Ojjaara (momelotinib)
200 mg • 150 mg • 100 mg tablets

Technical Instructions for the OncoEMR EHR System

Updating regimens with OJJAARA for the treatment of adult patients with intermediate or high-risk MF with anemia, including primary MF or secondary MF (post-PV and post-ET)

EHR = electronic health record; MF = myelofibrosis; post-ET = post-essential thrombocythemia; post-PV = post-polycythemia vera.

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.

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OVERVIEW

This document is intended to help provide health systems with technical instructions to add the product treatment plan in the EHR system for the treatment of adult patients with intermediate or high-risk MF with anemia, including primary MF or secondary MF (post-PV and post-ET). This guide is for the OncoEMR EHR system and is not appropriate for other conditions, treatments, or therapeutic areas or for other EHR systems.

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

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

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.

Considerations

Treatment plans are commonly used in the management of oncology patients (your organization may refer to these as regimens or protocols). After their initial release, treatment plans may benefit from a clinical update to incorporate new products or new indications. The optimization of treatment plans is a common process and provides an opportunity to incorporate treatment updates. Treatment plans are typically modified at the health system level to help reduce practice variation.

Typically, an organization will conduct a clinical review to confirm and approve the suggested optimization. Various stakeholders may participate in reviewing treatment plan optimization requests prior to implementation.

Suggested treatment plan content

Key clinical details from the OJJAARA Prescribing Information are included on the following pages and may be incorporated as part of the treatment plan update based on steps in the instructions section that follows.

The Prescribing Information in this section is to be used as a reference, and it is strongly recommended that clinical and operational leadership align the treatment plan contents with the expectations and goals of the organization. The organization may add or edit any details as desired to align with governing EHR policies and standards.

Please consult the most recent version of the OJJAARA Prescribing Information for full medication details.

IMPORTANT SAFETY INFORMATION (cont'd)

Risk of Infections (cont'd)

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.

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INDICATION

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DOSAGE AND ADMINISTRATION

Recommended dosage

- The recommended dosage of OJJAARA is 200 mg orally once daily
- OJJAARA may be taken with or without food
- Swallow OJJAARA tablets whole. Do not cut, crush, or chew tablets
- If a dose of OJJAARA is missed, the next scheduled dose should be taken the following day

Laboratory monitoring for safety

Obtain the following blood tests prior to starting treatment with OJJAARA, periodically during treatment, and as clinically indicated:

- Complete blood count (CBC) with platelets [see Warnings and Precautions (5.2)]
- Hepatic panel [see Warnings and Precautions (5.3)]

Dosage modification for hepatic impairment

The recommended starting dosage in patients with severe hepatic impairment (Child-Pugh Class C) is 150 mg orally once daily [see Use in Specific Populations (8.6)]. No dose adjustment is recommended for patients with mild or moderate hepatic impairment.

Dosage modification for adverse reactions

Manage hematologic and non-hematologic adverse reactions as described in the table below. Discontinue OJJAARA in patients unable to tolerate 100 mg once daily.

Contraindications

None.

Warnings and precautions

- Risk of Infections
- Thrombocytopenia and Neutropenia
- Hepatotoxicity
- Severe Cutaneous Adverse Reactions (SCARs)
- Major Adverse Cardiovascular Events (MACE)
- Thrombosis
- Malignancies

ADVERSE REACTIONS

See section 6 of the OJJAARA Prescribing Information for full details.

Thrombocytopenia

Baseline platelet count	Platelet count	Dose modification*
≥100 × 10^9/L	20 × 10^9/L to <50 × 10^9/L	• Reduce daily dose by 50 mg from the last given dose
	<20 × 10^9/L	• Interrupt treatment until platelets recover to 50 × 10^9/L • Restart OJJAARA at a daily dose of 50 mg below the last given dose†
≥50 × 10^9/L to <100 × 10^9/L	<20 × 10^9/L	• Interrupt treatment until platelets recover to 50 × 10^9/L • Restart OJJAARA at a daily dose of 50 mg below the last given dose†
<50 × 10^9/L	<20 × 10^9/L	• Interrupt treatment until platelets recover to baseline • Restart OJJAARA at a daily dose of 50 mg below the last given dose†

