

CONFIDENTIAL**Application for individual reimbursement approval of Tolvaptan (Jinarc®)***For MMP Use Only*

Case Reference

Date Received

Date of Application:

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: Approved Consultant DetailsName of approved
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 and 4 of this application form

Part 3: Patient Diagnosis

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

1. 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)		

2. 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-EPI}	
	or	
	eGFR _{MDRD}	
Measured GFR (optional) 24-hour urine creatinine clearance or isotope method (ml/min)		

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

Evidence of rapidly progressing disease

For reimbursement approval, evidence of rapidly progressing disease must be satisfied. *Refer to section 2.3.3 of the managed access protocol.*

3. Patient has demonstrated a sustained decline in eGFR of ≥ 3 ml/min/1.73 m² 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-EPI} or eGFR_{MDRD}

Please attach copies of lab reports to confirm eGFR measurements

Enclosed ☐

Part 4: Patient Clinical History/Status

1. Patient is aged 18 - 55 years at time of application

Yes ☐ No ☐

2. Does the patient meet any of the contraindications to treatment as outlined in the Summary of Product Characteristics (SmPC) for tolvaptan (Jinarc®)

Yes ☐ No ☐

Please refer to section 2.4 of the Managed Access Protocol and to SmPC

3. I confirm that treatment will be **discontinued** if renal insufficiency progresses to chronic kidney disease stage 5 (eGFR < 15 ml/min/1.73 m²)

Yes ☐ No ☐

Additional space for supporting information

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 **Approved
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.