

# Medical Drug Clinical Criteria

<b>Subject:</b>	Korsuva (difelikefalin acetate)		
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## Overview

This document addresses the use of Korsuva (difelikefalin acetate), a kappa opioid receptor agonist, indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) for adults undergoing hemodialysis.

CKD-aP, also known as uremic pruritus, is a common condition affecting HD patients. Clinical presentation varies, but often includes intense, generalized, systemic itching that can significantly impair patients' physical and mental health. The pathophysiology is not completely understood. Common theories include toxin deposition, metabolic disturbances, peripheral neuropathy, immune system dysregulation, and opioid imbalance, with kappa opioid receptors potentially playing a role.

There are no widely used or agreed upon treatment guidelines for the management of CKD-aP. Standard care may include optimal dialysis, treatment of mineral and bone disease (e.g., hyperparathyroidism, hyperphosphatemia), emollients, topical analgesics, antihistamines, corticosteroids, and gabapentin or pregabalin.

Korsuva (difelikefalin) is the first FDA-approved drug for CKD-aP, and is administered by intravenous (IV) injection at the end of each HD treatment.

### Definitions

Kt/V is a measure of dialysis adequacy. Per the 2015 Kidney Disease Outcomes Quality Initiative (KDOQI), Kt/V (fractional urea clearance) is considered "the most precise and tested measure of the dialyzer effect on patient survival," and the best measure of hemodialysis adequacy. KDOQI recommends a target single pool Kt/V of 1.4 per hemodialysis session for individuals receiving HD three times weekly, with a minimum delivered Kt/V of 1.2.

- K = clearance – the amount of urea the dialyzer can remove (liters/minute).
- t = time – the duration of treatment (minutes)
- V = volume – the amount of body fluid (liters)

## Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

### Korsuva (difelikefalin acetate)

Initial requests for Korsuva (difelikefalin acetate) may be approved if the following criteria are met:

- I. Individual has a diagnosis of chronic kidney disease; **AND**
- II. Individual is receiving hemodialysis at least 3 times per week; **AND**
- III. Individual is using for moderate to severe pruritus associated with hemodialysis (CKD-aP); **AND**
- IV. Individual has a trial and inadequate response, or intolerance to one (1) other pruritus therapy, such as antihistamines, glucocorticoids, and gabapentin (or pregabalin) (Fishbane 2020); **AND**
- V. Individual has received optimal dialysis treatment in the last 3 months defined as **one** of the following on different dialysis days (Fishbane 2020):
  - A. Two (2) single-pool Kt/V measurements greater than or equal to 1.2
  - B. Two (2) urea reduction ratio measurements greater than or equal to 65%
  - C. One (1) pool Kt/V measurement greater than or equal to 1.2 **and** one (1) urea reduction ratio measurement greater than or equal to 65%.

Continuation requests for Korsuva (difelikefalin acetate) may be approved if the following criteria are met:

- I. Individual continues to receive hemodialysis at least 3 times per week; **AND**
- II. Individual has received optimal dialysis treatment in the last 3 months defined as **one** of the following on different dialysis days (Fishbane 2020):
  - A. Two (2) single-pool Kt/V measurements greater than or equal to 1.2
  - B. Two (2) urea reduction ratio measurements greater than or equal to 65%
  - C. One (1) pool Kt/V measurement greater than or equal to 1.2 **and** one (1) urea reduction ratio measurement greater than or equal to 65%; **AND**
- III. There is confirmation of clinically significant improvement or stabilization in pruritus (CKD-aP) from baseline.

Requests for Korsuva (difelikefalin acetate) may not be approved for the following:

- I. Individual is using for pruritus associated with peritoneal dialysis.

#### Approval Duration:

Initial requests: 3 months

Continuation requests: 12 months

### Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

#### HCPCS

J0879 Injection, difelikefalin, 0.1 mcg

#### ICD-10 Diagnosis

N18.9 Chronic kidney disease, unspecified  
N18.5 Chronic kidney disease, stage 5  
N18.1 Chronic kidney disease, stage 1  
N18.3 Chronic kidney disease, stage 3 (moderate)  
N18.2 Chronic kidney disease, stage 2 (mild)  
N18.4 Chronic kidney disease, stage 4 (severe)  
L29.9 Pruritus, unspecified  
L29.8 Other pruritus

### Document History

Reviewed: 11/18/2022

Document History:

- 11/18/2022 – Annual Review: No changes. Coding Reviewed: No changes.
- 08/19/2022 – Annual Review: Add new clinical criteria document for Korsuva. Coding Reviewed: Added HCPCS J0879. Added ICD-10-CM N18.9, N18.5, N18.1, N18.3, N18.2, N18.4, L29.9, L29.8.

### References

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Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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