



ADDING OJJAARA (MOMELOTINIB) TO AN ORACLE HEALTH EHR PROTOCOL FOR APPROPRIATE PATIENTS WHO HAVE INTERMEDIATE TO HIGH-RISK MYELOFIBROSIS WITH ANEMIA

INDICATION

OJJAARA is indicated for the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)], in adults with anemia.

IMPORTANT SAFETY INFORMATION

Risk of Infections

- Serious (including fatal) infections (e.g., bacterial and viral, including COVID-19) occurred in 13% of patients treated with OJJAARA. Infections regardless of grade occurred in 38% of patients. Delay starting therapy until active infections have resolved. Monitor patients for signs and symptoms of infection and initiate appropriate treatment promptly.

Please see the [Indication](#) and [Important Safety Information](#) on pages 7-9.
[Click here for accompanying full Prescribing Information.](#)



ABOUT THIS GUIDE

This guide provides educational information to help healthcare providers who want to create Treatment Plans that include OJJAARA or want to add OJJAARA to an existing Treatment Plan. Treatment Plans include order sets for medications, lab testing, procedures, and other aspects of care based on the patient's diagnosis and condition. It is important to evaluate oncology protocols frequently as treatment options, such as OJJAARA, become available.

This guide does not constitute guidance for treatment or medical advice. It is the responsibility of the HCP to select a treatment based on their independent medical judgment and the needs of each individual patient.

The examples and instructions listed in this guide are based on the most recent version of Oracle Health. Locations, illustrations, and terminology are subject to change with system updates. This guide is meant to serve as an overview only and should not replace detailed instructions provided to you by your internal or external EHR support resources. GSK makes no claims or warranties about the applicability or appropriateness of this information. This guide has not been reviewed or endorsed by Oracle Health. GSK does not endorse or recommend any EHR system.



ROLE OF POWERPLANS OR TREATMENT PLANS

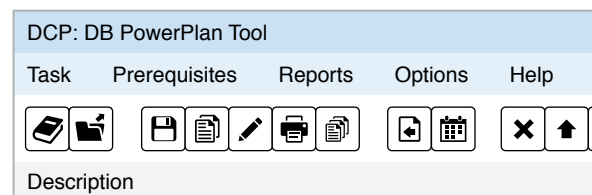
PowerPlans, also known as Treatment Plans to the clinical staff, are commonly used to help facilitate the care of patients. PowerPlans are frequently written orders grouped together for easier selection. They help enable consistency of care and streamline ordering of an entire regimen including specific care instructions.

As treatment options such as OJJAARA become available, it may be necessary to create an additional PowerPlan or to update an existing PowerPlan to remove system obstacles to prescribe OJJAARA for its approved indication. Updating relevant PowerPlans to include OJJAARA communicates to the care team that it is available for appropriate patients.

Refreshing protocols is a common process and provides an opportunity to incorporate treatment updates and guideline changes. PowerPlans are typically updated at the health system level to help reduce practice variation. Typically, an oncology practice will conduct a clinical review process to confirm and approve a suggested Treatment Plan update. Updating existing PowerPlans or adding new PowerPlans is typically managed by the practice IT Support team using an established process for requesting, approving, and implementing EHR changes. Various stakeholders may participate in reviewing PowerPlan Phase modification requests prior to the approval.

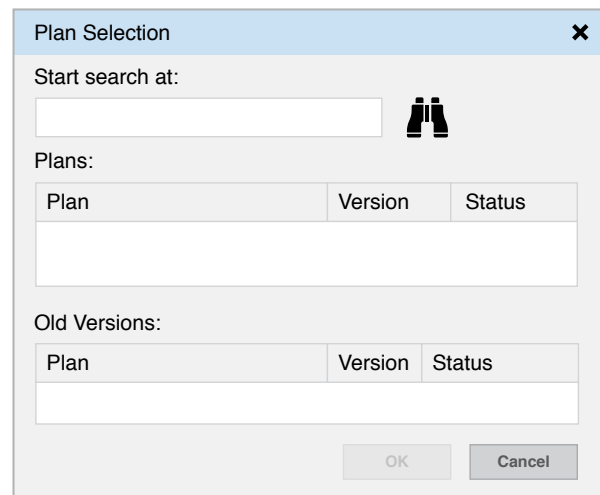
Adding Orders to an Existing PowerPlan Phase

