ELAHERE®
mirvetuximab soravtansine-gynx
injection 100 mg

EPIC

Instructions to Optimize Order Sets and Integrate an AIBW Calculator for ELAHERE® (mirvetuximab soravtansine-gynx) Into Your Epic® Electronic Health Record (EHR) System

INDICATION AND IMPORTANT SAFETY INFORMATION

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.**

AIBW=adjusted ideal body weight; FDA=US Food and Drug Administration.

Please see Important Safety Information for ELAHERE, including BOXED WARNING on pages 3-4, and click to access full Prescribing Information.

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Indication and Important Safety Information

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INDICATION

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- **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 (≥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.

Please see additional Important Safety Information for ELAHERE, including BOXED WARNING on page 4, and click to access full Prescribing Information.

Indication and Important Safety Information (cont'd)

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg

WARNINGS and PRECAUTIONS

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 (≥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

Background and Considerations

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg

EHR systems and order sets have varying methods of calculating average body weight. As a result, dosing may be specific to each EHR system and differ within institutions. The simple solution in this document provides a standardized workflow when calculating AIBW dosing for ELAHERE in the Epic EHR system.

Both the order set and the AIBW calculator are integral to providing accurate, consistent dosing for patients. If widely integrated, the AIBW calculator may help support accurate patient dosing and reduce the need for manual calculations to be done outside the EHR ELAHERE order set. Fully integrated dosing and order sets may allow for more efficient, accurate, and standardized treatment protocols and ease of use within your institution.

Dosage Form and Strength[1]

Injection: 100 mg/20 mL (5 mg/mL) in a single-dose vial (NDC 72903–853–01).

Helpful Links

- ELAHERE Prescribing Information: **https://www.rxabbvie.com/pdf/elahere_pi.pdf**
- ELAHERE patient information: **www.elahere.com**
- ELAHERE healthcare provider website: **www.elaherehcp.com**

NDC=National Drug Code.

ELAHERE Clinical Specifications Guide

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg

The Clinical Specifications Guide provides a high-level overview of treatment considerations and dosing instructions for ELAHERE. For detailed step-by-step instructions on how to optimize order sets for the use of ELAHERE, please refer to pages 6–10.

Indication[1]

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.

Patient Selection[1]

Select patients for the treatment of platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer with ELAHERE based on the presence of FRα tumor expression using an FDA-approved test.

Information on FDA-approved tests for the measurement of FRα tumor expression is available at **http://www.fda.gov/CompanionDiagnostics**.

FRα Test[1,2]

Confirm the FRα test is available in the lab catalog of the health system so it can be ordered. If the FRα test is not available, add the test as a procedure order according to the health system preferences and standard EHR conventions. Consider adding any additional information as desired (LOINC codes and charge/billing information).

FRα Testing

Procedural Type	Code	Description
FOLR1 IHC	88341	Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (list separately in addition to code for primary procedure)
FOLR1 IHC	88342	Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure
FOLR1 IHC	88360	Morphometric analysis, tumor immunohistochemistry (eg, HER-2/NEU, estrogen receptor/progesterone receptor), quantitative or semiquantitative, per specimen, each single antibody stain procedure; manual
FOLR1 IHC	88361	Morphometric analysis, tumor immunohistochemistry (eg, HER-2/NEU, estrogen receptor/progesterone receptor), quantitative or semiquantitative, per specimen, each single antibody stain procedure; using computer-assisted technology

The FRα test can be evaluated at these 11 participating lab partners:

- Labcorp
- NeoGenomics
- Caris Life Sciences
- BioReference Labs
- Foundation Medicine
- Fulgent Oncology
- Genomic Testing Cooperative
- GoPath Diagnostics
- Myriad
- Sonic Healthcare
- Tempus

LOINC=Logical Observation Identifiers Names and Codes.

Please see Important Safety Information for ELAHERE, including BOXED WARNING on pages 3-4, and click to access full Prescribing Information.

