminology; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; NDC=National Drug Code.

Please see additional Important Safety Information for ELAHERE, including Boxed Warning on pages 11–12, and click to access [full Prescribing Information](#).

PHYSICIAN OFFICE CODING



The tables below provide examples of codes that may be appropriate for ELAHERE for its FDA-approved indications. Please note, the use of the following codes does not guarantee payment or coverage for any product or service.

NDC¹

11-digit NDC

Administration method	Dosage Form	Code	Description
Physician Administered	For injection: 100 mg/20 mL (mg/mL) in single-dose vial, once every 3 weeks	72903-0853-01	One vial containing one single dose

10-digit NDC

Administration method	Dosage Form	Code	Description
Physician Administered	For injection: 100 mg/20 mL (mg/mL) in single-dose vial, once every 3 weeks	72903-853-01	One vial containing one single dose

CPT^{®2}

Submitting accurate codes and claims is important to ensure proper reimbursement of services.

Procedural type	Code	Description
Intravenous Infusion	96413	Chemotherapy administration, intravenous infusion; up to 1 hour, single or initial substance or drug
Intravenous Infusion	96415	Chemotherapy administration, intravenous infusion; each additional hour

FRa testing

Please see page 6 for available FRa testing codes.

Place of service code³

Code	Location	Description
11	Office	Office, other than a hospital, skilled nursing facility, military treatment facility, community health center, state or local public health clinic, or intermediate care facility, where the HCP routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis

This document is intended for informational purposes only and is not intended to provide reimbursement or legal advice. Providers are responsible for determining the appropriate codes and submitting true and correct claims for product and services rendered. Providers should contact the patient's payor for information on coverage, coding, and reimbursement.

HCP=healthcare provider.

Please see additional Important Safety Information for ELAHERE, including Boxed Warning on pages 11-12, and click to access [full Prescribing Information](#).

PHYSICIAN OFFICE CODING (cont'd)



HCPCS⁴

Effective July 1, 2023, the CMS released the 2023 Quarterly HCPCS file, which includes the designation of J9063 for injection, mirvetuximab soravtansine-gynx, 1 mg.

Please contact the payer or the ELAHERE Support Services Program at 1-833-ELAHERE for additional coding information.

Code	Description
J9063	Injection, mirvetuximab soravtansine-gynx, 1 mg

- **J9063** will replace miscellaneous and/or temporary codes that were previously used across various sites of care
- **J9063** applies to commercial and Medicare patients in both hospital outpatient and physician's office settings

ICD-10-CM diagnosis codes⁵⁻⁷

ICD-10-CM	Description
C48.1	Malignant neoplasm of the peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C56.1	Malignant neoplasm of ovary, right ovary
C56.2	Malignant neoplasm of ovary, left ovary
C56.3	Malignant neoplasm of bilateral ovaries
C56.9	Malignant neoplasm of ovary, unspecified
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs

Code Modifiers⁸

Code	Description
JW	Drug amount discarded/not administered to any patient
JZ	Zero drug amount discarded (Required after 7/1/2023)

CMS=Centers for Medicare and Medicaid Services.

Please see additional Important Safety Information for ELAHERE, including Boxed Warning on pages 11-12, and click to access [full Prescribing Information](#).

HOSPITAL/OUTPATIENT CODING



The tables below provide examples of codes that may be appropriate for ELAHERE for its FDA-approved indications. Please note, the use of the following codes does not guarantee payment or coverage for any product or service.

NDC¹

11-digit NDC

Administration method	Dosage Form	Code	Description
Physician Administered	For injection: 100 mg/20 mL (mg/mL) in single-dose vial, once every 3 weeks	72903-0853-01	One vial containing one single dose

10-digit NDC¹

Administration method	Dosage Form	Code	Description
Physician Administered	For injection: 100 mg/20 mL (mg/mL) in single-dose vial, once every 3 weeks	72903-853-01	One vial containing one single dose

CPT^{®2}

Submitting accurate codes and claims is important to ensure proper reimbursement of services.

