

TOLVAPTAN FOR ADPKD SHARED SYSTEM REMS PORTAL GUIDE

Prescribers and Delegates can utilize the REMS Portal to optimize the patient care process and experience

User type	Username/password	Authorized tasks
Prescriber	Can link to multiple Delegate (Office Liaison) users. Each Prescriber has their own username/password	<ul style="list-style-type: none">Enroll patient or complete a Patient Enrollment Form that was prepopulated by the DelegateSubmit Patient Status FormReceive alerts via email and in the Message Center in the REMS portalAccess to file or print previously submitted Patient Status Forms or Adverse EventsDeactivate/Reactivate patient in the REMS portalIdentify Last Ship Date and the Specialty Pharmacy associated with Last Ship DateUpdate contact informationAdd/edit/delete assigned Delegate to the Prescriber's REMS portal
Delegate (Office Liaison)	Can link to multiple Prescriber users. Each Delegate has their own username/password	<ul style="list-style-type: none">Submit Patient Status FormPre-enroll a patient onlineReceive alerts via email and in the Message Center in the REMS portalAccess to file or print previously submitted Patient Status Forms or Adverse EventsDeactivate/Reactivate patient in the REMS portalIdentify Last Ship Date and the Specialty Pharmacy associated with Last Ship DateUpdate an associated Prescriber's phone, fax, or email address

Please see **FULL PRESCRIBING INFORMATION**, including **BOXED WARNING**.



Steps to Enroll a New Patient (Prescriber Only)

The screenshot shows the 'MY PATIENTS' tab selected in the top navigation bar. Below it, a section titled 'Action Required' lists tasks such as 'Patient Status Form Due' and 'Patient Pre-enrolled by Delegate'. On the right side of the screen, there is a prominent blue button labeled 'ENROLL PATIENT' with a small icon above it.

- 1 Prescriber clicks **Enroll**, which drives to **Patient Enrollment Form**.

This screenshot displays the 'Tolvaptan for ADPKD Shared System REMS Patient Enrollment Form'. It includes sections for 'Prescriber Information' and 'Patient Information'. The 'Patient Information' section contains fields for First Name, Middle Initial, Last Name, Date of Birth, Sex, Race, and Ethnicity. Red asterisks are present next to 'First Name', 'Middle Initial', 'Last Name', 'Date of Birth', 'Sex', 'Race', and 'Ethnicity' to indicate they are required fields.

- 2 Complete **Patient Information** within **Patient Enrollment Form**.
Red asterisks indicate required fields.

This screenshot shows the 'Prescriber Agreement' section. It contains a question about liver function assessment and a statement about reviewing risks. Below these is a signature field for the prescriber, with a note to use a mouse or stylus. A red asterisk is present before 'Prescriber Name' to indicate it is a required field.

- 3 Complete the **Prescriber Agreement** by answering the question. Type name in box and sign below.
Red asterisks indicate required fields.

This screenshot shows the 'Patient Acknowledgement' section. It asks if the patient is currently available to sign. There is a 'Yes' radio button selected and a 'No' radio button. Below this is a signature field for the patient, with a note to use a mouse or stylus. A red asterisk is present before 'Patient Name' to indicate it is a required field.

- 4 Complete **Patient Acknowledgement** question:

- If the patient is currently available to sign, click "Yes," type patient's name and ask them to e-sign their signature in the space provided

This screenshot shows the 'Patient Acknowledgement' section again. It includes a question about receiving a text message with a link to sign. There is a 'Yes' radio button selected and a 'No' radio button. A red box highlights the 'Yes' radio button. Below this is a note about text message rates and a checkbox for receiving text messages. A red asterisk is present before 'Patient Name' to indicate it is a required field.

- If the patient is not available, select "no." Patient will receive an automated email containing a link to sign and complete the form

An optional check box will also appear that will allow the prescriber to send the link via text message to the patient.

Please see **FULL PRESCRIBING INFORMATION**, including **BOXED WARNING**.



Step-by-step Guide for Completing a Patient Status Form (Prescriber/Delegate)

The screenshot shows the homepage of the Tolvaptan for ADPKD Shared System REMS website. At the top right is a blue "LOGIN" button. Below it is a green navigation bar with links: HOME, PRESCRIBERS, PATIENTS, PHARMACIES, and RESOURCES. The main content area has a grey header: "Tolvaptan for ADPKD Shared System REMS (Risk Evaluation and Mitigation Strategy)".