ELAHERE Clinical Specifications Guide (cont'd)

ELAHERE mirvetuximab soravtansine-gynx injection 100 mg

Regimen Name (Display Name)[1]

ELAHERE (mirvetuximab soravtansine-gynx) 6 mg/kg AIBW every 3 weeks

ELAHERE Treatment Calendar: 6 mg/kg AIBW[1]

Cycle (21 days)	**Until disease progression or unacceptable toxicity**
Day	**1**

Component	Starting Dose	
ELAHERE	6 mg/kg AIBW	Day 1 only

AIBW Calculation – AdjBW* (also referred to as Adjusted Body Weight. Use the Adjusted Body Weight as an alternative as it may already be available in the EHR)[1]:

Calculate AIBW using the following formula:

AIBW = Ideal body weight (IBW [kg]) + 0.4 × (Actual weight [kg] − IBW)
Female IBW (kg) = 0.9 × height (cm) − 92

Note: for female IBW, consider the equation expressed in inches: ***45.5 kg + 2.3 x [height (in inches) − 60]***

*AIBW is equivalent to AdjBW.

ELAHERE Clinical Specifications Guide (cont'd)

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg

Dose Reductions[1]

	ELAHERE Dose Levels
First Dose Reduction	5 mg/kg AIBW once every 3 weeks (21-day cycle)
Second Dose Reduction	4 mg/kg AIBW once every 3 weeks (21-day cycle)*

Dose Modifications for Adverse Reactions[1]

Adverse Reaction	Severity of Adverse Reaction†	Dosage Modification
Keratitis/Keratopathy *[see Warnings and Precautions (5.1) and Adverse Reactions (6.1)]*	Nonconfluent superficial keratitis	Monitor
	Confluent superficial keratitis, a cornea epithelial defect, or 3-line or more loss in best corrected visual acuity	Withhold until improved or resolved, then maintain at same dose level or consider dose reduction
	Corneal ulcer or stromal opacity or best corrected distance visual acuity 20/200 or worse	Withhold until improved or resolved, then reduce by one dose level
	Corneal perforation	Permanently discontinue
Uveitis *[see Warnings and Precautions (5.1) and Adverse Reactions (6.1)]*	Grade 1/Rare cell in anterior chamber	Monitor
	Grade 2/1–2+ Cell or Flare in anterior chamber	Withhold until Grade 1 or less, then maintain dose at same dose level
	Grade 3/3+ Cell or Flare in anterior chamber	Withhold until Grade 1 or less, then reduce dose by one dose level
	Grade 4/Hypopyon	Permanently discontinue
Pneumonitis *[see Warnings and Precautions (5.2) and Adverse Reactions (6.1)]*	Grade 1	Monitor
	Grade 2	Withhold until Grade 1 or less, then maintain at same dose level or consider dose reduction
	Grade 3 or 4	Permanently discontinue
Peripheral Neuropathy *[see Warnings and Precautions (5.3) and Adverse Reactions (6.1)]*	Grade 2	Withhold until Grade 1 or less, then reduce by one dose level
	Grade 3 or 4	Permanently discontinue
Infusion-Related Reactions (IRRs)/Hypersensitivity *[see Adverse Reactions (6.1)]*	Grade 1	Maintain infusion rate
	Grade 2	• Interrupt infusion and administer supportive treatment • After recovery from symptoms, resume the infusion at 50% of the previous rate, and if no further symptoms appear, increase rate as appropriate until infusion is completed *[see Dosage and Administration (2.5)]* • Administer additional premedication for future cycles *[see Dosage and Administration (2.3)]*
	Grade 3 or 4	• Immediately stop infusion and administer supportive treatment • Advise patient to seek emergency treatment and immediately notify their healthcare provider if the infusion-related symptoms recur • Permanently discontinue

*Permanently discontinue in patients who cannot tolerate 4 mg/kg AIBW.[1]

†Unless otherwise specified, National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 5.0.[1]

Please see Important Safety Information for ELAHERE, including BOXED WARNING on pages 3-4, and click to access full Prescribing Information.

