CONFIDENTIAL

Application for individual reimbursement approval of Tolvaptan (Jinarc®)

For MMP Use Only	
Case Reference	*Date Received*

Date of Application	Nominated Community Pharmacy (Name & address- *leave blank if uncertain)*

Part 1: Patient Details

Name of patient				
Date of birth				
Gender	Male ☐		Female ☐	
Address				
GMS / DPS / PPS Number (Please tick and insert number)		GMS	DPS	PPSN
	Number:			

Part 2: Prescriber Details

Name of prescribing consultant	
Medical Council number	
Contact details:	Hospital:
	Address:
	Telephone:
	Email:

Please refer to the HSE-Managed Access Protocol for Tolvaptan (Jinarc®) when completing part 3 of this application form

Part 3: Patient Clinical History

Please indicate whether the patient meets the following criteria (*please tick which apply and complete requested detail*)

1. Patient is aged 18 - 55 years at time of application Yes ☐ No ☐

2. Patient has established Autosomal Dominant Polycystic Kidney Disease diagnosis Yes ☐ No ☐

A diagnosis was established by:

	Yes	No
age related modified Pei-Ravine imaging criteria (if family history)		
> 10 cysts per kidney and exclusion of other forms of cystic kidney disease (if no family history)		

3. Patient has chronic kidney disease stage 2 or 3 at initiation of treatment Yes ☐ No ☐

Please provide the following measurements for the patient at the time of application:

All measurements should be taken in the six week period prior to date of application

	Measurement	Date of measurement
Weight (kg)		
Height (cm)		
Serum creatinine (µmol/L)		
eGFR ($ml/min/1.73\ m^2$) $eGFR_{CKD\text{-}EPI}$ **or** $eGFR_{MDRD}$		
Measured GFR (optional) *24-hour urine creatinine clearance or isotope method* (ml/min)		

$eGFR_{CKD\text{-}EPI}$: estimated GFR using the Chronic Kidney Disease Epidemiology Collaboration equation;
$eGFR_{MDRD}$: estimated GFR using the Modification of Diet in Renal Disease study equation

Evidence of rapidly progressing disease

For reimbursement approval, evidence of rapidly progressing disease must be satisfied. *Refer to section 2.2.4 of the managed access protocol.*

4. Patient has demonstrated a sustained decline in eGFR of ≥ 3 ml/min/1.73 m^2 per year over a period of four years or greater — Yes ☐ No ☐

Please provide five measurements over a period of four years or greater as outlined in the managed access protocol:

- *The date of the first and last eGFR measurement must be at least four years apart*
- *Measurements must be provided for at least three individual years during this period*
- *The date of the most recent measurement must be within the six week period prior to date of application.*

	Date of measurement	eGFR* (ml/min/1.73 m^2)
1		
2		
3		
4		
5		

** $eGFR_{CKD\text{-}EPI}$ or $eGFR_{MDRD}$*

Please attach copies of lab reports to confirm eGFR measurements **Enclosed** ☐

Additional space for supporting information

Please indicate the status of the patient in relation to the following clinical parameters
(please tick which apply)

	Yes	No
Elevated liver enzymes and/or signs or symptoms of liver injury [*as per HSE-Managed Access Protocol (section 4) and SmPC for Jinarc® (Tolvaptan)]*		
Anuria		
Volume depletion		
Hypernatraemia		
Inability to perceive or respond to thirst		
Pregnant or breast-feeding		
Hypersensitivity to the active substance or to any of the excipients, or to benzazepine or benzazepine derivatives		

I confirm that treatment will be **discontinued** if renal insufficiency progresses to chronic kidney disease stage 5 (eGFR < 15 ml/min/1.73 m^2) ☐

Completed forms should be returned by:
email (using secure email, e.g. HSE email or healthmail) to mmp@hse.ie

Please note that the MMP will acknowledge receipt of each application.

Authorisation of Request	
Signature of **Prescribing Consultant**	
Institution	

Data Protection Notice

- The information on this form will be used by the Health Service Executive (HSE) to assess the suitability of the items listed to be provided under Section 20 of the Health (Pricing and Supply of Medical Goods) Act 2013.
- Details of prescription items dispensed to the named person may be notified to the HSE by the dispensing pharmacist to ensure that the named person receives the items required.
- The named person may access information relating to themselves only, on prescription claims processed in their name by the HSE.
- We may share information with the Department of Health, healthcare practitioners and other healthcare bodies.
- We may also disclose information to other parties if the law requires us to do so.
- The PCRS privacy statement can be located at www.pcrs.ie.