1

Go to TolvaptanADPKDSharedREMS.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 REMS CC to set up a new account or to reactivate an existing account.

This screenshot shows the "My Patients" section. It includes a heading "Action Required 3" with a blue box containing "1 Action Required Tasks". Inside the box are two items: "Patient Status Form Due" (Patient Name: Peggy Sue, Status Form Due Date: 99/99/9999) and "Patient Pre-enrolled by Delegate". To the right is a red box around the "Submit Patient Status Form" button. Below the box is a link "Complete Patient Enrollment".

2

There are 2 ways to submit a **Patient Status Form**:

1) Go to the **Action Required** box and click on submit patient status form.

This screenshot shows the "Patient Listing" section. It features a table with columns: 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, and Action. The "Action" column contains two buttons: "SUBMIT A STATUS FORM" and "REACTIVATE PATIENT". Red boxes highlight these buttons. The table also includes headers for "Download the list to spreadsheet format" and "Search/Filter the list by entering information in the textbox below any column header".

2) Go to **Patient Listing** and select patient by patient identifiers (REMS ID, Name, or Address). Click the button to **Submit a Status Form** for the selected patient.

Ensure the Status Form Due Date for the patient is updated and current.

This screenshot shows the "Patient Liver Monitoring and Authorization to Continue Treatment" section. It includes a note about liver function assessment and a question "Has the patient's liver function been assessed during this reporting period as described above?". Below is a question "Is this patient authorized to continue to receive tolvaptan for ADPKD?". The "Yes" option is checked. At the bottom is a "Serious Adverse Events Reporting" section with a note about reporting liver injury events.

3

Complete questions.

Red asterisks indicate required fields.

This screenshot shows a note about reporting liver injury cases to the REMS Coordinating Center. It includes a "Print Name" field (MAUBA BARR), a "Submitted By: Prescriber" field, and a "Please Note:" section. The note states: "A Tolvaptan for ADPKD Shared System REMS certified prescriber or prescriber delegate may complete and submit this form on behalf of the certified prescriber of record. The certified prescriber of record is responsible for compliance with the REMS requirements, including monitoring, evaluation, and management of each patient under his/her care." Below is a note: "If the patient has been discontinued from tolvaptan for ADPKD treatment, the prescriber/prescriber delegate must notify the REMS." At the bottom is a "Healthcare providers must report cases of liver injury to the REMS Coordinating Center." button.

4

Click **Submit** when done.

If submission is successful, you will automatically be returned to the dashboard and next due date will be updated.

Please see **FULL PRESCRIBING INFORMATION**, including **BOXED WARNING**.



Steps Demonstrating Patient Pre-Enrollment (Delegate)

Patients
Below is a list of your patients. Click "Pre-Enroll Patient" to add a new patient.

Action Required ②

Patient Status Form Due
Patient Name: Peggy Sue
Status Form Due Date: 99/99/9999

Missing Information on Patient Enrollment Form

PRE-ENROLL PATIENT

1 Delegate clicks **Pre-Enroll Patient** to access the **Patient Enrollment Form**.

PATIENTS PRESCRIBER PROFILE MANAGEMENT

Tolvaptan for ADPKD Shared System REMS Patient Enrollment Form

Instructions

Tolvaptan for Autosomal Dominant Polycystic Kidney Disease (ADPKD) is available only through the Tolvaptan for ADPKD Shared System REMS, a restricted distribution program. Only prescribers, pharmacies, and patients enrolled in the Tolvaptan for ADPKD Shared System REMS can prescribe, dispense, and receive tolvaptan for ADPKD. Your certified healthcare provider will help you complete this form and provide you with a copy.

Prescriber Information

National Provider Identifier No. [NPI]*: 1234567890
Practice/Facility Name: ABC Facility
City: SELLERSVILLE
Phone: 215-555-2333
Prescriber Name: MAURA BARR
Address Line 1: 999 Main Street
State: PA
Phone: 215-555-1800
Zip code: 18960-0150
Email: mbarr@abc.com

Patient Information

*First Name: _____ Middle Initial: _____ *Last Name: _____
*Date of Birth [MM/DD/YYYY]: _____ *Sex: Male Female
*Race: White Black or African American American Indian or Alaska Native Asian Hispanic or Latino Not Hispanic or Latino
*Address Line 1: _____ Address Line 2: _____
*City: _____ *State: _____ *Zip Code: _____
*Phone: _____ *Mobile Phone: _____ *Email: _____
Same as Phone: N/A:
SEND TO PRESCRIBER TO COMPLETE ENROLLMENT CANCEL

2 Delegate enters **Patient Information** in **Patient Enrollment Form**.

Red asterisks indicate required fields.