ELAHERE Clinical Specifications Guide (cont'd)

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg

Dose Modifications for Adverse Reactions (cont'd)[1]

Adverse Reaction	Severity of Adverse Reaction*	Dosage Modification
Hematological *[see Adverse Reactions (6.1)]*	Grade 3 or 4	Withhold until Grade 1 or less, then resume at one lower dose level
Other Adverse Reactions *[see Adverse Reactions (6.1)]*	Grade 3	Withhold until Grade 1 or less, then resume at one lower dose level
	Grade 4	Permanently discontinue

Additional Information[1]

Indication/disease	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
References	ELAHERE **Prescribing Information**
Regimen keywords	ELAHERE, mirvetuximab, epithelial ovarian, fallopian tube, or primary peritoneal cancer
Regimen type	Antibody-drug conjugate
Number of cycles	Until disease progression or unacceptable toxicity
Days per cycle	21 days
Maximum duration	Until disease progression or unacceptable toxicity
Safety information/ warnings	Refer to sections 5 and 6 of the **Prescribing Information**
Emetogenic risk	Please refer to your system guidelines when entering this information
Febrile neutropenic risk	Please refer to your system guidelines when entering this information
Premedications	• Corticosteroid, IV, at least 30 minutes prior to ELAHERE • Antihistamine, oral or IV, at least 30 minutes prior to ELAHERE • Antipyretic, oral or IV, at least 30 minutes prior to ELAHERE • Antiemetic, oral or IV, before each dose and thereafter as needed
Required eye care	• *Ophthalmic exam:* 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 • *Ophthalmic Topical Steroids:* The use of ophthalmic topical steroids is recommended. The initial prescription and renewals of any corticosteroid medication should be made only after examination with a slit lamp. Administer one drop of ophthalmic topical steroids in each eye 6 times daily starting the day prior to each infusion until day 4; then administer one drop in each eye 4 times daily for days 5–8 of each cycle of ELAHERE *[see Warnings and Precautions (5.1)]* • *Lubricating Eye Drops:* The use of lubricating eye drops at least four times daily and as needed is recommended during treatment with ELAHERE. Instruct patients to use lubricating eye drops and advise to wait at least 10 minutes after ophthalmic topical steroid administration before instilling lubricating eye drops *[see Warnings and Precautions (5.1)]*
Take home medications	Please refer to your system guidelines when entering this information (see Premedications and Required Eye Care, listed above)
Imaging	Please refer to your system guidelines when entering this information
Other medications (PRN)	Please refer to your system guidelines when entering this information

*Unless otherwise specified, NCI CTCAE version 5.0.[1]
IV=intravenous; PRN=as needed.

Please see Important Safety Information for ELAHERE, including BOXED WARNING on pages 3-4, and click to access full Prescribing Information.

ELAHERE Clinical Specifications Guide (cont'd)

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg

Additional Information (cont'd)[1]

Growth factor	Please refer to your system guidelines when entering this information
Hydration	**Mirvetuximab is only compatible with D5.** Please refer to your system guidelines when entering this information
Labs	Please refer to your system guidelines when entering this information
Renal impairment	See Renal Impairment, section 8.6 of the **Prescribing Information**
Hepatic impairment	See Hepatic Impairment, section 8.7 of the **Prescribing Information**
Use in specific populations	See Use in Specific Populations, section 8 of the **Prescribing Information**
Supportive care	Please refer to your system guidelines when entering this information (consider antiemetics, eye drops, etc)
Pregnancy	See Use in Specific Populations, section 8.1 of the **Prescribing Information**

D5=dextrose 5%.

ELAHERE is supplied as[1]

Carton Contents	NDC
1 single-dose vial containing 100 mg of mirvetuximab soravtansine-gynx in 20 mL (5 mg/mL)	72903-853-01

