blue california
Promise Health Plan

difelikefalin (Korsuva)

Medical Benefit Drug Policy

Place of Service
Home Infusion
Infusion Center Administration
Office Administration
Self-Administration

Drug Details

USP Category: DERMATOLOGICAL AGENTS
Mechanism of Action: Kappa opioid receptor agonist
HCPCS:
J0879:Injection, difelikefalin, 0.1 microgram, (for esrd on dialysis)
How Supplied:
65 mcg/1.3 mL (50 mcg/mL) single-dose vial

Condition(s) listed in policy *(see coverage criteria for details)*

- Moderate-to-Severe Pruritus Associated with Chronic Kidney Disease (CKD-aP) Due to Hemodialysis (HD)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Moderate-to-Severe Pruritus Associated with Chronic Kidney Disease (CKD-aP) Due to Hemodialysis (HD)
Meets medical necessity if all the following are met:

1. Being administered with hemodialysis
2. Inadequate response, or intolerable side effect to one prior therapy [e.g., dialysis modification, phototherapy, topical emollients, topical analgesics (capsaicin, pramoxine), oral antihistamines (hydroxyzine, diphenhydramine), gabapentin, pregabalin]

Covered Doses:
Up to 0.5 mcg/kg given intravenously at the end of each HD treatment

Coverage Period:
Yearly

ICD-10:
L29.8

References

1. Korsuva (difelikefalin) Prescribing Information. Cara Therapeutics Inc., Stamford, CT: 04/2024.
2. AHFS. Available by subscription at http://www.lexi.com
3. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch

Review History

Date of Last Annual Review: 2Q2025
Changes from previous policy version:

- No clinical change to policy following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee