

## **RX.PA.074.MPC Korsuva (difelikefalin) Injection**

The purpose of this policy is to define the prior authorization process for Korsuva™ (difelikefalin)

Korsuva™ (difelikefalin) is an opioid receptor agonist indicated for the treatment of moderate to severe pruritus associated with chronic kidney disease (CKD) in adults undergoing hemodialysis (HD).

### **PROCEDURE**

#### **A. Initial Authorization Criteria**

##### **1. Chronic Kidney Disease Associated Pruritus.**

Approve for 3 months if the patient meets all of the following criteria (i, ii, iii, iv, v, vi, vii, viii, ix, x, xi, and xii)

- i. Member must be at least 18 years of age or older
- ii. Must have a diagnosis of chronic kidney disease
- iii. Must have documented diagnosis of moderate to severe pruritus associated with chronic kidney disease
- iv. Documentation score of at least a 4 on the worst itching intensity numerical rating scale (WI-NRS)
  - Mild: 0 to 3
  - Moderate: 4 to 6
  - Severe: 7 to 9
- v. Must have documentation that pruritus is impairing quality of life (e.g. sleep disruptions, fatigue, depression, etc.)
- vi. Must have documentation that member is undergoing hemodialysis at least 3 times per week
- vii. Member must not be undergoing peritoneal dialysis
- viii. Pruritus is not localized to just the palms of the hands
- ix. Member has been evaluated for other causes of pruritus (e.g. eczema, dermatitis, allergies, liver disease, post herpetic neuralgia, etc.)
- x. Documentation of trial and failure, contraindication to or intolerance to at least 1 topical anti-pruritic medication for at least 30 days
- xi. Documentation of a trial and failure, contraindication to, or intolerance to at least 1 systemic antihistamine and corticosteroid each for at least 30 days
- xii. Must be prescribed by or in consultation with a nephrologist

**Reauthorization**

All prior authorization renewals are reviewed to determine the Medical Necessity for continuation of therapy. Authorization may be extended based upon:

**MPC Renewal**

- i. Must have documentation that member is undergoing hemodialysis at least 3 times per week
- ii. Member must not be undergoing peritoneal dialysis
- iii. Documentation of a clinical response, as determined by a reduction of itching compared to baseline
- iv. Compared to baseline, must have documentation that the member has an improvement of at least 4 points on the WI-NRS scale
- v. Must be prescribed by or in consultation with a nephrologist

**Renewal from Previous Insurer:**

- i. Members who have received prior approval (from insurer other than MPC) and have been taking Korsuva or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria); AND
- ii. Provider has a documented clinical response of the member's condition which has improved based upon the prescriber's assessment.

**B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.**

**C. Korsuva will be considered investigational or experimental for any other use and will not be covered.**

**Limitations:**

<b>Length of Authorization (if above criteria met)</b>	
Initial Authorization	3 months
Reauthorization	1 year

**Codes:**

<b>Code</b>	<b>Description</b>
J0879	Injection, difelikefalin, 0.1 microgram, (for esrd on dialysis)

**REFERENCES**

- 1. Korsuva™ (difelikefalin) injection [prescribing information]. Stamford, CT: Cara Therapeutics, Inc.; August 2021.



## REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Annual policy review. Update to reauthorization criteria for non-MPC renewals</i>	<i>02/2024</i>
<i>New Policy</i>	<i>03/2023</i>