Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: **Jynarque™ (tolvaptan)**
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: **August 2018**

Last P & T Committee Approval Date: *August 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Jynarque™ (tolvaptan).

Jynarque™ (tolvaptan) is indicated to slow kidney function decline in adults at risk of rapidly progressing ADPKD.

DEFINITIONS

ADPKD: autosomal dominant polycystic kidney disease. ADPKD is a life-threatening genetic disease where fluid-filled cysts develop in the kidneys, and is the fourth leading cause of kidney failure.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002

Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Jynarque™ (tolvaptan), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Member must be 18 years of age or older
- Members must have a diagnosis of ADPKD
- Must not have any of the following contraindications to use:
  - CrCl <10 mL/min
  - Anuria
  - Inability to sense and respond appropriately to thirst
  - Concomitant therapy with a strong CYP3A inhibitor
  - Diagnosis of hypovolemic hyponatremia
  - Underlying liver disease, including cirrhosis

Reauthorization Criteria:

All prior authorization renewals are reviewed on a yearly basis to determine if the member is eligible for continuation of therapy. Reauthorization may be approved based upon chart documentation from the prescriber that the member's ALT, AST, and bilirubin levels remain normal, and that the member's kidney disease progression has declined.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 6 months
Reauthorization	Up to 12 months
Quantity Level Limit	
45mg and 15mg Kit	1 box (56 tablets) per 28 day period
60mg and 30mg Kit	1 box (56 tablets) per 28 day period
90mg and 30mg Kit	1 box (56 tablets) per 28 day period

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Jynarque™ [prescribing information]. Tokyo, Japan: Otsuka; April 2018.

2. Torres, Vicente E., et al. “Tolvaptan in Patients with Autosomal Dominant Polycystic Kidney Disease.” New England Journal of Medicine, vol. 367, no. 25, 2012, pp. 2407–2418., doi:10.1056/nejmoa1205511.
3. Torres, Vicente E., et al. “Tolvaptan in Later-Stage Autosomal Dominant Polycystic Kidney Disease.” New England Journal of Medicine, vol. 377, no. 20, 2017, pp. 1930–1942., doi:10.1056/nejmoa1710030.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	*08/18*