

## Tolvaptan for the treatment for Autosomal Dominant Polycystic Kidney Disease Information for Primary Care

Patient Details:

Dear Dr.....

Your patient has been prescribed an Tolvaptan, supplies of which will be provided by the Renal unit at Hull and East Yorkshire Hospitals NHS Trust. As per responsibilities detailed overleaf please see information below.

Specific product prescribed, dose and frequency

I have asked patient to arrange at your surgery;

Monthly Biochemical profile, U&E, LFT, (code as secondary care generated bloods under local arrangements)

**If you are unable to perform the requested phlebotomy please contact the Renal Unit.**  
(Contact details overleaf)

I will monitor and review your patient's results monthly and adjust treatment as necessary. (Note patients results are reviewed via electronic records and patient contacted by telephone). After 18 months, reduction in frequency of monitoring may be recommended, on further advice from specialist team.

Information and instructions given to patient:

Hand held patient documentation.  
Patient information leaflet.

Other relevant clinical information / drug therapy.

**Name (Print).....Sign.....Date.....**

### Background

In October 2015, NICE recommended that Tolvaptan (JINARC®) therapy should be made available for selected patients with Autosomal Dominant Polycystic Kidney Disease (ADPKD) in England and Wales (<http://www.nice.org.uk/guidance/TA358>) to slow the progression of cyst development and renal insufficiency only if:

- they have chronic kidney disease stage G2 or G3 at the start of treatment - measured by eGFR (using CKD-EPI)
- are confirmed to have APKD -age related modified Pei-Ravine imaging criteria or if no family history, 10 cysts per kidney and exclusion of other forms of cystic kidney disease
- are aged between 18-50 years (>50y at discretion of nephrologist)
- there is evidence of rapidly progressing disease
- a sustained decline in eGFR of  $\geq 2.5\text{ml/min/1.73m}^2$  per year (with at least 5 measurements over 5 years) or a sustained decline in eGFR of  $>5\text{ml/min/1.73m}^2$  per year over 12 months (at least 2 measurements 6 months apart, with each measurement confirmed on 2 blood tests (over 72 hours)
- an increase in total kidney volume (TKV) ( $\geq 5\%$  per year) measured in at least 3 scans (CT or MRI) at least 6 months apart identifies rapid disease progression, or an ultrasound scan of enlarged kidneys  $>16.5\text{ cm}$  as high risk.
- the company provides it with the discount agreed in the patient access scheme

### Local arrangements

Management of autosomal dominant polycystic kidney disease is coordinated by renal consultants based at Hull and East Yorkshire Hospitals NHS Trust. Interpretation of blood tests and appropriate dose adjustments remains the responsibility of the renal unit. This document aims to clarify the responsibilities of the Primary and Secondary healthcare providers when patients are prescribed Tolvaptan for autosomal dominant polycystic kidney disease.

Patients are initiated on Tolvaptan therapy by the hospital. Supply of Tolvaptan is co-ordinated by the hospital team. The hospital team provides information to the GP on frequency of monitoring required. The hospital team are responsible for interpretation of the relevant tests and adjust Tolvaptan doses accordingly.

### Responsibilities

**Hospital Team:** (This may be Renal Pharmacist, Renal Nurse Practitioner or Renal Physician)

- Initiate and stabilise the patient's treatment of autosomal dominant polycystic kidney disease
- Provide GP with the following information:
  - Specific product prescribed, dose and frequency.
  - Arrangements for monitoring / reviewing patient and frequency. Information and instructions given to patient,
  - Other relevant clinical information / drug therapy.
- Supervise the management of autosomal dominant polycystic kidney disease.
- Give the GP advice where appropriate on management of any adverse drug reactions relating to Tolvaptan treatment.
- Provide the patient with information and support on Tolvaptan therapy.
- Provide supplies of Tolvaptan from HEY hospital pharmacy

### Primary care:

- Perform tests requested by the hospital team relating to treatment with Tolvaptan, including:
- Monthly Biochemical Profile (U&E, LFT)
- Monthly Full Blood Count
- Inform the hospital team, immediately if unable to perform monitoring requested
- Inform the hospital team in changes to the patients' condition and / or medication that may affect treatment.

### Contact details:

Responsible consultant via his/her secretary

During Office hours:

On call Renal Consultant via switchboard 01482 328541/875875

Out of hours:

Renal Pharmacist; Call 01482-875875 and ask for bleep 140 or the pharmacy department on 01482-675622 and ask for Renal Pharmacist