Neutropenia

Absolute neutrophil count	Dose modification*
<0.5 × 10^9/L	• Interrupt treatment until ANC ≥0.75 × 10^9/L • Restart OJJAARA at a daily dose of 50 mg below the last given dose†

Hepatotoxicity (unless other apparent causes)

	Dose modification*
ALT and/or AST >5 × ULN (or >5 × baseline, if baseline is abnormal) and/or total bilirubin >2 × ULN (or >2 × baseline, if baseline is abnormal)	• Interrupt treatment until AST and ALT ≤2 × ULN or baseline‡ and total bilirubin ≤1.5 × ULN or baseline§ • Restart OJJAARA at a daily dose of 50 mg below the last given dose† • If reoccurrence of ALT or AST elevations >5 × ULN, permanently discontinue OJJAARA

Other non-hematologic

	Dose modification*
Grade 3 or higher‖	• Interrupt treatment until the toxicity resolves to Grade 1 or lower (or baseline) • Restart OJJAARA at a daily dose of 50 mg below the last given dose†

*Reinitiate or escalate treatment up to starting dosage as clinically appropriate.
†May reinitiate treatment at 100 mg if previously dosed at 100 mg.
‡If baseline >2 × upper limit of normal (ULN).
§If baseline >1.5 × ULN.
‖Graded using the National Cancer Institute Common Terminology Criteria for Adverse Events.

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INSTRUCTIONS

An existing regimen may be used as the foundation for a new one. Consider modifying an existing plan as a starting template, while saving the original protocol.

1. Click the **User Name** in the top right corner and select **Customize**. A new window will show all customization options.
2. Select **Regimen List** to access all regimens and protocols. Search for existing regimens using search terms specific to each indication to find existing regimens that may serve as templates to optimize OJJAARA regimens.
3. Set the radio buttons to optimize the search process (My Practice, Me, etc).
4. If a regimen is available for optimization, select it to start applying the desired changes.
5. Update the **Regimen Name** to "OJJAARA for Myelofibrosis with anemia (primary and secondary MF)" or another name to align with internal naming conventions.
6. Set the version number as desired.
7. Update the **Description** field and enter "OJJAARA for the treatment of adult patients with intermediate or high-risk MF with anemia, including primary MF or secondary MF (post-PV and post-ET) or another description to align with internal naming conventions.
8. In the **Description**, **Reference**, or **ISI** field (select the desired field based on health system preference), enter the desired information
   - "OJJAARA Prescribing Information"
     - https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Ojjaara/pdf/OJJAARA-PI-PIL.PDF
   - "Additional OJJAARA resources for HCPs and patients"
     - https://ojjaarahcp.com and navigate to the **Resources and Support** section
   - "Clinical Study Reference for OJJAARA"
     - https://ojjaarahcp.com and navigate to the **Head-to-Head Clinical Trials** section or see section 14, Clinical Studies, of the OJJAARA Prescribing Information

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IMPORTANT SAFETY INFORMATION (cont'd)

Thrombocytopenia and Neutropenia

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

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INSTRUCTIONS (cont'd)

9. Click **Add Drug** to add OJJAARA to the treatment regimen and complete the medication details for OJJAARA. Details may include Sig, dose, route, frequency, offset time, admin over, and any free-form special admin instructions for the nurse.
   - The recommended dosage of OJJAARA is 200 mg orally once daily
   - OJJAARA may be taken with or without food
   - Swallow OJJAARA tablets whole. Do not cut, crush, or chew tablets
   - If a dose of OJJAARA is missed, the next scheduled dose should be taken the following day
   - Dosage Modification for Hepatic Impairment: The recommended starting dosage in patients with severe hepatic impairment (Child-Pugh Class C) is 150 mg orally once daily [see Use in Specific Populations (8.6)]. No dose adjustment is recommended for patients with mild or moderate hepatic impairment
10. Leave the cLen and cNum fields blank (the recommended dosage of OJJAARA is 200 mg orally once daily with or without food. For patients with severe hepatic impairment [Child-Pugh Class C], reduce the starting dose to 150 mg orally once daily).
11. Click the **Update Calendar** button to update the treatment calendar: In the Calendar, update OJJAARA.
    - The recommended dosage of OJJAARA is 200 mg orally once daily
    - OJJAARA may be taken with or without food
    - Swallow OJJAARA tablets whole. Do not cut, crush, or chew tablets
    - If a dose of OJJAARA is missed, the next scheduled dose should be taken the following day
    - Dosage Modification for Hepatic Impairment: The recommended starting dosage in patients with severe hepatic impairment (Child-Pugh Class C) is 150 mg orally once daily [see Use in Specific Populations (8.6)]. No dose adjustment is recommended for patients with mild or moderate hepatic impairment

