Jynarque (tolvaptan) and Samsca (tolvaptan)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Jynarque is indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).
2. Samsca is indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium <125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure and Syndrome of Inappropriate Antidiuretic Hormone (SIADH)

Important Limitations

Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms should not be treated with Samsca. It has not been established that raising serum sodium with Samsca provides a symptomatic benefit to patients.

POLICY

Required Documentation for Jynarque

The following information is necessary to initiate the prior authorization review:

A. Imaging used for diagnosis and confirmation of rapidly progressing disease (ultrasonography, magnetic resonance imaging [MRI], computed tomography [CT])
B. Genetic testing results if applicable

Criteria for Initial Approval

I. Jynarque is considered **medically necessary** for the treatment of autosomal dominant polycystic kidney disease (ADPKD) when all of the following criteria are met:
   - The member is 18 years of age or older and with a diagnosis of ADPKD as confirmed by any of the following:
     i. In members aged 18 to less than 40 years with a first degree relative with ADPKD: greater than or equal to 3 cysts (unilateral or bilateral) using any radiologic method
     ii. In members aged 40 to less than 60 years with a first degree relative with ADPKD: greater than or equal to 2 cysts per kidney using any radiologic method
     iii. In members aged 60 or older with a first degree relative with ADPKD: greater than or equal to 4 cysts per kidney using any radiologic method
     iv. In members with no family history (no first degree relative with disease): positive genetic test for ADPKD (mutation in PKD1 or PKD2 gene)
   - The member has or is at risk for rapidly progressing disease as confirmed by height-adjusted total kidney volume compatible with Mayo class 1C, 1D, or 1E disease
   - The member's estimated glomerular filtration rate (eGFR) is greater than or equal to 25 mL/min/1.73m^2.

   Approval is for **12 months**

II. Samsca is considered **medically necessary** for the treatment of hypervolemic/euvolemic hyponatremia when all of the following criteria are met:
   - Therapy was initiated (or re-initiated) in the hospital, for hypervolemic or euvolemic hyponatremia
   - Serum sodium was less than 125 mEq/L or serum sodium was less than 135 mEq/L with symptoms (e.g., nausea, vomiting, headache, lethargy, confusion) at the time of therapy initiation
   - The member will not receive Samsca continually for greater than 30 days.

   Approval is for **30 days**

Continuation of Therapy

I. Jynarque is considered **medically necessary** for the continued treatment of autosomal dominant polycystic kidney disease (ADPKD) when all of the following criteria are met:
   - The member has demonstrated a beneficial response to Jynarque therapy (e.g., slowed kidney function decline, decreased kidney pain)
   - The member's estimated glomerular filtration rate (eGFR) is greater than or equal to 25 mL/min/1.73m^2

   Approval is for **12 months**

II. All members (including new members) requesting authorization for continuation of therapy with Samsca must meet ALL initial authorization criteria.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Jynarque - 56 tablets (4 blister cards) per 28 days

Samsca 15mg tablet – 30 tablets per 30 days
Samsca 30mg tablet – 60 tablets per 30 days

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

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POLICY HISTORY

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