3 Delegate clicks **Send to Prescriber to Complete Enrollment**.

Action Required ③

Action Required Tasks

Patient Status Form Due
Patient Name: Peggy Sue
Status Form Due Date: 99/99/9999

Patient Pre-enrolled by Delegate

Missing Information on Patient Enrollment Form

Complete Patient Enrollment

View Patient

4 There are 2 ways for **Prescriber** to complete enrollment:

1) Log into REMS portal and click **Complete Patient Enrollment** (in the Action Required box).

Prescriber can now access the Enrollment Form, pre-populated with Patient Information. Go to [Steps to Enroll a New Patient](#) and follow the signature instructions.

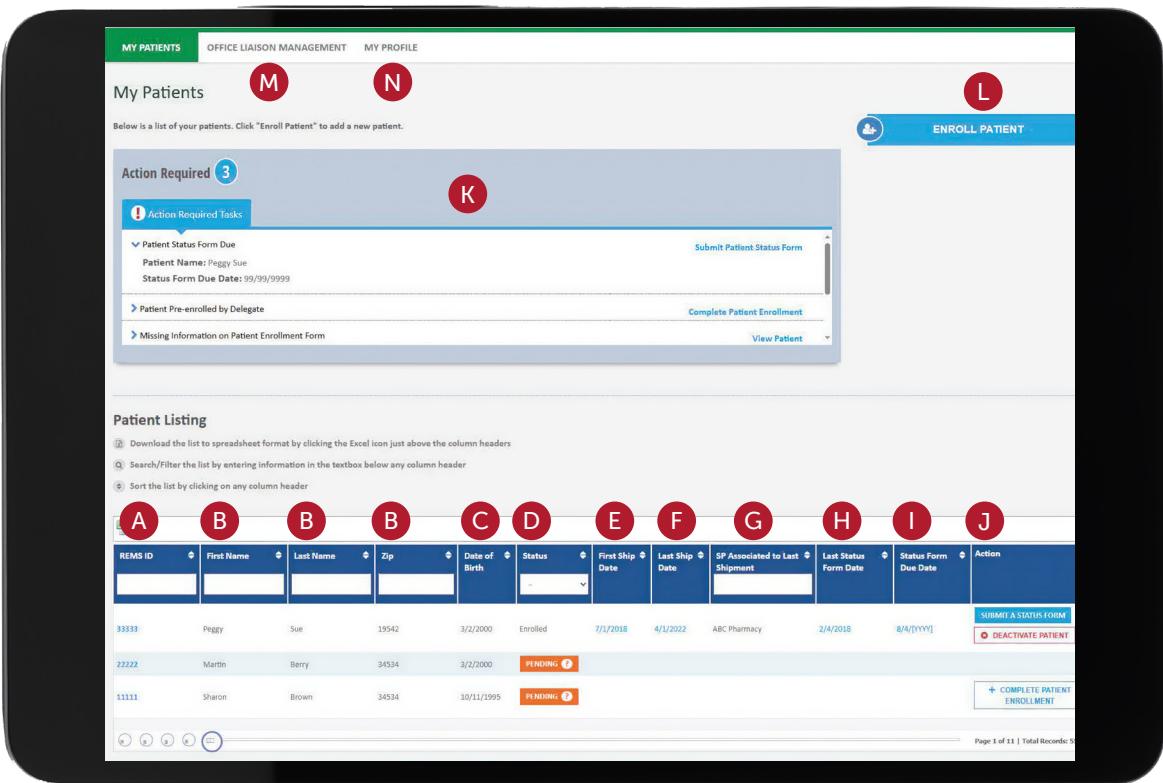
2) Go to **Patient Listing** and find **Status column**. Click on drop down arrow and select "Pre-Enrolled." Select patient by additional identifiers.

—In the **Action column**, select **Complete Patient Enrollment** button

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



Prescriber View of REMS 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, Submit a Status Form button, and Complete Patient Enrollment button**
- K. Message Center**
- L. Enroll Patient**
- M. Office Liaison (Delegate) Management**
- N. My Profile**

For any questions:

Call: 1-866-244-9446 Fax: 1-866-750-6820
REMS Coordinating Center Mon-Fri, 8am-8pm ET

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