AIBW Calculator Instructions

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg

AIBW Calculator for ELAHERE as a Flowsheet

1. Access the **Flowsheet** activity
2. Select **Create Group/Row**
3. Enter a new ID and hit **enter**
4. Enter a new record name, eg, AIBW Calculator for ELAHERE, and hit **enter**
5. Accept the new ID and name and click **Accept**
6. Create the record for the **Height in cm row** by completing the **Record Name** and **Display Name**
7. Set the **Row Type** to **Data**, the **Value Type** to **Patient Height**, and the **Context** to **Over-time**
8. Accept and release the new row
9. Use the "Make a Copy" functionality, copy the previous row, and configure for **Weight in kg**
10. Create the record for the **Weight in kg** row by completing the **Record Name** and **Display Name**
11. The next 2 rows are calculated rows with a different configuration. Copy the previous row and configure it for the first part of the calculation. Set the **Row Type** to **Custom Formula** and the **Value Type** to **Numeric Type**:
    - In the **Row Information** field, enter: (0.9 x height in cm) – 92
    - In the **Custom Formula** field, enter the following equation:

      (0.9 x [enter the ID for the Row ID for the height in cm]) – 92
12. Repeat the same process to create the AIBW for ELAHERE calculated row. Set the **Row Type** to **Custom Formula** and the **Value Type** to **Numeric Type**:
    - In the **Row Information** field, enter: IBW (kg) + 0.4 x (actual weight [kg] – IBW [kg])
    - In the **Custom Formula** field, enter the following equation:

      ((0.9 x [enter the ID for the row for the height in cm]) – 92) + 0.4 x ([enter the Row ID for the weight in kg]) – (0.9 x [enter the ID for the row for the height in cm]) – 92))
13. After the 4 rows are created, create the Flowsheet template by entering the **Flowsheet template ID** and hit **enter**
14. Enter the unique name for the Flowsheet template and hit **enter**
15. Complete all details. Consider a **Record, Display and Tab Name** of AIBW Calculator for ELAHERE. Enter the 4 previously created rows in the **Rows and Groups** field
16. Add the completed Flowsheet template to the users **Flowsheet Preference** list (can be found in ITEM 35150 of their profile)

Epic Order Set Instructions

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg

Updating Beacon protocols in the Epic EHR system requires 3 steps:

STEP 1 – Pages 12-16 Create order groups to hold ELAHERE; the ELAHERE Premedications and Required Eye Care; ELAHERE Monitoring and Hold Parameters; ELAHERE Warnings, Precautions, and Adverse Reactions; and the ELAHERE AIBW Calculator

STEP 2 – Page 17 Add the ELAHERE package insert link to the medication record

STEP 3 – Page 17 Add the Order Groups to the Beacon protocol

STEP 1 Create order groups

1. Review the **Regimen Category Order Group** to confirm all values for the Order Groups are available in the category list
2. Select the **Order Group Builder (Admin > Beacon Admin > Order Group Builder)**
3. Create the following Order Groups:

Order Group 1: ELAHERE

- **ELAHERE** can be selected and added by selecting **Add > Orders**
- Complete the ELAHERE medication details: 6 mg/kg adjusted ideal body weight (AIBW) administered once every 3 weeks (21-day cycle) as an intravenous infusion until disease progression or unacceptable toxicity
- For the administration instructions, dose reductions, dose modifications, and other information, refer to **https://www.rxabbvie.com/pdf/elahere_pi.pdf**

Epic Order Set Instructions (cont'd)

STEP 1 Create order groups (cont'd)

Order Group 2: ELAHERE Premedications and Required Eye Care

1. Review the Regimen Category Order Group to confirm ELAHERE Premedications and Required Eye Care
2. Select the **Order Group Builder (Admin > Beacon Admin > Order Group Builder)**
3. Create a new Order Group named ELAHERE Premedications and Required Eye Care
4. Set the default category to ELAHERE Premedications and Required Eye Care
5. Complete the following ELAHERE Premedications and Required Eye Care:
   a. Right click in the empty field located at the bottom of the window
   b. Select **Add > ELAHERE Premedications and Required Eye Care**
   c. Consider adding the following information:
   Premedication
   Administer the premedications in Table 1 prior to each infusion of ELAHERE for prevention of infusion-related reactions (IRRs), nausea, and vomiting

Table 1: Premedication Prior to Each ELAHERE Infusion[1]

Premedication	Route of Administration	Examples (or Equivalent)	Administration Time Prior to ELAHERE Infusion
Corticosteroid	IV	Dexamethasone 10 mg	At least 30 minutes prior
Antihistamine	Oral or IV	Diphenhydramine 25 mg to 50 mg	
Antipyretic	Oral or IV	Acetaminophen 325 mg to 650 mg	
Antiemetic	Oral or IV	5-HT_3 serotonin receptor antagonist or appropriate alternatives	Before each dose and thereafter as needed

Consider additional premedications including corticosteroids the day prior to ELAHERE administration for patients who have experienced IRRs.

