Table 1: Selected countries funding tolvaptan for therapy of polycystic kidney disease (PCKD).[24–26]

Country	Submission date	Status
United States of America	March 2013	Approved April 2018
Japan	May 2013	Approved March 2014
European Union	November 2013	Approved May 2015
Canada	March 2014	Approved February 2015
Switzerland	October 2014	Approved April 2016
Republic of Korea	June 2015	Approved December 2015
Australia	February 2016	Approved March 2017

Figure 2: Tolvaptan – recommended special authority criteria.[28]

Initial application—(autosomal dominant polycystic kidney disease) from a renal physician or on the recommendation of a renal physician. Approvals valid for three months for applications meeting the all of the following criteria:

1. Patient has a confirmed diagnosis of autosomal dominant polycystic kidney disease (ADPKD);
2. Patient has an eGFR of between 25mL and 65mL/min/1.73m^2 at treatment initiation;
3. Patient's disease is rapidly progressing, defined as either:

a. A decline in eGFR of greater than or equal to 5mL/min/1.73m^2 within one year; or

b. An average decline in eGFR of greater than or equal to 2.5mL/min/1.73m^2 per year over a five-year period.

Note: Tolvaptan must be initiated and monitored under the supervision of physicians with expertise in managing ADPKD, and a full understanding of the risks of tolvaptan therapy including hepatic toxicity and monitoring requirements (liver function tests are required prior to tolvaptan initiation, monthly for the first 18 months and three-monthly thereafter; concurrent monitoring for symptoms of possible liver injury is recommended).

Renewal—(autosomal dominant polycystic kidney disease) from a renal physician or on the recommendation of a renal physician. Approvals valid for three months for applications meeting the following criteria:

All of the following:

1. Patient has previously received tolvaptan for confirmed ADPKD;
2. The treatment remains appropriate and the patient is benefitting from treatment;
3. Patient has not developed end-stage renal disease (defined as an eGFR of less than 15mL/min/1.73 m^2);
4. Patient has not undergone a kidney transplant.

Note: Tolvaptan must be monitored under the supervision of physicians with expertise in managing ADPKD, and a full understanding of the risks of tolvaptan therapy including hepatic toxicity and monitoring requirements (liver function tests are required monthly for the first 18 months and three-monthly thereafter; concurrent monitoring for symptoms of possible liver injury is recommended).