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Electronic Health Record (EHR) Support Tool

Creating an Alert in the Oracle Cerner® EHR System to Help Identify Patients Who May Be Candidates for FRα Testing—An Actionable Biomarker for Patients With Platinum-Resistant Ovarian Cancer

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.**

FRα=folate receptor alpha.

Please see additional Important Safety Information for ELAHERE, including Boxed WARNING on pages 8-9, and click to access Full Prescribing Information.

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Background, Considerations, and Limitations

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This support tool can help to create a Discern alert to identify patients with ovarian cancer who may be candidates for FRα testing in the Oracle Cerner EHR system. The alert supports awareness of patients with platinum-resistant ovarian cancer who may have an actionable biomarker (FRα). Understanding the FRα status of a patient can provide valuable information to support treatment sequencing decisions.

The processes outlined in this piece are variable, and not all steps will apply to every health system. Any steps or settings 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 ongoing operation of any EHR tools.

The suggested alert criteria outlined in this document may be modified by the health system. While EHRs may assist providers in identifying patients, 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. A manual chart review is suggested to confirm the patient's eligibility for FRα testing.

Oracle Cerner Instructions

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The Oracle Cerner clinical decision support solution, a Discern alert, may be created or customized to align with the health system's clinical preferences and workflow. A Discern alert creates a reminder for the clinical staff to identify patients with ovarian cancer who may be candidates for FRα testing. Analyst administrative rights are typically required to create a Discern alert.

STEP I
Create an Alert

STEP II
Set Logic Parameters

STEP III
Set Action Section Parameters and Test

STEP I: Create an Alert

1. To start creating an alert, open the **Expert Knowledge Module** by selecting **DiscernDev.exe** or **DiscernLaunch.exe**
2. Complete the desired name (FRα test for ovarian cancer patient). Set the status to **Testing**
3. Create the **Evoke** section parameters:

E1

A. Select **OPENCHART**

B. Select **EKS_APPLICATION_E** and select **APPLICATION** select **HNA: Powerchart**

E2

A. Select **OPENCHART**

B. Select **EKS_USER_POSITION_E** and for **POSITION**, select the desired Provider Type and set the desired role types, limiting the role if desired (medical oncology)

C. An encounter location/setting may be added to restrict the alert to the oncology care setting. Select the appropriate template to limit the alert

Oracle Cerner Instructions (cont'd)

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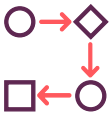
STEP I
Create an Alert



STEP II
Set Logic Parameters

STEP III
Set Action Section Parameters and Test

STEP II: Set Logic Parameters

1. Set the **Logic** section parameters:

L1

A. Select **EKS_DIAGNOSIS_FIND_L**

B. Set the **OPT_DIAGNOSIS** to the ovarian cancer ICD-10-CM codes: C48.1, C48.2, C48.8, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.8

C. Select **OK** to complete setting the parameter

L2

A. Select **EKS_ORDER_FIND_L**

B. Set the **ORD_METHOD** to whose primary mnemonic is

i. Set the **OPT_ORDERS** to the CPT® codes for FRα testing (88341, 88342)

C. Set the **OPT_ORDERS_STATUS** to **COMPLETED**

D. Select **OK** to complete setting the parameter

L3

A. Select **EKS_ORDER_FIND_L**

B. Set the **ORD_METHOD** to whose primary mnemonic is

i. Set the **OPT_ORDERS** to the recurrent treatment for ovarian cancer, such as cisplatin, carboplatin, docetaxel, paclitaxel, pegylated liposomal doxorubicin (pld), topotecan, and oral cytoxan

C. Set the **OPT_ORDERS_STATUS** to **COMPLETED**

D. Select **OK** to complete setting the parameter

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

Oracle Cerner Instructions (cont'd)

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STEP I
Create an Alert

STEP II
Set Logic Parameters

STEP III
Set Action Section Parameters and Test

STEP III: Set Action Section Parameters and Test

1. Finally, set the **Action** section parameters:
   - **A.** Set the **operator logic** to **((L1 AND L3)** AND NOT L2)
   - **B.** To set up a text alert, select **EKS_BUILD_MESSAGE_A**. Enter the following message: *This ovarian cancer patient may be a candidate for FRalpha (FRα) testing and may be resistant to platinum-based treatments for ovarian cancer. Consider ordering the FRalpha (FRα)/Folate receptor 1 (FOLR1) test.*

     Note: Consider adding substitution values with the patient's current and past medications and treatment protocols, if available. Providing this information may help determine how many cycles of platinum chemotherapy the patient has received and their readiness for platinum-resistant treatment options.

   - **C.** Complete the text alert by inserting a link to the FRα test order
2. Select the individual recipients or pools to receive the **Discern alert notification**
3. Test the new alert, cycle the Discern servers, and activate and release the alert

Notes

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- The Customers (ie, physician, medical group, IDN) 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 individual EHR system vary. AbbVie shall not be responsible for revising the implementation instructions it provides to any Customer if that 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 and treatment, 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
- All products are trademarks of their respective holders, all rights reserved. Reference to these products is not intended to imply affiliation with or sponsorship of AbbVie and/or its affiliates

IDN=integrated delivery network.

Indication and Important Safety Information

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- **Administer prophylactic artificial tears and ophthalmic topical steroids.**
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- **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, and click to access Full Prescribing Information.

Indication and Important Safety Information (cont'd)

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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 Full Prescribing Information, including Boxed WARNING.

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