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).

Limitation 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 for patients 18 years and older for pruritus associated with chronic kidney disease and if the conditions indicated below are met.

Korsuva may be considered investigational in patients less than years 18 of age and 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

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 3, 2021 and is effective on January 1, 2022.