Tolvaptan for ADPKD Shared System REMS | PATIENT STATUS FORM

This form must be regularly completed for all patients treated with tolvaptan for Autosomal Dominant Polycystic Kidney Disease (ADPKD). At the time this form is due, this form may also be used to report adverse events suggestive of a serious or potentially fatal liver injury. Once completed, you may submit the form to the Tolvaptan for ADPKD Shared System REMS by fax or online.

This form must be completed and submitted:

- every 3 months for the first 18 months of treatment and
- every 6 months thereafter.

Note:

The completion of the laboratory tests (see frequency below) and the submission of the **Patient Status Form** (per the schedule shown above) are done at different intervals.

Adverse events suggestive of serious and potentially fatal liver injury must be reported to the REMS by any one of the following actions:

- Contact the REMS Coordinating Center by phone
- Submit a completed **Patient Status Form**

If an event is submitted via the Patient Status Form, it is not necessary to contact the REMS Coordinating Center by phone to report the same event.

**Indicates required field*

Patient Information

First Name*: _____ Last Name*: _____

Date of Birth (MM/DD/YYYY)*: _____ REMS ID: _____

Address Line 1*: _____

Address Line 2: _____

City*: _____ State*: _____ Zip code*: _____

Prescriber Information

First Name*: _____ Last Name*: _____ REMS ID: _____

National Provider Identifier No. (NPI)*: _____ Practice/Facility Name: _____

Address Line 1: _____

Address Line 2: _____

City: _____ State: _____ Zip code: _____

Phone*: _____ Fax: _____ Email: _____

PATIENT STATUS FORM

Patient Liver Monitoring and Authorization to Continue Treatment

Following each treatment initiation, certified prescribers must assess each patient's liver function (ALT, AST, and bilirubin) and appropriateness of continuing treatment as follows:

- 2 weeks after treatment initiation
- 4 weeks after treatment initiation
- Monthly for the first 18 months; and then every 3 months

*Has the patient's liver function been assessed during this reporting period as described above?

☐ Yes ☐ No

*Is this patient authorized to continue to receive tolvaptan for ADPKD?

☐ Yes ☐ No

Serious Adverse Events Reporting

*My patient experienced a serious and potentially fatal liver injury event? ☐ Yes ☐ No

Liver injury events meeting any of the following criteria should be considered and reported as serious and potentially fatal liver injury.

- Development of any liver injury events leading to liver transplantation or resulting in a fatal outcome or considered to be life-threatening, or
- Development of any liver injury events meeting any of the laboratory criteria presented below:
  - ALT (Alanine aminotransferase) or AST (Aspartate aminotransferase) >8 × ULN (Upper limit of normal), or
  - ALT or AST >5 × ULN for more than 2 weeks, or
  - ALT or AST >3 × ULN and (TBL [Total Bilirubin] >2 × ULN or International Normalized Ratio [INR] >1.5) (TBL measurement can be within 30 days of the ALT elevation), or
  - ALT or AST >3 × ULN with the appearance of fatigue, nausea, vomiting, right upper quadrant pain or tenderness, fever, rash, and/or eosinophilia (>5%)

Event Information:

****Please see definition of seriousness criteria on page 3****

*Please select Yes or No for each seriousness criteria below:

Death*	☐ Yes	☐ No	
Life-threatening*	☐ Yes	☐ No	
Hospitalization*	☐ Yes	☐ No	
Important Medical event*	☐ Yes	☐ No	
*Treatment was discontinued due to this event	☐ Yes	☐ No	☐ Not available

Liver Laboratory Information:

Were the liver enzymes (ALT/AST) elevated > 3 x ULN?*	☐ Yes	☐ No	☐ Not available
Were there Symptoms of Liver Injury?*	☐ Yes	☐ No	

If an event of serious and potentially fatal liver injury is reported, the patient's prescriber will be contacted for further information regarding the report. Pertinent laboratory test results will be requested.

Signature*: _____ Date*_____

Print Name*: _____

Submitted by*: ☐ Prescriber Delegate ☐ Prescriber

Please Note:

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.

If the patient has been discontinued from tolvaptan for ADPKD treatment, the prescriber/prescriber delegate must notify the REMS.

PATIENT STATUS FORM

Definition of Seriousness Criteria

Death

Report if you suspect that the death was an outcome of the liver event, and include the date if known.

Life-threatening

Report if suspected that the patient was at substantial risk of dying at the time of the liver event, or use or continued use of product might have resulted in the death of the patient.

Hospitalization (initial or prolonged)

Report if admission to the hospital or prolongation of hospitalization was a result of the liver event.

Emergency room visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes (e.g., life-threatening; required intervention to prevent permanent impairment or damage; other serious medically important event).

Important Medical Events

Report when the liver event does not fit the other outcomes, but the liver event may jeopardize the patient and may require medical or surgical intervention (treatment) to prevent one of the other outcomes. Examples include allergic bronchospasm (a serious problem with breathing) requiring treatment in an emergency room, serious blood dyscrasias (blood disorders) or seizures/convulsions that do not result in hospitalization. The development of drug dependence or drug abuse would also be examples of important medical events.