ELAHERE®
mirvetuximab soravtansine-gynx
injection 100 mg

ORACLE CERNER

Instructions to Optimize Order Sets and Integrate an AIBW Calculator for ELAHERE® (mirvetuximab soravtansine-gynx) Into Your Oracle Cerner® 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.

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 additional Important Safety Information, including BOXED WARNING, on pages 3-4.
Please see accompanying full Prescribing Information.

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mirvetuximab soravtansine-gynx
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Indication and Important Safety Information

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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 on page 4.
Please see accompanying full Prescribing Information.

Indication and Important Safety Information (cont'd)

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg

WARNINGS and PRECAUTIONS (cont'd)

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 additional Important Safety Information, including BOXED WARNING, on page 3.
Please see accompanying full Prescribing Information.

Background and Considerations

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 Oracle Cerner 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**
- AIBW Calculator: **https://elaherehcp.com/dosing#calculating-aibw**

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 13–17.

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 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 either at your local validated in-house lab or commercial labs, including:

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

LOINC=Logical Observation Identifier Name and Code.

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, or AdjBW (adjusted body weight; use as an alternative if already 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 adjusted body weight (AdjBW).

ELAHERE Clinical Specifications Guide (cont'd)

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg

Dose Reduction Schedule[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/ 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, including BOXED WARNING, on pages 3-4.
Please see accompanying 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, including BOXED WARNING, on pages 3-4.
Please see accompanying 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 (5% dextrose).** 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**

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

A PowerForm in Oracle Cerner can help calculate the AIBW result for ELAHERE. Once the AIBW has been calculated, the dosage for ELAHERE can be selected. To consolidate all ELAHERE-related information in a centralized location in the EHR, consider adding the AIBW calculation for ELAHERE in a PowerPlan.

Administrative rights are required to create PowerForms in Oracle Cerner. Set any label properties and discrete task assays (DTAs) as per governing PowerForm principles. Cycle servers as needed.

STEP 1 Create DTAs for the assessment

First, prior to creating the PowerForm, confirm if DTAs are available. If no existing DTAs are available, follow the steps below to create new DTAs:

1. Launch **DCPTools.exe** to access the DTA Wizard under **Documentation Management**
2. Click **Clear** in the DTA Wizard
3. Create the new DTAs with the same Unique Mnemonic and Description (unique DTAs for the height and weight input, and unique DTAs for the scores for the IBW and AIBW, based on the organization's naming conventions)
4. Set the Result type to **Numeric** for the height and weight input and to **Calculation** for the equations to calculate the IBW and AIBW. Please note that the suggested DTAs can be captured in alternative ways. Create all DTAs as desired, click **Apply** to save the entry and press **OK** once completed
5. Set all fields as **Required**
6. For the Calculated fields, select the **Equation** tool and leverage the previously created DTAs for input. After completing the equation, click the **Test Equation** tab to confirm the equations work as expected. A sample grid is provided:

DTA Description/ DTA Mnemonic	DTA Result Type	Comments
Height in cm	Numeric	Set the range from 0 to 250 and the Unit of Measure to cm
Weight in kg	Numeric	Set the range from 0 to 500 and the Unit of Measure to kg
IBW	Calculation	Equation: IBW (kg) = (0.9 * height in cm) – 92 IBW will be used to calculate the AIBW (see below)
AIBW	Calculation	Equation: AIBW = IBW (kg) + 0.4 * (actual weight kg) – IBW (kg)) AIBW includes the IBW (calculated above)

Data elements for the AIBW Calculator for ELAHERE

7. Associate the **Event Code** by clicking on the binoculars icon. Select a desired **Event Code** for the assessment or create a new one. Click **Apply** to complete the DTA creation process

AIBW Calculator Instructions (cont'd)

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STEP 2 Create the AIBW Calculator for ELAHERE PowerForm

1. Launch **DCPTools.exe** to access the PowerForm Tool under **Documentation Management**
2. Create a Form Section by clicking **Section > New**
3. Enter the name, eg, AIBW Calculator for ELAHERE, as the Section Name and Section Display and click **OK**
4. Drag any labels for additional context for the assessment. This applies to pre- and post-text components
5. Add any header and boxes in the PowerForm to contain the DTAs created in the first step. Create two areas:
   - Step 1: Calculate Ideal Body Weight (IBW) in kg, if unknown, with the below formula. Ensure that height is measured in cm. Enter the equation: IBW (kg) = (0.9 * height in cm) – 92
   - Step 2: Calculate AIBW using IBW (kg) and the patient's actual weight in kg, with the below formula. Enter the equation: AIBW = IBW (kg) + 0.4 * (actual weight (kg) – IBW (kg))
6. Associate any **Event Code** to the PowerForm as desired
7. Plug the sections in the new Form and click **File > Save**
8. Cycle the PowerForm servers once the Form has been created. Consider adding the PowerForm with the assessment to the system's hierarchy of folders per health system conventions (AdHoc folder)

DCP=dynamic clinical planning.

