



Tolvaptan Prior Authorization

Drug(s) Applied:	tolvaptan
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Criteria:

Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

I. Initial Therapy Criteria

A. Autosomal Dominant Polycystic Kidney Disease (ADPKD) as indicated by chart notes within past 90 days

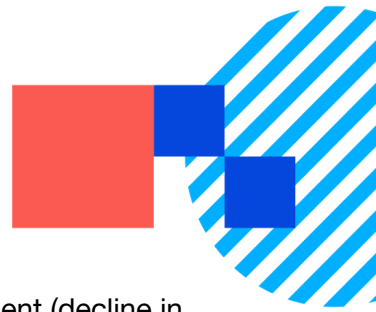
1. Patient is 18 years of age or older **and**
2. Diagnosis of ADPKD confirmed by ONE of the following:
 - a) Ultrasonography
 - b) MRI or CT scan
 - c) Genetic testing **and**
3. Patient has $\text{eGFR} \geq 25 \text{ ml/min per } 1.73 \text{ m}^2$ **and**
4. Patient is at risk of rapid disease progression as indicated by ONE of the following:
 - a) ADPKD has been classified as 1C, 1D, or 1E using the Mayo ADPKD Classification assessment
 - b) Historical rate of eGFR decline ($\geq 3 \text{ ml/min per } 1.73 \text{ m}^2$ per year) **and**
5. Patient does not have Stage 5 chronic kidney disease **and**
6. Patient is not receiving dialysis **and**
7. Patient will NOT be using the requested agent in combination with another tolvaptan agent **and**
8. Prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrology)
9. Chart notes and/or prescriber do not provide documentation of any FDA labeled contraindications to tolvaptan, including but not limited to significant liver disease, planning pregnancy, pregnancy, or breastfeeding

Approval Duration: 12 months

II. Continued Therapy Criteria

A. Autosomal Dominant Polycystic Kidney Disease (ADPKD) as indicated by chart notes within past 12 months

1. Patient meets the initial therapy criteria above **and**



2. Documented clinical benefit since starting the requested agent (decline in patient's kidney function has slowed) **and**
3. Patient will NOT be using the requested agent in combination with another tolvaptan agent **and**
4. Prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrology) **and**
5. Chart notes and/or prescriber do not provide documentation of any FDA labeled contraindications to tolvaptan, including but not limited to significant liver disease, planning pregnancy, pregnancy, or breastfeeding

Approval Duration: 12 months

Policy Owned by: Curative PBM team