Prescriber Enrollment Form

Juxtapid (lomitapide) capsules

REMS Program

THERE ARE 2 PAGES TO THIS FORM | ALL FIELDS ARE REQUIRED | PLEASE PRINT

JUXTAPID is only available through the JUXTAPID Risk Evaluation and Mitigation Strategy (REMS)

All prescribers of JUXTAPID must become certified in the JUXTAPID REMS.
The 3-step process for prescriber certification is outlined below.

1. **REVIEW** the JUXTAPID Prescribing Information and Fact Sheet
2. **COMPLETE** the online Prescriber Training Module and Prescriber Enrollment Form
3. **AGREE** to counsel each patient using the Patient Guide, and to complete a Patient-Prescriber Acknowledgement Form with each patient

PRESCRIBER INFORMATION

First Name: _____ Middle Initial: _____ Last Name: _____

Credentials: ☐ MD ☐ DO ☐ NP ☐ PA ☐ Other (specify): _____

Physician Specialty: ☐ Cardiology ☐ Endocrinology ☐ Internal Medicine ☐ Other (specify): _____

Practice Type (check all that apply): ☐ Individual Practice ☐ Group Practice ☐ Hospital ☐ University (Academic) Center

Practice/Facility Name: _____ Department: _____

Address: _____

City: _____ State: _____ Zip: _____

Phone: _____ Fax: _____

Email: _____ NPI #: _____

OFFICE CONTACT

First Name: _____ Last Name: _____

Phone (if different from above): _____ Fax (if different from above): _____

Email: _____

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If you have any questions, please contact the JUXTAPID REMS Coordinating Center.
Phone: 1-85-JUXTAPID (1-855-898-2743) | Fax: 1-855-898-2498 | www.juxtapidREMSprogram.com

PRESCRIBER ATTESTATION

By signing this form, I attest that:

- JUXTAPID® (lomitapide) capsules are only available through the JUXTAPID REMS and that I must comply with the program requirements in order to prescribe JUXTAPID.
- I have reviewed the **Prescribing Information**, **Fact Sheet** and **Prescriber Training Module**.
- Successfully completed the **Prescriber Knowledge Assessment** and submitted it to the JUXTAPID REMS.

Use:

- I understand that JUXTAPID is only indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL-apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B) and non-high density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH).
- I understand that the safety and effectiveness of JUXTAPID has not been established in patients with hypercholesterolemia who do not have HoFH, including those with heterozygous familial hypercholesterolemia (HeFH).

Hepatotoxicity Risk:

- I understand that there is a risk of hepatotoxicity associated with JUXTAPID.
- I understand the Recommendations for Monitoring of Transaminases with JUXTAPID treatment:

Before treatment initiation (first dose), I must:

- Counsel patients on the approved indication for use in patients with HoFH, the risk of hepatotoxicity with JUXTAPID and the need for regular monitoring using the **Patient Guide**.
- Provide the patient a copy of the **Patient Guide**.
- Enroll the patient by completing and submitting the **Patient-Prescriber Acknowledgement Form** to the JUXTAPID REMS.
- Assess the patient to confirm a clinical or laboratory diagnosis consistent with the approved indication.
- Assess the patient's liver function.
- Order the prescription using the **Prescription Authorization Form**.

Lab Requirements:

- I must assess liver-related tests for this patient as recommended in the JUXTAPID Prescribing Information and in the chart below.

Monitoring of Transaminases

Before Initiating therapy

– Measure ALT, AST, alkaline phosphatase, and total bilirubin.

During the first year

– Measure liver-related tests (ALT and AST, at a minimum) **monthly** or prior to each increase in dose, whichever occurs first.

After the first year

– Measure liver-related tests (ALT and AST, at a minimum) at least **every 3 months** and before any increase in dose.

During Treatment:

- I agree to complete and sign the **Prescription Authorization Form** for each prescription.
- I agree that personnel from the JUXTAPID REMS may contact me to gather further information or resolve discrepancies or to provide other information related to JUXTAPID or the JUXTAPID REMS.
- I agree that Amryt, its agents and contractors such as the pharmacy providers may contact me via phone, mail, or email to survey me on the effectiveness of the program requirements for the JUXTAPID REMS.

Prescriber Signature:_____ Date: _____

Prescriber Name:_____ Phone: _____

IMPORTANT

REVIEW TO ENSURE ALL FIELDS ARE COMPLETED | RETURN BOTH PAGES

Fax this form to 1-855-898-2498 or scan and email it to REMS@amrytpharma.com

If you have any questions, please contact the JUXTAPID REMS Coordinating Center.
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