Clinical Policy Title:	difelikefalin acetate
Policy Number:	RxA.708
Drug(s) Applied:	Korsuva™
Original Policy Date:	12/07/2021
Last Review Date:	12/07/2021
Line of Business Policy Applies to:	All lines of business

Background

Difelikefalin acetate (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 (HD).

Limitation of Use:
Korsuva™ has not been studied in patients on peritoneal dialysis and is not recommended for use in this population.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
difelikefalin acetate (Korsuva™)	Moderate-to-severe pruritus associated with CKD-aP in adults undergoing hemodialysis (HD).	0.5 mcg/kg intravenous bolus injection into the venous line of the dialysis circuit at the end of each HD treatment.	0.5 mcg/kg/dose intravenous

Dosage Forms

- Injection: 65 mcg /1.3 mL (50 mcg/mL)

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Pruritus associated with CKD on HD (must meet all)**:**

1. Diagnosis of moderate-to-severe pruritus associated with CKD-aP in adults undergoing hemodialysis (HD);
2. Age ≥ 18 years;
3. Member is receiving hemodialysis 3 times per week for at least 3 months;
4. Previous trial of a conventional therapy, such as a topical agent (e.g. glycerol/paraffin emulsion, capsaicin; pramoxine), oral antihistamine, gabapentin, or pregabalin;

5. Dose does not exceed 0.5 mcg/kg/dose.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Pruritus associated with CKD on HD (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. Dose does not exceed 0.5 mcg/kg/dose.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
CKD-aP: Chronic kidney disease-associated pruritus
HD: hemodialysis

APPENDIX B: Therapeutic Alternatives
None

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported

- Boxed Warning(s):
  - None reported

APPENDIX D: General Information

- Dizziness, Somnolence, Mental Status Changes, and Gait Disturbances: Dizziness, somnolence, mental status changes, and gait disturbances, including falls, have occurred. Centrally-acting depressant medications, sedating antihistamines, and opioid analgesics should be used with caution during treatment with Korsuva™.
- Risk of Driving and Operating Machinery: May impair mental or physical abilities. Advise patients not to drive or operate dangerous machinery until the effect of Korsuva™ on a patient's ability to drive or operate machinery is known.
- The WI-NRS used to evaluate the effectiveness of Korsuva is a validated 11-point scale to assess patient-reported severity of itching in the past 24 hours. A score of 0 implies no itch and a score of 10 is the worst imaginable itch. A decrease of at least 3 points represents a clinically meaningful improvement in itch severity.
  - Score 0 = no pruritus
  - Score 1–3 = mild pruritus
  - Score 4–6 = moderate pruritus
  - Score 7–8 = severe pruritus
  - Score ≥9 = severe pruritus

References

1. Korsuva™ Prescribing Information. Stamford, CT: Cara Therapeutics Inc; August 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214916s000lbl.pdf. Accessed October 5, 2021.
2. IPD Analytics Payer and Provider Update: Cara Therapeutics/Vifor Pharma's Korsuva Approved for Pruritis in Chronic Kidney Disease. IPD Analytics. Available at: https://secure.ipdanalytics.com/User/Handler/ViewReport.ashx?type=RP&file=s3%3a%2f%2fipdanalytics%2fReports%2fIPD+Analytics+Payer+and+Provider+Update_Korsuva+Approved+for+Pruritis+in+CKD_08+24+2021+(2).pdf. Accessed October 5, 2021.
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6. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: https://www.clinicalkey.com/pharmacology/monograph/5355?sec=monindi&n=KORSUVA. Accessed October 5, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	12/07/2021	12/07/2021