



ADDING OJJAARA (MOMELOTINIB) TO AN OncoEMR 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 5-7.
[Click here for accompanying full Prescribing Information.](#)



ABOUT THIS GUIDE

This guide provides educational information to help healthcare providers who want to create Regimens that include OJJAARA or want to add OJJAARA to an existing Regimen. Regimens 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 OncoEMR. 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 OncoEMR. GSK does not endorse or recommend any EHR system.

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ROLE OF REGIMENS

Regimens are commonly used to help facilitate patient care. Regimens help enable consistency of care and streamline ordering of an entire treatment protocol including specific care instructions.

As treatment options such as OJJAARA become available, it may be necessary to create an additional Regimen or to update an existing Regimen to remove system obstacles to prescribing OJJAARA for its approved indication. Once a regimen is selected, it becomes part of the patient chart and can be managed by the Flowsheet. Updating relevant Regimens 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. Regimens 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 Regimen optimization. Various stakeholders may participate in reviewing Regimen modification requests prior to the approval.

Adding OJJAARA to a Regimen

1. Navigate to the **Customize** page and choose **Regimen List**. Search for an appropriate Regimen, such as *Myelofibrosis*.

Regimens/Protocols

[Back to Customize](#) [Print](#) [Print Regimen Details](#) [Opt-in to NCCN Regimens](#)

Enter a few characters of the regimen name and click Find, Separate items with a •

[Find](#)

Regimens to Show:

Regimen type: ☒ Chemotherapy ☐ Premed ☐ Followup ☐ OrderSet

Owned by: ☐ The system (built-in) ☐ All ☐ My practice ☒ Me ☐ Label Guided ☒ NCCN ☒ Flatiron Regimens

Disease:

[Refresh List](#)

Sort by: ☒ By Name ☐ By Disease

[New Regimen](#) [Insurer Reimbursability](#) [Assign Emetogenic Risk](#)

<input type="checkbox"/>	Name	Version	Type
<input type="checkbox"/>	Myelofibrosis	1.0	Chem

Example of the Regimens/Protocols selection screen in OncoEMR

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Adding OJJAARA to a Regimen (cont'd)

2. Select the Regimen to access the Edit Process.
3. From the **-Select an Action-** dropdown, choose **Copy to Personal**, and update the title.

Regimen Edit

Enter/Edit Regimen Details

-- Select an Action --
-- Select an Action --
Copy to Personal
Move (promote) to PRACTICE

You own this regimen and m Move (promote) to PRACTICE be thoroughly rev

Example of the Regimens/Protocols selection screen in OncoEMR

4. From the **Add:** options, select **Drug**.
5. Search for and select OJJAARA to add to the regimen.
 - Strengths of OJJAARA include
 - OJJAARA 200 mg
 - OJJAARA 150 mg
 - OJJAARA 100 mg
6. Select **Save**.

Add details and other orders as consistent with the [Prescribing Information](#) and per clinical discretion. When edits are completed, from the **Select an Action** dropdown, choose **Move (promote) to PRACTICE**.

Add: Drug, Test, Radiology, Activity, RuleSet, Regimen, Linked Regimen, Label, GradeScale, CDG Tools

Action: Reorder Items Collapse All Copy from cycle

Cycle & Day			PreTreat	1								
				1	2	3	4	5	6	7	8	9
OJJAARA PO	200 mg	All Insurers		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Example of OJJAARA 200 mg added to the Regimen, but you could also select 150 mg or 100 mg dosages

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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

- Mometinib 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

- Mometinib 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

- Mometinib 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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