Ophthalmic Exams and Premedication

Ophthalmic Exam: 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.

Ophthalmic Topical Steroids: The use of ophthalmic topical steroids is recommended. The initial prescription and renewals of any corticosteroid medication should be made only after examination with a slit lamp. Administer one drop of ophthalmic topical steroids in each eye 6 times daily starting the day prior to each infusion until day 4; then administer one drop in each eye 4 times daily for days 5–8 of each cycle of ELAHERE *[see Warnings and Precautions (5.1)]*.

Lubricating Eye Drops: The use of lubricating eye drops at least four times daily and as needed is recommended during treatment with ELAHERE. Instruct patients to use lubricating eye drops and advise to wait at least 10 minutes after ophthalmic topical steroid administration before instilling lubricating eye drops *[see Warnings and Precautions (5.1)]*.

5-HT_3=5-hydroxytryptamine type 3 receptor.

Epic Order Set Instructions (cont'd)

STEP 1 Create order groups (cont'd)

Order Group 3: ELAHERE Monitoring and Hold Parameters (alternatively, consider Treatment Conditions)

- **ELAHERE Monitoring and Hold Parameters** can be selected and added by selecting **Add > Orders**
  - Consider adding the following information:

WARNING: OCULAR TOXICITY[1]

- **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.**

- **FRα test:** Confirm the FRα test is available in the lab catalog of the health system so it can be ordered. Additional information on the FRα test specifics can be found in the Background and Considerations section.

Dose Modifications for Adverse Reactions[1]

Adverse Reaction	Severity of Adverse Reaction*	Dosage Modification
Keratitis/Keratopathy *[see Warnings and Precautions (5.1) and Adverse Reactions (6.1)]*	Nonconfluent superficial keratitis	Monitor
	Confluent superficial keratitis, a cornea epithelial defect, or 3-line or more loss in best corrected visual acuity	Withhold until improved or resolved, then maintain at same dose level or consider dose reduction
	Corneal ulcer or stromal opacity or best corrected distance visual acuity 20/200 or worse	Withhold until improved or resolved, then reduce by one dose level
	Corneal perforation	Permanently discontinue
Uveitis *[see Warnings and Precautions (5.1) and Adverse Reactions (6.1)]*	Grade 1/Rare cell in anterior chamber	Monitor
	Grade 2/1–2+ Cell or Flare in anterior chamber	Withhold until Grade 1 or less, then maintain dose at same dose level
	Grade 3/3+ Cell or Flare in anterior chamber	Withhold until Grade 1 or less, then reduce dose by one dose level
	Grade 4/Hypopyon	Permanently discontinue
Pneumonitis *[see Warnings and Precautions (5.2) and Adverse Reactions (6.1)]*	Grade 1	Monitor
	Grade 2	Withhold until Grade 1 or less, then maintain at same dose level or consider dose reduction
	Grade 3 or 4	Permanently discontinue
Peripheral Neuropathy *[see Warnings and Precautions (5.3) and Adverse Reactions (6.1)]*	Grade 2	Withhold until Grade 1 or less, then reduce by one dose level
	Grade 3 or 4	Permanently discontinue

*Unless otherwise specified, NCI CTCAE version 5.0.[1]

Epic Order Set Instructions (cont'd)

STEP 1 Create order groups (cont'd)

Dose Modifications for Adverse Reactions (cont'd)[1]