1. From the DCP Tool, launch the **PowerPlan Tool**.
Select **Open Existing Plan**.



Example of PowerPlan Toolbar

2. From the **Plan Selection** window, select the appropriate Plan.
3. Select **OK**.



Example of searching for a PowerPlan

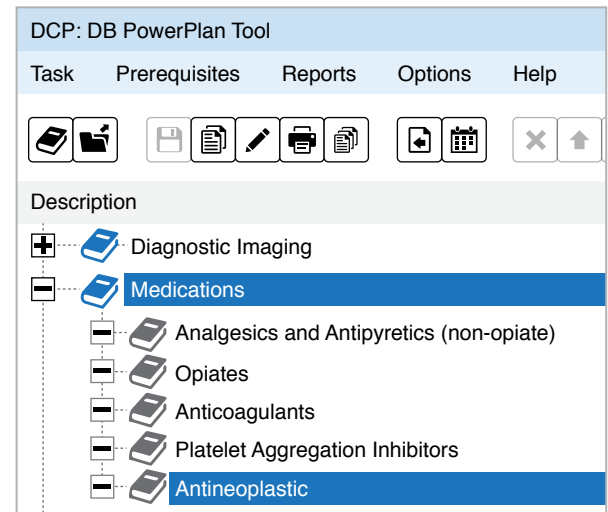
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Adding Orders to an Existing PowerPlan Phase (cont'd)

- If the PowerPlan has multiple phases, from the **Description** column, select the phase.
- Select the **Order** tab in the lower-right section of the main window.
- Enter text into the **Start Search At** box and click the **Find** button to search for OJJAARA.
- Filter by types (Mnemonic, Catalog, or Activity) as desired to narrow your search.
- Select the item or items in the **Search Results** box you want to add to the PowerPlan. Click the right arrow to add the selected orderable item(s) to the **Current List**.

Note: Once the order component is added to the Current List, the default clinical category is displayed. Select a different clinical category from the list to display the orderable item in a category other than the default.



Example of multiple-phase selection

- Select **Add**.
- With the item highlighted in the description column, Select the **Order Sentence** tab; move all appropriate instructions to the **Current list**.
- Select **Add** to add all three strengths of OJJAARA to the Current List.
- Select **Save**.

Order	Note	Outcome	Order Sentence	Copy Components	Sub Phase	Prescription
<div>Order Sentences:<div>OJJAARA 200 mg, PO, Daily OJJAARA 150 mg, PO, Daily OJJAARA 100 mg, PO, Daily</div><div>Current list:<div></div></div></div>						

Example of adding Order Sentences

Please see the [Indication](#) and [Important Safety Information](#) on pages 7-9.
[Click here for accompanying full Prescribing Information.](#)



Create New PowerPlan

1. From the DCP Tool, launch the **PowerPlan Tool**.
2. Select **Task, New Plan**.
3. In the **Add a Plan** window, enter **Plan Name**, and select either Single Phase or Multiple Phase option as appropriate.
4. Select **Plan Type** of **Medical** and **Display Method** of **Clinical Category**.
5. If the Multiple Phase option is chosen, select **Add Phases**. Then add Phase names and rearrange using the up/down arrows.
6. Select **OK**.

