

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:

Length of Authorization (if above criteria met)	
Initial Authorization	3 months
Reauthorization	1 year

Codes:

Code	Description
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 review</i>	<i>02/2026</i>
<i>Annual Review</i>	<i>02/2025</i>
<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>