

JYNARQUE® (tolvaptan) REMS QUICK REFERENCE GUIDE

The REMS enhancements will help healthcare providers and delegates optimize their patient care process and the patient experience by utilizing the REMS Portal

New REMS Enhancements

HCP and Delegate Portal:

- Ability to Deactivate/Reactivate patient in the REMS portal
- Able to view the last ship date and the Specialty Pharmacy associated with the last ship date
- Ability to receive alerts in the Message Center for actionable tasks, including Patient Status Forms due, and Patient Enrollment Form to be completed by HCP for signatures and missing information

Delegate Portal:

- Allow a Delegate to “pre-enroll” a patient online by completing the patient demographic information and passing the enrollment to the prescriber for patient education and signatures
- Update an associated prescriber’s phone, fax, or email address
- Complete and submit a Liver Adverse Event Reporting Form online

HCP Portal:

- Allow for patients to complete the patient enrollment online using the Spanish Patient Enrollment Form
- Assign Delegates through the HCP portal as well as edit/delete existing Delegates
- Update contact information online
- Complete a Patient Enrollment Form that was prepopulated by the Delegate

Please see [FULL PRESCRIBING INFORMATION](#), including **BOXED WARNING**.

Step-by-step Guide for Completing a Patient Status Form



1 Go to www.jynarquerems.com and log in using your User ID and password

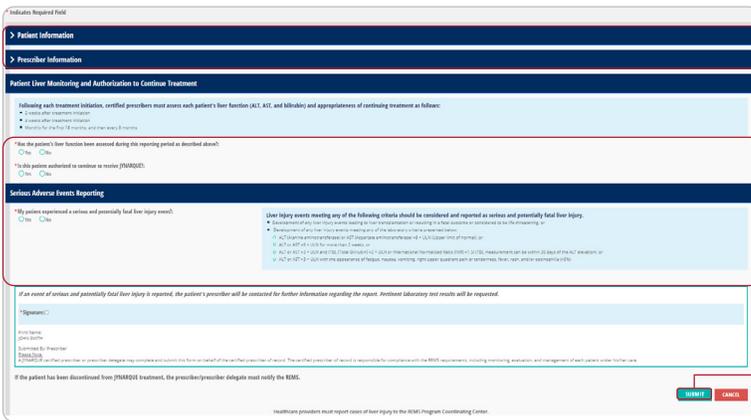
User IDs are in *firstname.lastname* format. User IDs may include digits if multiple users with the same name are registered. Call UBC to set up a new account or to reactivate an existing account.



2 Find the patient by filtering by patient identifiers (eg, REMS ID, Name, or Address) or sorting by **Status Form Due Date**

Upcoming or overdue PSFs are shown in red. To access a patient's historical PSFs and AE Reports, click directly on their **REMS ID** number.

3 Click **Submit a Status Form** button for the appropriate patient

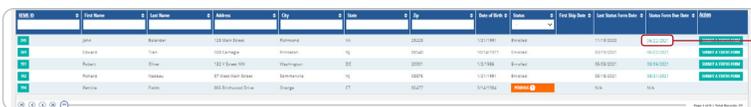


4 Click and expand the **Patient Information** and **Prescriber Information** headers to review the prepopulated data, if desired

5 Complete required questions

6 Click **Submit** when all fields are completed

You will not be able to submit the PSF without completing all required questions. If submission is successful, you will automatically be returned to the dashboard and next due date will be updated.



7 Ensure the **Status Form Due Date** for the patient is updated and shown in green

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Steps Demonstrating Patient Pre-Enrollment (Delegate/ Prescriber)

MY PATIENTS PRESCRIBER PROFILE MANAGEMENT

Patients

Below is a list of patients enrolled by your prescriber(s). Click "Pre-Enroll Patient" to start the enrollment process for a new patient.

ACTION REQUIRED 1

Action Required Tasks

> Missing Information on Patient Enrollment Form **Complete Patient Enrollment**

PRE-ENROLL PATIENT - ENGLISH

PRE-ENROLL PATIENT - SPANISH

1 Delegate clicks **Pre-Enroll** (English or Spanish)

JYNARQUE REMS Patient Enrollment Form

Instructions

JYNARQUE is available only through the JYNARQUE REMS, a restricted distribution program. Only prescribers, pharmacies, and patients enrolled in the program can prescribe, dispense, and receive JYNARQUE. Your certified healthcare provider will help you complete this form and provide you with a copy. Fields marked * are required.

*First Name: John *Last Name: Doe *Birthdate: 9/29/2022

CONTINUE

2 Enter patient's first name, last name, and DOB. Click **Continue**

Patient Information

*First Name: John *Middle Initial: *Last Name: Doe

*Birthdate: 9/29/2022 *Sex: Male Female

*Race: White Black or African American American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Other, Specify

*Ethnicity: Hispanic or Latino Not Hispanic or Latino

*Address Line 1: 2000 WALNUT STREET, SUITE 101 *Address Line 2:

*City: FAIRFAX *State: VA *Zip Code: 22030-4738

3 Complete Patient Information and Medical History

Medical History

The information in this section is only collected to help determine if there are reasons why some people have elevations in their liver function tests and others do not.

