curative

Tolvaptan Prior Authorization

Drug(s) Applied:	tolvaptan

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 of 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 eGFR ≥ 25 ml/min per 1.73 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 (≥ 3 ml/min per 1.73 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