Adverse Reaction	Severity of Adverse Reaction*	Dosage Modification
IRRs/Hypersensitivity *[see Adverse Reactions (6.1)]*	Grade 1	Maintain infusion rate
	Grade 2	• Interrupt infusion and administer supportive treatment • After recovery from symptoms, resume the infusion at 50% of the previous rate, and if no further symptoms appear, increase rate as appropriate until infusion is completed *[see Dosage and Administration (2.5)]* • Administer additional premedication for future cycles *[see Dosage and Administration (2.3)]*
	Grade 3 or 4	• Immediately stop infusion and administer supportive treatment • Advise patient to seek emergency treatment and immediately notify their healthcare provider if the infusion-related symptoms recur • Permanently discontinue
Hematological *[see Adverse Reactions (6.1)]*	Grade 3 or 4	Withhold until Grade 1 or less, then resume at one lower dose level
Other Adverse Reactions *[see Adverse Reactions (6.1)]*	Grade 3	Withhold until Grade 1 or less, then resume at one lower dose level
	Grade 4	Permanently discontinue

*Unless otherwise specified, NCI CTCAE version 5.0.[1]

Epic Order Set Instructions (cont'd)

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg

STEP 1 Create order groups (cont'd)

Recommended Dose Reduction Schedule (adjust the schedule of administration to maintain a 3-week interval between doses)[1]

	ELAHERE Dose Levels
First Dose Reduction	5 mg/kg AIBW once every 3 weeks (21-day cycle)
Second Dose Reduction	4 mg/kg AIBW once every 3 weeks (21-day cycle)*

Order Group 4: ELAHERE Warnings, Precautions, and Adverse Reactions

- **ELAHERE Warnings, Precautions, and Adverse Reactions** can be selected and added by selecting **Add > Orders**
- Consider adding the following information:
  - See section 5 of the ELAHERE PI for Warnings and Precautions (Ocular Disorders, Pneumonitis, Peripheral Neuropathy, and Embryo-Fetal Toxicity)
  - See section 6 of the ELAHERE PI for Adverse Reactions (Clinical Trials Experience): **https://www.rxabbvie.com/pdf/elahere_pi.pdf**

Adding the AIBW Calculator for ELAHERE in an order set

STEP 1 Update the SmartGroup:

1. Open the management console **Tools > Management Console** and select **SmartGroups (OSQ_)** from the **Decision Support** menu to launch a new window
2. Create a new SmartGroup. Set the **Record Name and Display Name** to **AIBW Calculator for ELAHERE**
3. Select **Configuration** from the menu
4. Click **Add Item** from the menu and add the Flowsheet
5. Check the radio button for the **Pathway Row Flowsheet** to the **AIBW Calculator for ELAHERE**
6. Click **Release** from the menu
7. Open the management console **Tools > Management Console** and select **SmartGroups (OSQ_)** from the **Decision Support** menu to launch a new window

PI=Prescribing Information.
*Permanently discontinue in patients who cannot tolerate 4 mg/kg AIBW.[1]

Epic Order Set Instructions (cont'd)

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg

STEP 2 Add the ELAHERE package insert links to the medication record

- Access the **Medication Master File (ERX)** with authorized user credentials
- Use the search feature in the Medication Master File to search and select **ELAHERE**
- In the **Patient Medication References** screen, a link to the ELAHERE PI can be added
- Row 1: For **Display Name**, enter **Package Insert**
  - In the URL field, enter this hyperlink: **https://www.rxabbvie.com/pdf/elahere_pi.pdf**
- Consider additional rows for ELAHERE patient education and assistance resources and any other ELAHERE-related information

STEP 3 Add the Order Groups to the desired Beacon protocols for FRα-positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer after one to three prior system treatment regimens

Follow these steps to add the Order Groups (4 order groups) created in Step 1 to a Beacon protocol to create a new ELAHERE order set:

1. Click the **Epic logo > Admin > Beacon Admin > Protocol Builder**

   Search for order sets using the search query "FRα-positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer." Note that an existing ELAHERE order set may be available to optimize

   Note: the existing order set will serve as a template for the new ELAHERE order set only. If the original order set used to create or optimize the new ELAHERE order set includes ELAHERE, confirm it is retired or removed from the EHR production system according to the Customer's EHR governing principles
2. Select the desired cycle and add the newly created order group(s) from the previous Step 1 to the cycles:

