CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Jynarque (tolvaptan)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 60 tablets per 30 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Jynarque (tolvaptan) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE (ADPKD)

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with a nephrologist; AND
3. Member has progressive autosomal dominant polycystic kidney disease (ADPKD) confirmed by genetic testing or imaging (e.g. ultrasound, CT scan, or MRI scan) and documented in chart notes; AND
4. Member is at high risk for rapidly declining kidney function, defined as having at least **one** of the following:
   a) Mayo classification 1C, 1D or 1E;
   b) A total kidney volume (TKV) of ≥ 750 mL by MRI or a TKV increase >5% on repeated imaging;
   c) A confirmed eGFR decline of ≥5 ml/min per 1.73 m^2 in 1 year;
   d) A confirmed eGFR decline of ≥2.5 ml/min per 1.73 m^2 per year over a period of 5 years;
   e) Average kidney length > 16.5cm in a patient < 45 years old;
   f) PROPKD score > 6 in patients with genetic data available; AND
5. Member does NOT have any of the following:
   a) eGFR < 25 mL/min/1.73m^2;
   b) Concurrent use with a diuretic agent (e.g. thiazide, furosemide);
   c) Prior kidney transplant and/or dialysis.
6. **Dosage allowed:** Initial dose: 45 mg in the morning and 15mg 8 hours later. Titrate to 60mg + 30mg then to 90mg + 30mg per day based on tolerability at least weekly intervals between titrations.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided that show slower decline in kidney function and improvement of symptoms (such as slowing of cyst growth and/or rate of eGFR decline, less kidney pain, etc.).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Jynarque (tolvaptan) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
06/09/2020	New policy for Jynarque created.

References:

1. Jynarque [Package Insert]. Rockville, MD: Otsuka Pharmaceutical Co., Ltd.; January 2020.
2. ClinicalTrials.gov. Efficacy and safety of tolvaptan in subjects with chronic kidney disease between late stage 2 to early stage 4 due to autosomal dominant polycystic kidney disease. NCT02160145.
3. ClinicalTrials.gov. Tolvaptan phase 3 efficacy and safety study in autosomal dominant polycystic kidney disease (ADPKD) (TEMPO3:4). NCT00428948.
4. Srivastava A, Patel N. Autosomal dominant polycystic kidney disease. *Am Fam Physician*. 2014;90(5):303-307.
5. Chebib FT, Perrone RD, Chapman AB, et al. A practical guide for treatment of rapidly progressive ADPKD with tolvaptan. JASN Oct 2018, 29 (10) 2458-2470.

Effective date: 09/01/2020
Revised date: 06/09/2020