

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 Delegate• Submit Patient Status Form• Receive alerts via email and in the Message Center in the REMS portal• Access to file or print previously submitted Patient Status Forms or Adverse Events• Deactivate/Reactivate patient in the REMS portal• Identify Last Ship Date and the Specialty Pharmacy associated with Last Ship Date• Update contact information• Add/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 Form• Pre-enroll a patient online• Receive alerts via email and in the Message Center in the REMS portal• Access to file or print previously submitted Patient Status Forms or Adverse Events• Deactivate/Reactivate patient in the REMS portal• Identify Last Ship Date and the Specialty Pharmacy associated with Last Ship Date• Update 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)

MY PATIENTS OFFICE LIAISON MANAGEMENT MY PROFILE

My Patients

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

Action Required 3

1 Action Required Task

✓ Patient Status Form Due Submit Patient Status Form

Patient Name: Peggy Sue

Status Form Due Date: 9/9/9999

> Patient Pre-enrolled by Delegate Complete Patient Enrollment

> Missing Information on Patient Enrollment Form View Patient

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

MY PATIENTS OFFICE LIAISON MANAGEMENT MY PROFILE

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 Prescriber Name: MAURA BARR

Practice/Facility Name: ABC Facility Address Line 1: 999 Main Street

City: SELLERSVILLE State: IN Zip code: 10960-0930

Phone: 215-555-2333 Fax: 215-555-1800 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

*Ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino

2 Complete **Patient Information** within **Patient Enrollment Form**.

Red asterisks indicate required fields.

Prescriber Agreement

*Has the patient's liver function been assessed by evaluating ALT, AST, and bilirubin prior to enrolling this patient in the REMS?

☐ Yes ☐ No

If the answer is No, you must assess the patient's liver function by evaluating ALT, AST, and bilirubin prior to submitting this form to the REMS.

By signing below, I acknowledge that I have reviewed and discussed the risks of tolvaptan for ADPKD and the requirements of the Tolvaptan for ADPKD Shared System REMS with this patient.

*Prescriber Name:

Please use your mouse or stylus to sign below

Clear Signature

3 Complete the **Prescriber Agreement** by answering the question. Type name in box and sign below.

Red asterisks indicate required fields.

Patient Acknowledgement

*Is patient currently available to complete patient signature during online enrollment?

☒ Yes ☐ No

*Patient Name:

Please use your mouse or stylus to sign below

Clear Signature

Patient Acknowledgement

*Is patient currently available to complete patient signature during online enrollment?

☐ Yes ☒ No

☐ Would the patient like to receive a text message containing the link to sign this Tolvaptan for ADPKD Shared System REMS Patient Enrollment form? Message and data rates may apply. By clicking this check box, you are confirming that the patient has verbally agreed to receive text messages.

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
- 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)

- 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.

- 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.

- 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.

- 3 Complete questions. Red asterisks indicate required fields.

- 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

Action Required Tasks

- Patient Status Form Due**
Patient Name: Peggy Sue
Status Form Due Date: 99/99/9999
Submit Patient Status Form
- Missing Information on Patient Enrollment Form**
View Patient

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

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Prescriber Information

National Provider Identifier No. (NPI)*: 1234567890
Practice/Facility Name: ABC Facility
City: GILLESPIE, MD
Phone: 215-555-2333
Prescriber Name: MAURA BARR
Address Line 1: 999 Main Street
State: IN
Fax: 215-555-1800
Zip code: 18903-0000
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 ☐ Native Hawaiian or Other Pacific Islander ☐ Other, Specify:
 *Ethnicity: ☐ 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
Submit Patient Status Form
- Patient Pre-enrolled by Delegate**
Complete Patient Enrollment
- Missing Information on Patient Enrollment Form**
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.

Patient Listing

Download the list to spreadsheet format by clicking the Excel icon just above the column headers
 Search/Filter the list by entering information in the textboxes below any column header
 Sort the list by clicking on any column header

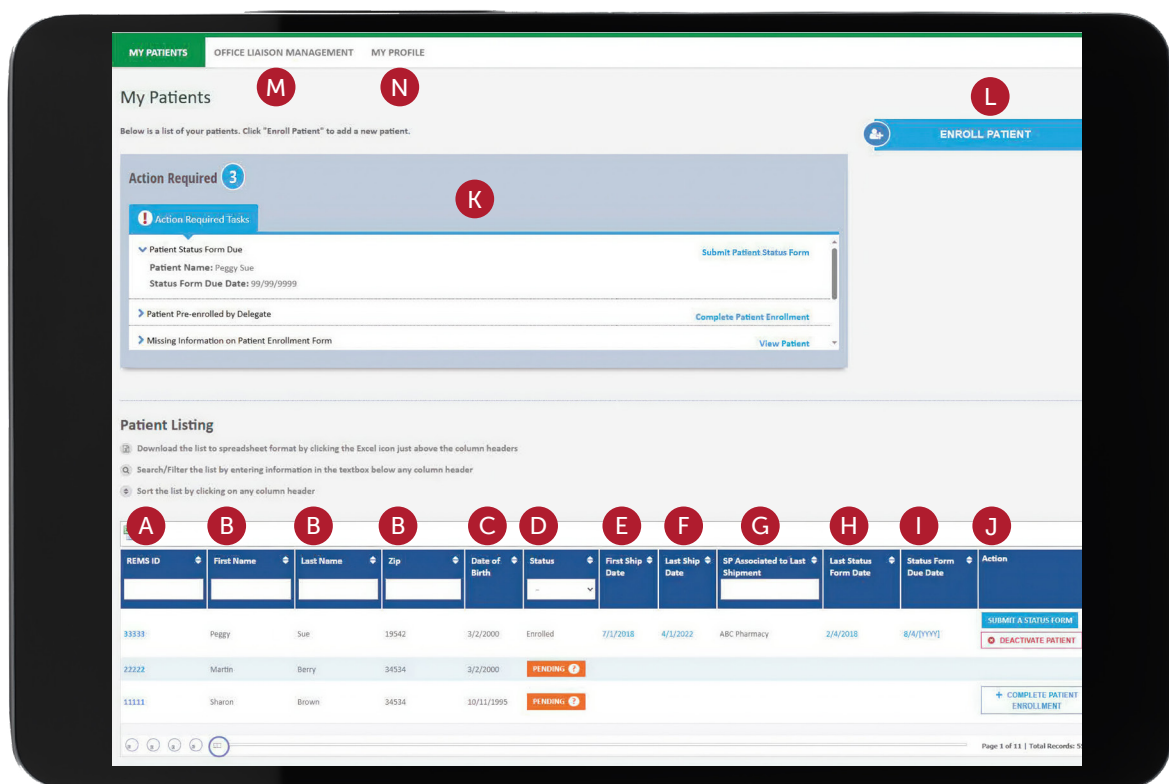
REMS ID	First Name	Last Name	Zip	Date of Birth	Status	First Ship Date	Last Ship Date	SP Associated to Last Shipment	Last Status Form Date	Status Form Due Date	Action
11009	Peggy	Sue	18902	3/1/2000	Enrolled	7/1/2008	4/1/2012	ABC Pharmacy	3/1/2018	8/1/2019	SUBMIT A STATUS FORM DEACTIVATE PATIENT
11010	Martin	Berry	34034	3/2/2000	PENDING						
11011	Sharon	Brown	34034	10/11/1995	PRE-ENROLL						COMPLETE PREVIEW ENROLLMENT

- 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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