Oracle Cerner Order Set Instructions

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg

Existing PowerPlans may be used as a foundation to optimize new PowerPlans. Consider modifying a PowerPlan as a starting template, while saving the original PowerPlan.

STEP 1 Finding an existing PowerPlan to modify

1. Open **DCP tools**
2. Select the **PowerPlan** tool in the **Order Management** section
3. Click **Task > Open Plan** and enter the search query "FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer." In addition, an existing ELAHERE order set may be available to optimize. Double-click on the plan to display its contents

Note: The existing PowerPlan will serve as a template for the new ELAHERE PowerPlan only. If the original PowerPlan used to create or optimize the new PowerPlan includes ELAHERE, confirm it is retired or removed from the EHR production system according to the Customer's EHR governing principles.

STEP 2 Modifying the PowerPlan to create a new ELAHERE order set

1. Update the display description:
   i. 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
2. Update the description:
   i. 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
3. In the reference text field, enter this text:

   "The most recent version of the ELAHERE PI can be found here **https://www.rxabbvie.com/pdf/elahere_pi.pdf**"
4. In the evidence text field, add any link to an evidence-based resource or ELAHERE studies as desired
5. Click the **Cycle Settings** field. Select the number of cycles (until disease progression or unacceptable toxicity) and number of days in each cycle (21 days):
   i. 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**
6. Select the **Medications** category and complete the medication details:
   i. 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**
7. Enter ELAHERE 6 mg/kg in the lower right-hand panel in the Start Search field. Click the right arrow to move ELAHERE to the Current List box and click **Add**

PI=Prescribing Information.

Oracle Cerner Order Set Instructions (cont'd)

STEP 2 Modifying the PowerPlan to create a new ELAHERE order set (cont'd)

8. In the Pre-Treatments section, consider adding the following information:

ELAHERE Premedications and Required Eye Care:
Premedication
Administer the premedications in Table 1 prior to each infusion of ELAHERE for prevention of infusion-related reactions (IRRs), nausea, and vomiting.

Premedication Prior to Each ELAHERE Infusion[1]

Premedication	Route of administration	Examples (or equivalent)	Administration time prior to ELAHERE infusion
Corticosteroid	Intravenous	Dexamethasone 10 mg	At least 30 minutes prior
Antihistamine	Oral or intravenous	Diphenhydramine 25 mg to 50 mg	
Antipyretic	Oral or intravenous	Acetaminophen 325 mg to 650 mg	
Antiemetic	Oral or intravenous	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)]*.

9. In the Monitoring and Hold Parameters (alternatively, consider Treatment Conditions) section, 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.**

Oracle Cerner Order Set Instructions (cont'd)

STEP 2 Modifying the PowerPlan to create a new ELAHERE order set (cont'd)

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/ 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

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

Oracle Cerner Order Set Instructions (cont'd)

STEP 2 Modifying the PowerPlan to create a new ELAHERE order set (cont'd)

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

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)†

10. In the Warnings, Precautions, and Adverse Reactions section, consider adding the following Warnings, Precautions, and Adverse Reactions 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**"

11. Click **Task > Save Plan**

12. Validate the newly optimized order set

13. Release to production environment after satisfactory testing has been completed

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

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

Oracle Cerner Order Set Instructions (cont'd)

ELAHERE® mirvetuximab soravtansine-gynx injection 100 mg

STEP 3 Add the AIBW Calculator for ELAHERE PowerForm to the PowerPlan

1. Open **DCP tools**
2. Select the **PowerPlan** tool in the **Order Management** section
3. Click **Task > Open Plan** to search for an existing PowerPlan that includes ELAHERE
4. In the reference text field, enter the following text:
   - AIBW Calculator for ELAHERE and add a link to the PowerForm with the calculator
   - Click **OK**
5. Select the **Medications** category. Find the ELAHERE medication order and add an order to the PowerForm with the AIBW Calculator for ELAHERE. Consider selecting the **Patient Care Clinical** category for the calculator. Click **Save** when complete
6. Click **Task > Save Plan**
7. Validate the newly optimized PowerPlan
8. Release to production environment after satisfactory testing has been completed

STEP 4 Adding links to ELAHERE resources

1. Find ELAHERE in the medication database and select the **Reference Text** tab. Click **Customize** to launch the Edit Interaction window
2. Enter:
   "For the ELAHERE package insert, navigate to **https://www.rxabbvie.com/pdf/elahere_pi.pdf**"
   Consider additional rows for ELAHERE patient education and assistance resources and any other ELAHERE-related information
3. Click **OK > Save** to save the customized reference text

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 herein 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 **6–10** 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 provided 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, including BOXED WARNING, on pages 3-4.
Please see accompanying 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 February 13, 2025. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=57611