Difelikefalin (Korsuva™)

<u>Place of Service</u> Office Administration Infusion Center Administration Home Infusion Self-Administration

HCPCS: J0879 per 0.1 mcg

Condition listed in policy (see criteria for details)

• Moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP)

AHFS therapeutic class: Central nervous system agent

Mechanism of action: Kappa opioid receptor agonist

(1) Special Instructions and Pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s) All requests for Korsuva[™] (difelikefalin) must be <u>sent for clinical review</u> and receive authorization prior to drug administration or claim payment.

<u>Moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) due to hemodialysis</u> (HD):

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

Covered Doses

0.5 mcg/kg IV at the end of each HD treatment

Coverage Period Yearly

ICD-10: L29.8

(3) The following condition(s) <u>DO NOT</u> require Prior Authorization/Preservice All requests for Korsuva[™] (difelikefalin) must be <u>sent for clinical review</u> and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

<u>Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code</u> § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

PHP Medi-Cal

Difelikefalin (Korsuva™)

(5) Additional Information

How Supplied:

• 65 mcg/1.3 mL (50 mcg/mL) single-dose vial

(6) References

- Korsuva (difelikefalin) [Prescribing Information]. Stamford, CT: Cara Therapeutics Inc.; 08/2021.
- AHFS[®]. Available by subscription at <u>http://www.lexi.com</u>
- DrugDex[®]. Available by subscription at <u>http://www.micromedexsolutions.com/home/dispatch</u>

(7) Policy Update

Date of last review: 2Q2023 Date of next review: 2Q2024 Changes from previous policy version:

• No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity Reviewed by P&T Committee