Add a Plan

Plan Name:
OJJAARA Therapy

☒ Single Phase ☐ Multiple Phase

Plan Type: Discharge Display Method: Clinical Category

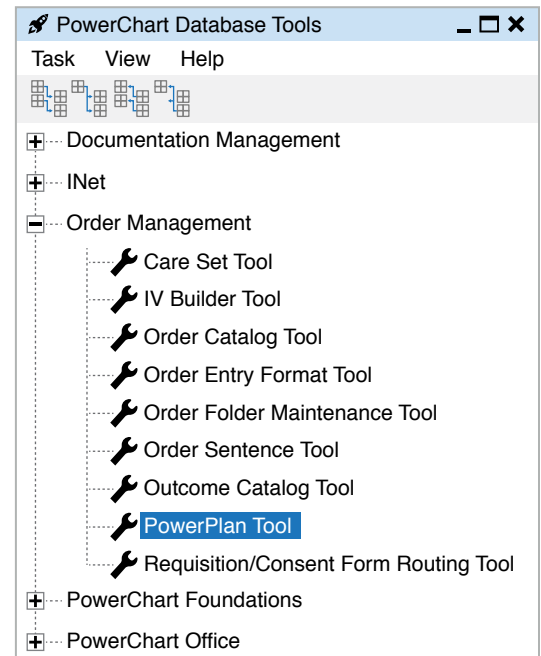
Status: Production

Add new phase:
[Text Box] Add

Phases:
[List Box] [Add] [Delete] [Up] [Down]

OK Cancel

*Example of entering settings
for a new PowerPlan*



*Example of navigation
to the PowerPlan Tool*

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Add Orders to the PowerPlan

1. In a single-phase PowerPlan, select the Order tab to begin adding orders. For a PowerPlan with multiple phases, select the phase to which the item(s) belong.
2. Select the **Prescription** tab in the upper-right section of the main window.
3. Enter text into the **Start Search At** **Search At** box and click the **Find** button to search for OJJAARA.
4. Select the item or items in the **Search Results** box you want to add to the PowerPlan. Click the right arrow to add the selected orderable item(s) to the **Current List**.
5. Add other orders as consistent with the [Prescribing Information](#) and per clinical discretion.

Order	Note	Outcome	Order Sentence	Copy components	Sub Phase	Prescription
Start search at: OJJAARA						
Mnemonic type filter:		All Facilities				
Activity type filter:		Catalog type filter: Medication				
Search results: OJJAARA 200 mg OJJAARA 150 mg OJJAARA 100 mg				Current list: Synonym Clinical Category Clinical Subcategory OJJAARA Meds		
						Add Reset

Example of selecting an orderable item as a prescription

Task	Prerequisites	Reports	Options	Help
DCP: DB PowerPlan Tool				
Description				
Order Set Name				
Laboratory				
Medications				
Patient Care				

Example of an Order Set shown in the PowerPlan Tool (in Oracle Health)

6. Select **Add** to add the items in the **Current List** to the plan. The component is displayed in the **Description** column.
7. Select **Save**.

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INDICATION

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IMPORTANT SAFETY INFORMATION

Risk of Infections

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Hepatitis B Reactivation

- Hepatitis B viral load (HBV-DNA titer) increases, with or without associated elevations in alanine transaminase (ALT) or aspartate transaminase (AST), have been reported in patients with chronic hepatitis B virus (HBV) infection taking Janus Kinase (JAK) inhibitors, including OJJAARA. The effect of OJJAARA on viral replication in patients with chronic HBV infection is unknown. In patients with HBV infections, check hepatitis B serologies prior to starting OJJAARA. If HBsAg and/or anti-HBc antibody is positive, consider consultation with a hepatologist regarding monitoring for reactivation versus prophylactic hepatitis B therapy. Patients with chronic HBV infection who receive OJJAARA should have their chronic HBV infection treated and monitored according to clinical HBV guidelines..

Thrombocytopenia and Neutropenia

- New or worsening thrombocytopenia, with platelet count less than $50 \times 10^9/L$, was observed in 20% of patients treated with OJJAARA. Eight percent of patients had baseline platelet counts less than $50 \times 10^9/L$.
- Severe neutropenia, absolute neutrophil count (ANC) less than $0.5 \times 10^9/L$, was observed in 2% of patients treated with OJJAARA.

- Assess complete blood counts (CBC), including platelet and neutrophil counts, before initiating treatment and periodically during treatment as clinically indicated. Interrupt dosing or reduce the dose for thrombocytopenia or neutropenia.