*Alcohol Classification: Never drink Ex-Drinker (stopped drinking at least 1 month ago) Current Drinker

*Previously Treated with Tolvaptan Prior to REMS Enrollment: Yes No

Was this part of a clinical trial?: Yes No

SEND TO PRESCRIBER TO COMPLETE ENROLLMENT **CANCEL**

4 Click **Send to Prescriber to Complete Enrollment**

REMS ID	First Name	Last Name	Zip	Date of Birth	Status	First Ship Date	Last Ship Date	SP Associated to Last Shipment	Last Status Form Date	Status Form Due Date	Action
544	John	Doe	22030-4738	9/29/2022	PRE-ENROLLED				N/A	N/A	+ COMPLETE PATIENT ENROLLMENT
477	Mindy	Small	15146	9/4/2001	PRE-ENROLLED				N/A	N/A	+ COMPLETE PATIENT ENROLLMENT

5 Prescriber logs into REMS portal, reviews Message Center by selecting **Review/Sign Patient Enrollment Form** or finds the patient's name and clicks on **+Complete Patient Enrollment**

Tip: In the "Status" column, click the drop-down button to select "Pre-Enrolled." This will show the newest patients pre-enrolled by delegates

Patient Acknowledgement

*Is patient currently available to complete patient signature during online enrollment?: Yes No

*Patient Name: John Doe

Clear Signature

Please use your mouse or stylus to sign below.

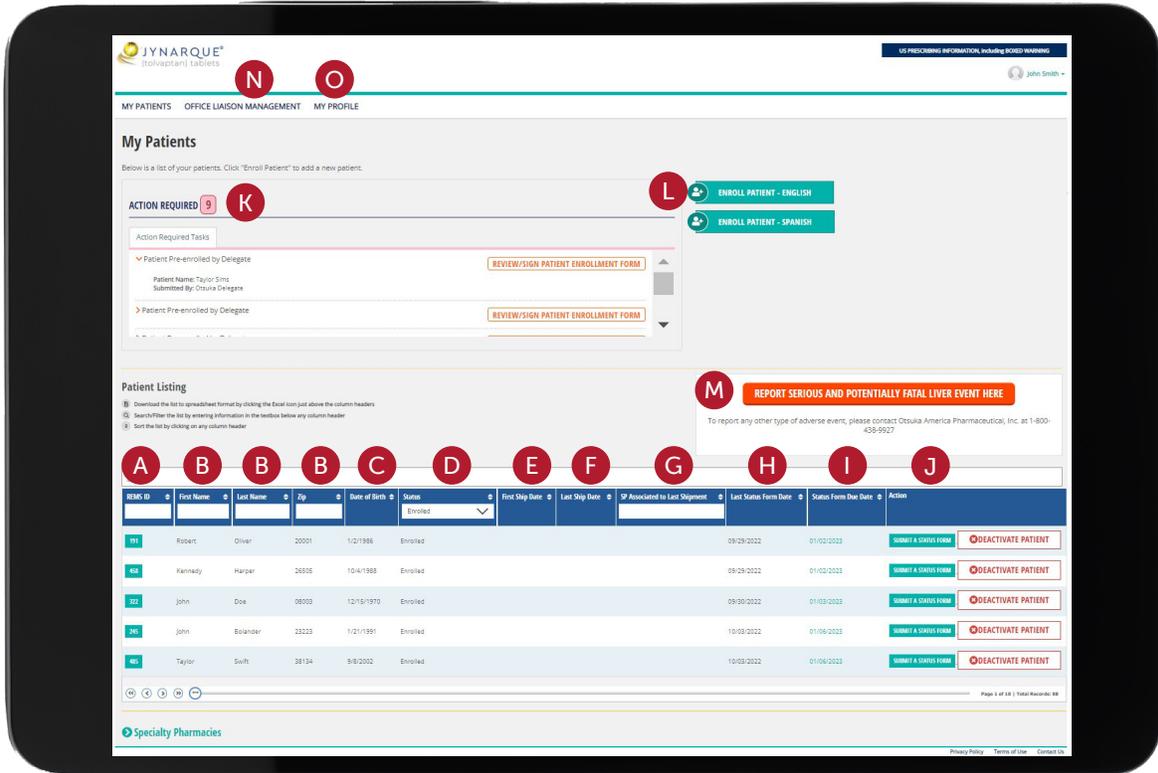
SUBMIT **RESET**

6 Complete Prescriber Agreement and Patient Agreement. Click **Submit**

Please see [FULL PRESCRIBING INFORMATION](#), including **BOXED WARNING**.

HCP View of REMS

REMS enhancements on the portal



This is not actual patient information and only used to depict how the information will render.

- A. REMS ID
- B. First Name, Last Name, and Zip
- C. DOB
- D. Status (Pending, Inactive, Not Complete, Enrolled, Pre-Enrolled)
- E. First Ship Date
- F. Last Ship Date
- G. SP Associated to Last Shipment
- H. Last Status Form Date
- I. Status Form Due Date
- J. Action: Deactivate patient button, Reactivate patient button, and Submit a status form button
- K. Message Center
- L. Enroll Patient-English or Spanish
- M. Report Serious and Potentially Fatal Liver Event button
- N. Office Liaison Management
- O. My Profile

Please see [FULL PRESCRIBING INFORMATION](#), including **BOXED WARNING**.