

ELAHERE OCULAR BILLING AND CODING GUIDE

PERMANENT ELAHERE HCPCS CODE
Effective July 1, 2023¹

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



This guide is intended to be a reference that provides examples of billing and coding information that may be appropriate to facilitate eye exams and eye care for patients receiving ELAHERE®, as is customary for treatment with all antibody drug conjugates. Please note, use of the following codes does not guarantee payment or coverage for any product or service.

ICD-10-CM DIAGNOSIS-SPECIFIC CODES

When billing for eye exams, it is recommended to include the primary condition, long-term medication, and any ocular conditions your patient is experiencing.

ICD-10-CM diagnosis codes²⁻⁴

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

ICD-10-CM Z code⁵

Code	Description
Z79.899	Other long-term (current) drug therapy

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.

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.

FDA=US Food and Drug Administration; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

Please see additional Important Safety Information for ELAHERE, including Boxed Warning on pages 4-5, and click to access [full Prescribing Information](#).

ELAHERE OCULAR BILLING AND CODING GUIDE



Ancillary ocular examination CPT® codes^{6,7}

Code	Description
92285	External ocular photography with interpretation and report for documentation of medical progress (eg, close-up photography, slit lamp photography, gonio photography, stereo-photography)
92025	Computerized corneal topography, unilateral or bilateral, with interpretation and report

Ocular adverse effect ICD-10-CM codes⁸

Code	Description
T45.1X5A	Adverse effect of antineoplastic and immunosuppressive drugs, initial encounter
T45.1X5D	Adverse effect of antineoplastic and immunosuppressive drugs, subsequent encounter
T45.1X5S	Adverse effect of antineoplastic and immunosuppressive drugs, sequela

IMPORTANT SAFETY INFORMATION (CONT'D)

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.

CPT=Current Procedural Terminology.

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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 OFFERS

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



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INDICATION AND IMPORTANT SAFETY INFORMATION



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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.

Please see additional Important Safety Information for ELAHERE, including Boxed Warning on page 5, and click to access [full Prescribing Information](#).

IMPORTANT SAFETY INFORMATION (CONT'D)



IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS and PRECAUTIONS (cont'd)

Pneumonitis (cont'd)

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.

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%), hypoesthesia (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**

To report adverse events, visit www.fda.gov/Safety/MedWatch or call 1-800-FDA-1088.

References: 1. 2022/2023 HCPCS code J9063. HCPCS data. Accessed May 3, 2023. <https://www.cms.gov/medicare/coding/hcpcsreleasecodesets/hcpcs-quarterly-update> 2. Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum. ICD10 data. Accessed April 11, 2023. <https://www.icd10data.com/ICD10CM/Codes/C00-D49/C45-C49/C48-/C48.8> 3. Malignant neoplasm of ovary. ICD 10 data. Accessed April 11, 2023. <https://www.icd10data.com/ICD10CM/Codes/C00-D49/C51-C58/C56-> 4. Malignant neoplasm of other and unspecified female genital organs. ICD 10 data. Accessed April 11, 2023. <https://www.icd10data.com/ICD10CM/Codes/C00-D49/C51-C58/C57-> 5. ICD-10-CM diagnosis code Z79.899. ICD data. Accessed April 11, 2023. <https://www.icd10data.com/ICD10CM/Codes/Z00-Z99/Z77-Z99/Z79-/Z79.899> 6. Billing and coding: ocular photography. Centers for Medicare & Medicaid Services. Accessed April 11, 2023. <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=57068&ver=8> 7. Billing and coding: computerized corneal topography. Centers for Medicare & Medicaid Services. Updated February 2, 2022. Accessed April 11, 2023. https://localcoverage.cms.gov/mcd_archive/view/article.aspx?articleInfo=56816:8 8. ICD-10-CM codes T45-. ICD data. Accessed April 11, 2023. <https://www.icd10data.com/ICD10CM/Codes/S00-T88/T36-T50/T45->