

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 (ADCs). 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.

INDICATIONS AND USAGE

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.

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.

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.

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 full [Prescribing Information](#), including [Boxed Warning](#), and additional [Important Safety Information](#) throughout.

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

Questions? Connect with an ELAHERE Support Services Program specialist

 1-833-ELAHERE (1-833-352-4373),
Monday to Friday, 8 AM to 8 PM ET

 ELAHERESupport@cardinalhealth.com

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 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 ($\geq 5\%$) 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.

CPT=Current Procedural Terminology.

Please see full [Prescribing Information](#), including Boxed Warning, and additional Important Safety Information throughout.

ELAHERE OCULAR BILLING AND CODING GUIDE



IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS and PRECAUTIONS

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 \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)

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.

ADVERSE REACTIONS

Serious adverse reactions occurred in 31% of patients. The most common (\geq 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 (\geq 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 \leq 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 \geq 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 \geq 3% of patients included visual impairment (9%) and keratopathy (7%).

The most common (\geq 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.

Please see full [Prescribing Information](#), including Boxed Warning, and additional Important Safety Information throughout.

ELAHERE OCULAR BILLING AND CODING GUIDE



IMPORTANT SAFETY INFORMATION (CONT'D)

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**.

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. ICD-10-CM codes T45-. ICD data. Accessed April 11, 2023. <https://www.icd10data.com/ICD10CM/Codes/S00-T88/T36-T50/T4>

ELAHERE and the ELAHERE logo are trademarks or registered trademarks of ImmunoGen, Inc. ImmunoGen and the ImmunoGen logo are trademarks or registered trademarks of ImmunoGen, Inc. CPT® copyright 2023 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.

© 2023 ImmunoGen, Inc. All rights reserved. US-MIRV-2300135 05/2023

immu•gen