Procedural type	Code	Description
Intravenous Infusion	96413	Chemotherapy administration, intravenous infusion; up to 1 hour, single or initial substance or drug
Intravenous Infusion	96415	Chemotherapy administration, intravenous infusion; each additional hour

FRa testing⁹

Procedural type	Code	Description
FOLR1 IHC	88342	Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure
FOLR1 IHC	88341	Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (list separately in addition to code for primary procedure)

Place of service code³

Code	Location	Description
19	Off Campus: Outpatient Hospital	A portion of an off-campus hospital provider based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization
22	On Campus: Outpatient Hospital	A portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization

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HOSPITAL/OUTPATIENT CODING (cont'd)



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C56.2	Malignant neoplasm of ovary, left ovary
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C56.9	Malignant neoplasm of ovary, unspecified
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs

Revenue Codes^{10,11}

Code	Description
0636	Drugs Requiring Detailed Coding (ELAHERE)
0335	Chemotherapy Administration - IV
025x	General Pharmacy
0510	Clinic Visit

Code Modifiers^{8,12}

Code	Description
JW	Drug amount discarded/not administered to any patient
JZ	Zero drug amount discarded (Required after 7/1/2023)
TB*	Drug or biological acquired with 340b drug pricing program discount, reported for informational purposes for select entities
JG*	Drug or biological acquired with 340b drug pricing program discount, reported to trigger the payment reduction

*As of January 1, 2023, these modifiers are informational only.

Please see additional Important Safety Information for ELAHERE, including Boxed Warning on pages 11-12, and click to access [full Prescribing Information](#).

SAMPLE CMS 1500 CLAIM FORM

Box 21 (Electronic Claim Form = Loop 2300, Segment H101-2 through H112=2): Enter the patient's diagnosis from the patient's medical record. Be as specific as possible. Use Box 21 B-L fields for secondary diagnoses.

Box 23 (Electronic Claim Form = Loop 2300, REF02): Enter prior authorization number if one exists.

Box 24A-B (Electronic Claim Form):
Box 24A (Electronic Claims = Loop 2400, DTP02)
Box 24B (Loop 2300/2400, Segment CLM05-1/SV105)

In the non-shaded area, enter the appropriate date of service and place of service code. Example: Office = 11

In the shaded area, enter the N4 indicator first, then the 11-digit NDC code. In the third space, list the quantity and, last, the unit of measurement code.

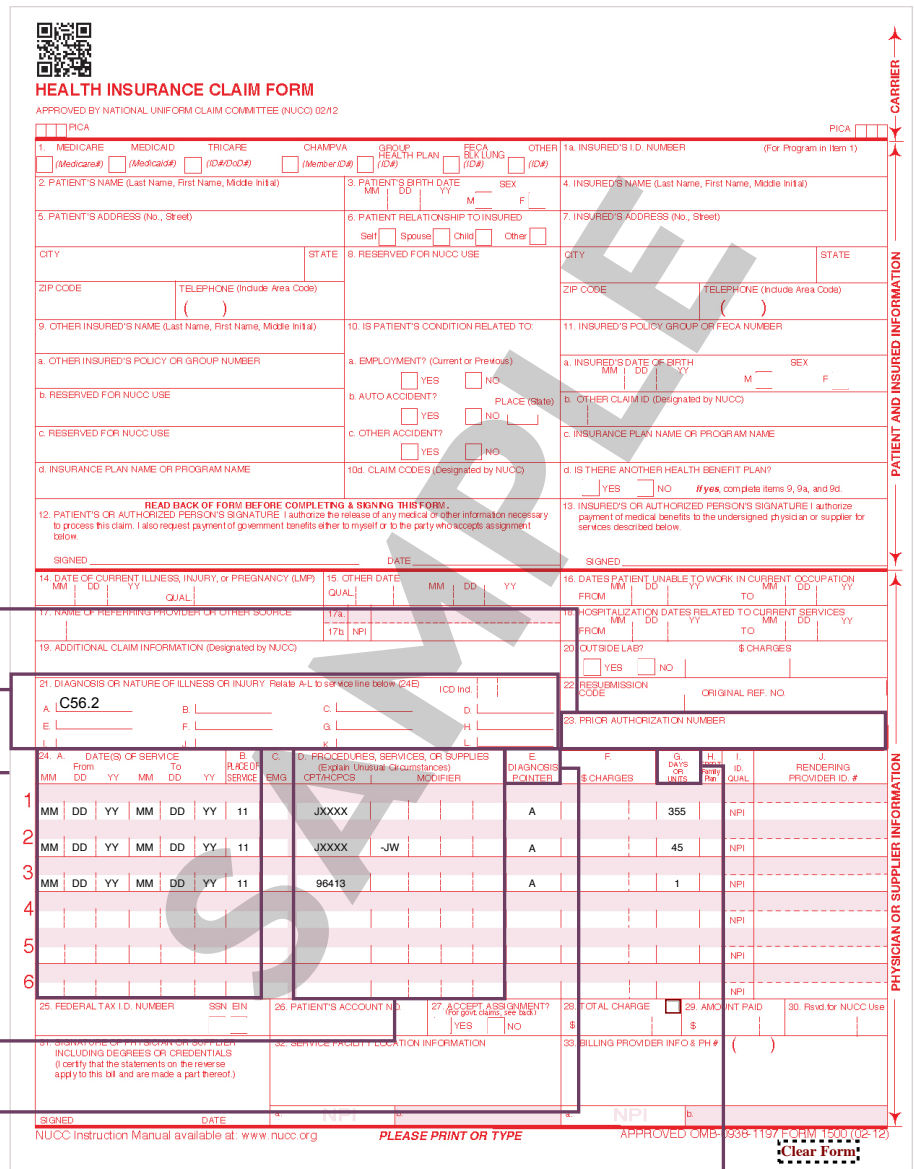
An example for ELAHERE is N472903085301 80ML.