   Cycle 1 and onward: 21-day cycles (3 weeks)
   - **a.** ELAHERE 6 mg/kg adjusted ideal body weight (AIBW) administered once every 3 weeks (21-day cycle) as an intravenous infusion until disease progression or unacceptable toxicity
   - **b.** Add desired recommended eye care as per section 2.3 of the PI: **https://www.rxabbvie.com/pdf/elahere_pi.pdf**
3. Confirm the following cycle settings:

   Select the **Medications Category** and complete the medication details as follows:

   Cycle 1 and onward: 21-day cycles (3 weeks) until disease progression or unacceptable toxicity:
   - **a.** (Day 1) ELAHERE 6 mg/kg adjusted ideal body weight (AIBW) administered once every 3 weeks (21-day cycle) as an intravenous infusion until disease progression or unacceptable toxicity
   - **b.** Add desired recommended eye care as per section 2.3 of the PI: **https://www.rxabbvie.com/pdf/elahere_pi.pdf**
4. Add in the second Order Group created in Step 1 with the ELAHERE Premedications and Required Eye Care
5. Add in the third Order Group created in Step 1 with the ELAHERE Monitoring and Hold Parameters
6. Add in the fourth Order Group created in Step 1 with the ELAHERE Warnings, Precautions, and Adverse Reactions
7. Add in the fifth Order Group created in Step 1 with the ELAHERE AIBW Calculator
8. Update the Beacon protocol description to:

   ELAHERE for the treatment of adult patients with FRα-positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens
9. Click **Save**
10. Release to production environment after satisfactory testing has been completed

Notes and Disclaimer

The instructions are not fully inclusive of all details of the ELAHERE Prescribing Information, and the clinical data elements are suggestions only. The customer must determine the final elements to include in line with the organization's expectations, goals, and EHR governing principles.

These instructions will not work for other conditions, treatments, or therapeutic areas and are not applicable for other EHR systems. This document is not intended to provide any clinical advice or clinical recommendations, which are solely the responsibility of the clinician and health system.

The process outlined below is variable and not all steps will apply to every health system. Any steps or settings below that are not part of a health system's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider. The practice is solely responsible for implementing, testing, monitoring, and the ongoing operation of any EHR tools.

Please refer to Clinical Specifications on pages 7–11 for a quick reference guide on the usage of ELAHERE. Please consult the most recent version of the ELAHERE package insert for full medication details. The most recent version of the package insert can be found at **https://www.rxabbvie.com/pdf/elahere_pi.pdf**

- The Customer (ie, physician, medical group, integrated delivery network) shall be solely responsible for implementation, testing, and monitoring of the instructions to ensure proper orientation in each Customer's EHR system
- Capabilities, functionality, and set-up (customization) for each EHR system may vary. AbbVie shall not be responsible for revising the implementation instructions it provides to any customer if the Customer modifies or changes its software or the configuration of its EHR system, after such time as the implementation instructions have been initially provided by AbbVie
- While AbbVie tests its implementation instructions on multiple EHR systems, the instructions are not guaranteed to work for all available EHR systems and AbbVie shall have no liability thereto
- While EHRs may assist providers in identifying appropriate patients for consideration of assessment, treatment and referral, the decision and action should ultimately be decided by a provider in consultation with the patient, after a review of the patient's records to determine eligibility, and AbbVie shall have no liability thereto
- The instructions have not been designed to and are not tools and/or solutions for meeting Advancing Care Information and/or any other quality/accreditation requirement
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Please see Important Safety Information for ELAHERE, including BOXED WARNING on pages 3-4, and click to access full Prescribing Information.

References: 1. ELAHERE® (mirvetuximab soravtansine-gynx). Prescribing Information. Waltham, MA: AbbVie Inc.; 2024. **2.** Billing and Coding: Lab: Special histochemical stains and immunohistochemical stains. Centers for Medicare & Medicaid Services. Accessed January 23, 2025. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=57611