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IMPORTANT SAFETY INFORMATION (cont'd)

Hepatotoxicity (cont'd)

- 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.

Severe Cutaneous Adverse Reactions (SCARs)

- Severe cutaneous adverse reactions (SCARs), including toxic epidermal necrolysis (TEN), have been observed in some patients treated with OJJAARA.
- If signs or symptoms of SCARs occur, interrupt OJJAARA until the etiology of the reaction has been determined. Consider early consultation with a dermatologist for evaluation and management.
- If etiology is considered to be associated with OJJAARA, permanently discontinue OJJAARA and do not reintroduce OJJAARA in patients who have experienced SCARs or other life-threatening cutaneous reactions during treatment with OJJAARA.

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INSTRUCTIONS (cont'd)

12. Click **Add Test** to add the OJJAARA Lab Monitoring for Safety.
    - Obtain the following blood tests prior to starting treatment with OJJAARA, periodically during treatment, and as clinically indicated
      - Complete blood count (CBC) with platelets [see Warnings and Precautions (5.2)]
      - Hepatic panel [see Warnings and Precautions (5.3)]
13. Adjust the **Treatment Calendar** with the premedication and concomitant medications.
14. Click **Add Drug** to add any other desired orderable items and information to the regimen and treatment schedule (OJJAARA treatment conditions, monitoring and hold parameters, Warnings and Precautions, supportive care, schedulable orders, HCP communications, hydration, and other sections) as desired. Consider the information below:
    - There are dosage modifications for hepatic impairment. For **Dose Modifications**, see section 2.3 of the Prescribing Information
    - There are dosage modifications for adverse reactions. For **Dose Modifications**, see section 2.4 of the Prescribing Information
    - For **Warnings and Precautions**, see section 5 of the Prescribing Information
      - Risk of infections (section 5.1 of the PI)
      - Thrombocytopenia and neutropenia (section 5.2 of the PI)
      - Hepatotoxicity (section 5.3 of the PI)
      - SCARs (section 5.4 of the PI)
      - MACE (section 5.5 of the PI)
      - Thrombosis (section 5.6 of the PI)
      - Malignancies (section 5.7 of the PI)
    - For **adverse reactions**, see section 6 of the Prescribing Information
15. Click **Save** once the treatment regimen is completed.
16. Validate the new regimen, and release it to the production environment after completing testing. Consider sending a communication to relevant users announcing that the new regimen with OJJAARA is now available.

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.

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IMPORTANT SAFETY INFORMATION (cont'd)

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 (≥20% in either study) are thrombocytopenia, hemorrhage, bacterial infection, fatigue, dizziness, diarrhea, and nausea.

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

- Momelotinib is an OATP1B1/B3 substrate. Concomitant use with an OATP1B1/B3 inhibitor increases momelotinib maximal concentrations (Cmax) 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

- Momelotinib 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.

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

- Momelotinib 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).

DISCLAIMERS

- The user (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 user's EHR system.
- Capabilities, functionality, and set-up (customization) for each EHR system may vary. GSK is not responsible for revising the implementation instructions it provides to any user if user modifies or change its software, or the configuration of its EHR system, after such time as the implementation instructions have been initially provided by GSK.
- While GSK tests its implementation instructions on multiple EHR systems, the instructions are not guaranteed to work for all available EHR systems, and GSK shall have no liability thereto.
- While EHRs may assist providers in identifying patients who may be appropriate for consideration of assessment, treatment, and referral, the decision and action must ultimately be decided by a provider in consultation with the patient, after a review of the patient's records to determine eligibility.
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Reference: OJJAARA (momelotinib). Prescribing Information. GSK; 2025.

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