Box 24D (Electronic Claim Form = Loop 2400, Segment SV101): Enter the correct HCPCS code for ELAHERE, which as of July 1, 2023, is **J9063 for 1 mg.**

If applicable, the discarded product should be billed on a separate line with Modifier -JW.* Add modifier -JZ† on 1 line if there is no waste.

For administration, enter the appropriate code or codes for the infusion duration. For example, a 60-minute infusion of ELAHERE will require 96413.‡

Box 24E (Electronic Claim Form = Loop 2400, Segment SV107): Specify the diagnosis letter that corresponds with ELAHERE and the drug administration code(s) in Box 21



HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE (Medicare) MEDICAID (Medicaid) TRICARE (TRICARE) CHAMPVA (Member ID) GROUP HEALTH PLAN (Group Health Plan) FECA (FECA) OTHER (Other)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE (MM DD YY) SEX (M F)

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED (Self Spouse Child Other)

7. INSURED'S ADDRESS (No., Street)

8. RESERVED FOR NUCC USE

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE

14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (IMP)

15. OTHER DATE

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? \$ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service line below (24E))

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

LINE	A. DATE(S) OF SERVICE			B. PLACE OF SERVICE	C. PROCEDURE, SERVICE, OR SUPPLIES (Explain Unusual Circumstances) (CPT/HCPCS)	D. MODIFIER	E. DIAGNOSIS (ICD-10)	F. \$ CHARGES	G. DAYS OF USE	H. QUANTITY	I. ID. QUAL.	J. RENDERING PROVIDER ID.#
	From	To	YY									
1	MM DD YY	MM DD YY	YY	11	JXXXX		A	355			NPI	
2	MM DD YY	MM DD YY	YY	11	JXXXX	-JW	A	45			NPI	
3	MM DD YY	MM DD YY	YY	11	96413		A	1			NPI	
4											NPI	
5											NPI	
6											NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (YES NO)

28. TOTAL CHARGE \$

29. AMOUNT PAID \$

30. Pwd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER

32. SERVICE FACILITY LOCATION INFORMATION

33. BILLING PROVIDER INFO & PI#

SIGNED DATE NPI

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED CMB-1197 FORM 1500 (02-12) Clear Form

Box 24G (Electronic Claim Form = Loop 2400, Segment SV104): Enter the number of service units for each item. For J9063, each unit corresponds to 1 mg of ELAHERE.

On separate lines, add the units for the drug administered and the units of the drug wasted with modifier-JW. If there is no waste, use Modifier-JZ.

*Since January 1, 2017, Medicare has required Modifier -JW for waste. Check with other payers as to their requirements for identifying waste.

†Effective July 1, 2023, Medicare requires the -JZ modifier on all claims for single-dose containers with no discarded amounts.

‡CPT Code 96413 Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug. Initial infusion times may vary.

SAMPLE UB-04 / CMS 1450 CLAIM FORM



Form Locator (FL) 42 (Electronic Claim Form = Loop 2400, Segment Type SV201): List the appropriate revenue code for ELAHERE. Medicare requires Revenue Code 0636. Medicaid may use 0636, but other payers may use General Pharmacy 0250 or other revenue codes —always check with the billed payer.

Additionally, enter an appropriate revenue code for the administration service, 0335 for chemotherapy, or others based on the cost center in which the service was performed.

FL 45 (Electronic Claim Form = Loop 2400, Segment DTP/472/03): Enter the date of service.

FL 43 (NOT REQUIRED BY MEDICARE): Enter the description of the procedure for the Revenue Code billed. If required, enter the N4 indicator first, then the 11-digit NDC code. In the third place, list the quantity and, last, the unit of measurement code.

An example for ELAHERE is N472903085301 80ML.

