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5.60.053

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	September 24, 2021
Subject:	Korsuva	**Page:**	1 of 4

Last Review Date: March 7, 2025

Korsuva

Description

Korsuva (difelikefalin)

Background
Korsuva (difelikefalin) is a kappa opioid receptor (KOR) agonist. There are four known opioid receptors: mu-(MOR), kappa-(KOR), delta-(DOR), and opioid receptor-like 1 (ORL-1). A well-known side-effect of agents that stimulate this receptor family is pruritus, or the urge to itch. Interestingly, specific stimulation of the KOR attenuates pruritus symptoms. The exact relationship between KOR stimulation and itch-relief is unknown (1).

Regulatory Status
FDA-approved indication: Korsuva is a kappa opioid receptor agonist indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis (1).

Limitations of Use:
Korsuva has not been studied in patients on peritoneal dialysis and is not recommended for use in this population (1).

Korsuva has warnings regarding the following: dizziness, somnolence, mental status changes, gait disturbances, and risk of driving and operating machinery (1).

The safety and effectiveness of Korsuva in pediatric patients have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Korsuva may be considered **medically necessary** if the conditions indicated below are met.

Korsuva may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP)
    a. Currently undergoing hemodialysis (HD)

AND ALL of the following:

1. Prescriber will not exceed FDA recommended dose of 0.5 mcg/kg per HD treatment
2. Patient is **NOT** receiving peritoneal dialysis

Prior–Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Pruritus associated with chronic kidney disease (CKD-aP)

a. Currently undergoing hemodialysis (HD)

AND ALL of the following:

1. Prescriber will not exceed FDA recommended dose of 0.5 mcg/kg per HD treatment
2. Patient is **NOT** receiving peritoneal dialysis
3. Improvement in pruritus symptoms

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Duration 12 months

Prior–Approval *Renewal* Limits

Same as above

Rationale

Summary

Korsuva is a KOR agonist indicated for the treatment of moderate to severe dialysis in adult patients receiving hemodialysis. Korsuva is not indicated for patients receiving peritoneal dialysis. Although stimulation of the opioid receptor family traditionally associated with pruritus, or the urge to itch, specific agonism of the kappa opioid receptor attenuates itching. The precise mechanism of action through which Korsuva relieves pruritus is currently unknown (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Korsuva while maintaining optimal therapeutic outcomes.

References

1. Korsuva [package insert]. Stamford, CT: Cara Therapeutics, Inc.; April 2024.

Policy History

Date	Action
September 2021	Addition to PA
December 2021	Annual review
June 2022	Annual review
June 2023	Annual review. Changed policy number to 5.60.053
March 2024	Annual review
March 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.