PriorityHealth

jynaPharmacy Prior Authorization Form

For Prior Authorization, please fax to: 877 974-4411 toll free, or 616 942-8206

This form applies to: ☒ **Commercial (Traditional)** ☒ **Commercial (Individual/Optimized)** ☐ **Medicaid**

This request is: ☐ **Urgent** (life threatening) ☐ **Non-Urgent** (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

Jynarque® (tolvaptan)

Member

Last Name: _____ First Name: _____

ID #: _____ DOB: _____ Gender: _____

Primary Care Physician: _____

Requesting Provider: _____ Prov. Phone: _____ Prov. Fax: _____

Provider Address: _____

Provider NPI: _____ Contact Name: _____

Provider Signature: _____ Date: _____

Product and Billing Information

☐ New Request ☐ Continuation Request

Drug product:
- ☐ Jynarque 45mg/15mg tablets
- ☐ Jynarque 60mg/30mg tablets
- ☐ Jynarque 90mg/30mg tablets

Start date (or date of next dose): _____

Date of last dose (if applicable): _____

Dosage & dosing frequency: _____

Drug cost information

The wholesale acquisition cost for each 28-day supply of Jynarque is $15,024. The annual cost of maintenance therapy with this drug is more than $195,000.

Precertification Requirements

Before this drug is covered, the patient must meet all of the following requirements:

1. Must have a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) confirmed via ultrasound.
2. Prescribed or recommended by a nephrologist.
3. Age between 18 and 65 years.
4. Estimated glomerular filtration rate (eGFR) 25-90 mL/min/1.73m^2.
5. Disease must be rapidly progressing or likely to rapidly progress as evidenced by:
    a. Total kidney volume (TKV) ≥750mL; or
    b. Rapid loss of eGFR ≥2.5mL/min/1.73m^2 per year.
6. Hypertension, if present, must be adequately controlled (to 130/80mmHg or less)
7. The patient and prescriber must be enrolled in Jynarque REMS Program and liver function tests will be monitored at baseline and ongoing as required (at 2 weeks, 4 weeks, and monthly for the first 18 months of treatment then every 3 months thereafter).

For continuation, patient must have met the following requirements every 12 months:

1. Patient must show signs of declining rate of progression in CKD via increase in total kidney volume of <5% per year or decline in eGFR by <2.5mL/min/1.73m^2.
2. Must maintain an 85% adherence rate to therapy, which will be verified based on Priority Health's medication fill history for the patient.

All fields must be complete and legible for review. Your office will receive a response via fax. No changes made since 09/2018

Last reviewed 07/2020

Note: Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

New request
Priority Health Precertification Documentation

A. What condition is this drug being requested for?
- ☐ autosomal dominant polycystic kidney disease (ADPKD)
- ☐ *Other, rationale*: _____

B. What is the patient's most recent estimated GFR?
- ☐ Date_____ ☐ Result_____

C. What is the patient's total kidney volume?
- ☐ Date_____ ☐ Result_____
- ☐ *Other – if TKV not available, does the patient have rapid loss of eGFR ≥2.5mL/min/1.73m^2 per year (please provide eGFR values)?:* _____

D. Does the patient have hypertension?
- ☐ Yes, but it is adequately controlled (less than or equal to 130/80mmHg)
- ☐ Yes, uncontrolled (greater than 130/80mmHg)
  Rationale for use of Jynarque: _____
- ☐ No

E. Patient and prescriber are enrolled in Jynarque REMS Program and liver function tests will be monitored as required?
- ☐ Yes
- ☐ *No, rationale*:_____

Continuation—Priority Health Precertification Documentation

A. Provide rationale for patient's CKD progression response:
- ☐ The patient had a declining rate of progression in CKD as evidenced by:
  - ☐ The patient's most recent TKV results are: _____ on _____ (date)
  - ☐ The patient's most recent eGFR results are: _____ on _____ (date)
- ☐ The patient had other decrease in worsening kidney function, *Please explain*:

_____

_____

_____

_____

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Last reviewed 07/2020