FL 46 (Electronic Claim Form = Loop 2400, SV205): Enter the units for the HCPCS code billed.

Enter the number of service units for each item. For J9063, each unit corresponds to 1 mg of ELAHERE.

For Medicare (and some other payers), bill the units given and the units wasted on separate lines with the units wasted corresponding to Modifier -JW.[†]

FL 63 (Electronic Claim Form = Loop 2300, REF/G1/02): Enter treatment authorization code.

FL 67A-Q (Electronic Claim Form = Loop 2300, H101-2 (H101-1=BK): Enter a diagnosis code for ELAHERE documented in the medical record.

Be as specific as possible. The code listed here is an example, C56.2, malignant neoplasm of the left ovary.

FL 44 (Electronic Claim Form = Loop 2400, SV202-2 (SV202-1=HC/HP): Enter the appropriate HCPCS code for ELAHERE Injection, mirvetuximab soravtansine-gynx, 1 mg,* which, as of July 1, 2023, is J9063.

This HCPCS code may not be acceptable to all payers on July 1, 2023. If applicable, the discarded product must be reported on a separate line with Modifier -JW.[†] If no waste is reported, apply Modifier -JZ[‡] for dates of service on or after January 1, 2023. Also, Modifier -TB or -JB must be applied for 340B providers in most cases. As of January 1, 2023, both are informational modifiers. For administration, enter the appropriate code or codes for the infusion duration. As an example, a 60-minute infusion of ELAHERE requires 96413.[§]

*HCPCS Code C9146 is effective April 1-July 1, 2023. Before July 1st, 2023, you may continue to bill ELAHERE using unclassified codes such as J3590 – Unclassified biologics or J9999–Not otherwise classified, antineoplastic drugs.

[†]Since January 1, 2017, Medicare has required Modifier -JW for waste. Check with other payers as to their requirements for identifying waste.

[‡]Effective July 1, 2023, Medicare requires the JZ modifier on all claims for single-dose containers with no discarded amounts.

[§]CPT Code 96413 Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug. Initial infusion times may vary.

ELAHERE SUPPORT SERVICES



HERE TO HELP YOU NAVIGATE ACCESS FOR YOUR PATIENTS

ELAHERE Support Services (ESS) is committed to helping appropriate patients **start on ELAHERE** by offering **access** and **reimbursement** support, **affordability** assistance, and dedicated **nursing support** for patient questions based on Prescribing Information.

ENROLL YOUR PATIENT IN ELAHERE SUPPORT SERVICES

Visit ELAHEREhcp.com to download and complete the enrollment form.

WHAT ELAHERE SUPPORT SERVICES (ESS) CAN DO

Once enrolled, ESS offers the following services and programs for patients:

Access & reimbursement

- Benefits investigation
- Prior authorization assistance
- Appeals assistance

Co-pay assistance*

- Support for commercially eligible patients with out-of-pocket costs
- Patients could **pay as little as \$0** for their medication

Patient assistance

- Support for uninsured or underinsured patients who meet eligibility requirements to access medication at no charge[†]

Nurse Navigators

- A resource available to patients and their caregivers to answer questions about their treatment based on the Prescribing Information

*Terms and conditions apply. Patients are eligible for co-pay assistance if enrolled in private commercial health insurance and are not covered by state or federal healthcare programs, and who meet the eligibility criteria. Patients will be enrolled for 12 months. There are no income requirements to participate in the program.

[†]Criteria include patients who are uninsured or have insurance that excludes coverage for ELAHERE (including patients on Medicare or Medicaid), residents of the United States or Puerto Rico, and patients who meet the financial eligibility requirements. Terms and conditions apply.

GET IN TOUCH WITH ELAHERE SUPPORT SERVICES

For questions, connect with an ELAHERE Support Services Program specialist by calling 1-833-ELAHERE (1-833-352-4373) Monday to Friday, 8:00 AM to 8:00 PM ET or email to ELAHERESupport@cardinalhealth.com



1-833-ELAHERE (1-833-352-4373)



1-833-464-6329



www.ELAHEREhcp.com



ELAHERESupport@cardinalhealth.com



INDICATION AND IMPORTANT SAFETY INFORMATION



INDICATION

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

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.

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 ($\geq 5\%$) 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 \leq 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.

Please see additional Important Safety Information for ELAHERE, including Boxed Warning on pages 11-12, and click to access [full Prescribing Information](#).

IMPORTANT SAFETY INFORMATION (cont'd)



WARNINGS and PRECAUTIONS (cont'd)

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.

ADVERSE REACTIONS

The most common ($\geq 20\%$) 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**

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