Hepatotoxicity

- Two of the 993 patients with MF who received at least one dose of OJJAARA in clinical trials experienced reversible drug-induced liver injury. Overall, new or worsening elevations of ALT and AST (all grades) occurred in 23% and 24%, respectively, of patients treated with OJJAARA; Grade 3 and 4 transaminase elevations occurred in 1% and 0.5% of patients, respectively. New or worsening elevations of total bilirubin occurred in 16% of patients treated with OJJAARA. All total bilirubin elevations were Grades 1-2. The median time to onset of any grade transaminase elevation was 2 months, with 75% of cases occurring within 4 months.
- Delay starting therapy in patients presenting with uncontrolled acute and chronic liver disease until apparent causes have been investigated and treated as clinically indicated. When initiating OJJAARA, refer to dosing in patients with hepatic impairment.
- Monitor liver tests at baseline, every month for 6 months during treatment, then periodically as clinically indicated. If increases in ALT, AST or bilirubin related to treatment are suspected, modify OJJAARA dosage based upon Table 1 within the Prescribing Information.



IMPORTANT SAFETY INFORMATION (cont'd)

Major Adverse Cardiovascular Events (MACE)

- Another JAK inhibitor increased the risk of MACE, including cardiovascular death, myocardial infarction, and stroke [compared with those treated with tumor necrosis factor (TNF) blockers] in patients with rheumatoid arthritis, a condition for which OJJAARA is not indicated.
- Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with OJJAARA, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Inform patients receiving OJJAARA of the symptoms of serious cardiovascular events and the steps to take if they occur.

Thrombosis

- Another JAK inhibitor increased the risk of thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis (compared with those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which OJJAARA is not indicated. Evaluate patients with symptoms of thrombosis and treat appropriately.

Malignancies

- Another JAK inhibitor increased the risk of lymphoma and other malignancies excluding nonmelanoma skin cancer (NMSC) (compared with those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which OJJAARA is not indicated. Current or past smokers were at increased risk.
- Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with OJJAARA, particularly in patients with a known malignancy (other than a successfully treated NMSC), patients who develop a malignancy, and patients who are current or past smokers.

Adverse Reactions

- The most common adverse reactions ($\geq 20\%$ in either study) are thrombocytopenia, hemorrhage, bacterial infection, fatigue, dizziness, diarrhea, and nausea.

Organic Anion Transporting Polypeptide (OATP)1B1/B3 Inhibitors

- Mometotinib is an OATP1B1/B3 substrate. Concomitant use with an OATP1B1/B3 inhibitor increases mometinib maximal concentrations (C_{max}) and area under the concentration-time curve (AUC), which may increase the risk of adverse reactions with OJJAARA. Monitor patients concomitantly receiving an OATP1B1/B3 inhibitor for adverse reactions and consider OJJAARA dose modifications.

Breast Cancer Resistance Protein (BCRP) Substrates

- Mometotinib is a BCRP inhibitor. OJJAARA may increase exposure of BCRP substrates, which may increase the risk of BCRP substrate adverse reactions. When administered concomitantly with OJJAARA, initiate rosuvastatin (BCRP substrate) at 5 mg and do not increase to more than 10 mg once daily. Dose adjustment of other BCRP substrates may also be needed. Follow approved product information recommendations for other BCRP substrates.

Pregnancy

- Available data in pregnant women are insufficient. OJJAARA should only be used during pregnancy if the expected benefits to the mother outweigh the potential risks to the fetus.



IMPORTANT SAFETY INFORMATION (cont'd)

Lactation

- It is not known whether OJJAARA is excreted in human milk. Because of the potential for serious adverse reactions in a breastfed child, patients should not breastfeed during treatment with OJJAARA, and for at least 1 week after the last dose of OJJAARA.

Females and Males of Reproductive Potential

- Advise females of reproductive potential who are not pregnant to use highly effective contraception during therapy and for at least 1 week after the last dose of OJJAARA.

Hepatic Impairment

- Mometotinib exposure increased with severe hepatic impairment (Child-Pugh C). The recommended starting dose of OJJAARA in patients with severe hepatic impairment (Child-Pugh C) is 150 mg orally once daily. No dose modification is recommended for patients with mild hepatic impairment (Child-Pugh A) or moderate hepatic impairment (Child-Pugh B).

Please [click here to see accompanying full Prescribing Information](#).

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