All sections of this form must be completed

CONFIDENTIAL

Application for individual reimbursement approval of Jinarc® (Tolvaptan)

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 Jinarc® when completing part 3 of this application form

Part 3: Patient Clinical History

Please indicate whether the patient meets the following criteria

Patient is aged 18 - 50 years at time of application Yes ☐ No ☐

Patient has established Autosomal Dominant Polycystic Kidney Disease diagnosis

Yes ☐ No ☐

Diagnosis established by:

☐ If family history, age related modified Pei-Ravine Imaging criteria (*see Appendix*)

☐ If no family history, 10 cysts per kidney and exclusion of other forms of cystic kidney disease

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:

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

$CrCl_{CG}$; creatinine clearance using the Cockcroft–Gault equation;
$eGFR_{CKD-EPI}$: estimated GFR using the Chronic Kidney Disease Epidemiology Collaboration equation;
$eGFR_{MDRD}$: estimated GFR using the Modification of Diet in Renal Disease study equation

Please indicate whether the patient has evidence of rapidly progressing disease
For reimbursement approval, option 1, 2, or 3 must be satisfied (please tick which apply and complete requested detail)

1. A sustained decline in eGFR of ≥ 2.5 ml/min/1.73 m^2 per year over a five year period ☐
(with at least five measurements over a five year period)

Please provide five measurements over a five year period as outlined in managed access protocol:

Date of measurement	eGFR* (ml/min/1.73 m^2)

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

2. A sustained decline in eGFR of > 5 ml/min/1.73 m^2 per year over 12 months ☐
(with at least three sets of repeated measurements six months apart)

Please provide three sets of repeated measurements six months apart as outlined in managed access protocol:

	Measurement 1	Repeat measurement†
Date of measurement		
eGFR* (ml/min/1.73 m^2)		

	Measurement 2	Repeat measurement†
Date of measurement		
eGFR* (ml/min/1.73 m^2)		

	Measurement 3	Repeat measurement†
Date of measurement		
eGFR* (ml/min/1.73 m^2)		

** $eGFR_{CKD\text{-}EPI}$ or $eGFR_{MDRD}$* *†: two to six weeks after initial measurement*

3. An increase in total kidney volume (TKV) ≥ 5% per year ☐
(measured in at least three scans (CT or MRI), each at least six months apart)

Please provide three measurements by CT/MRI at least six months apart:

Date of measurement	TKV (ml)

CT: computed tomography; MRI: magnetic resonance imaging

Please indicate the status of the patient in relation to the following clinical parameters:

	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		

ALT: Alanine transaminase; AST: Aspartate aminotransferase; BT; Bilirubin-total; INR: International normalised ratio; ULN: Upper limit of normal

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) Yes ☐

European Best Practice recommendations suggest discontinuation of tolvaptan treatment when patients approach end-stage renal disease. Therefore clinicians should consider discontinuation of treatment for patients with Chronic Kidney Disease stage 4 whose eGFR falls below 25 ml/min/1.73m^2.

Completed forms should be emailed to:

HSE Medicines Management Programme

Email: mmp@hse.ie

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.

Appendix

Unified ultrasound age-related modified Pei-Ravine Imaging criteria are outlined below. These criteria are only valid in patients with a positive family history and are specific for ultrasound imaging only

Age (years)	Diagnostic criteria
15 - 29	≥ 3 cysts (total)
30 - 39	≥ 3 cysts (total)
40 - 59	≥ 2 cysts (each kidney)