**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 pruritis 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. Pruritis is not localized to just the palms of the hands
ix. Member has been evaluated for other causes of pruritis (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

**Non-MPC Renewal:**

i. Members who have previously been taking Korsuva (difelikefalin) and are requesting a non-MPC renewal should be considered under criterion A (initial Authorization Criteria).
ii. Member has not been receiving medication samples for Korsuva (difelikefalin)
iii. 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 |
|---|---|
| *New Policy* | *03/2023* |