HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Korsuva (difelikefalin)
BILLING CODE	J0879
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient
STATUS	Prior Authorization Required

Korsuva is an injectable kappa opioid receptor (KOR) agonist which targets the peripheral nervous system. It is the first FDA-approved treatment for moderate-to-severe pruritus (itching) associated with chronic kidney disease (CKD-aP) in adults on hemodialysis. Uremic pruritis is thought to affect between 40 and 50% of CKD patients on dialysis. Moderate to severe uremic pruritus is associated with decreased quality of life, higher probability of depression, and poor sleep quality. The approval of Korsuva was largely based on data from 2 pivotal Phase 3 clinical trials, KALM-1and KALM-2, which compared Korsuva 0.5 mg/kg to placebo; both were administered 3 times weekly after each dialysis session. Both trials demonstrated patients on Korsuva had at least a 4-point improvement from baseline using the 24-hour Worst Itching Intensity Numeric Rating Scale (WI-NRS) score versus patients receiving placebo at Week 12.

Korsuva (difelikefalin) will be considered for coverage when the following criteria are met:

Uremic Pruritus associated with Chronic Kidney Disease

For **initial** authorization:
1. Member is at least 18 years of age or older; AND
2. Diagnosis of end-stage renal disease (ESRD) receiving hemodialysis 3 times per week for at least 3 months
3. Documentation the moderate-to-severe pruritis is impairing quality of life (e.g. sleep disruptions, fatigue, and depression).
4. **Dosage allowed/Quantity limit:** 0.5 mcg/kg intravenously three times per week

If all the above requirements are met, the medication will be approved for 12 weeks.

For **reauthorization**:
Korsuva will be reauthorized when chart notes show at least one of the following:
1. Documentation of improvement in itch-related quality of life (e.g. sleep disruptions, fatigue, and depression); OR
2. Documentation of significant reduction in itch intensity.

If all the above requirements are met, the medication will be approved for an additional 12 months.

HAP CareSource considers Korsuva (difelikefalin) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/07/2021	Korsuva policy creation
05/05/2022	Updated J code. Removed pregabalin and gabapentin trial.

References:

1. Korsuva [package insert]. Stamford, CT; Cara Therapeutics; August 2021. Accessed October 2021.
2. Fishbane S, Jamal A, Munera C, Wen W, Menzaghi F, et al. A Phase 3 Trial of Difelikefalin in Hemodialysis Patients with Pruritis; 2020 Jan 16; *New England Journal of Medicine*. 382:222-232.
3. Hercz D, Jiang SH, Webster AC. Interventions for itch in people with advanced chronic kidney disease. Cochrane Database Systemic Review. 2020 Dec 7;12:CD011393.
4. Simonsen B, Komenda P, Lerner B, Shaw J, Tangri N. Rigatto C, et. Al. Treatment of Uremic Pruritis: A Systemic Review. *American Journal of Kidney Diseases*.
5. Ishida J., et al. Gabapentin and Pregabalin Use and Association with Adverse Outcomes among Hemodialysis Patients, *J Am Soc Nephrol*; 2018: vol 29: 1970–1978.

Effective date: 01/01/2025
Creation date: 05/05/2022