

Medical Policy:

Korsuva (difelikefalin) intravenous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.354	February 7, 2024	May 12, 2022

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definition

Korsuva is indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis (HD).

Length of Authorization

Coverage will be provided for 12 months

Dosing Limits [Medical Benefit]

- Approve up to 0.5 mcg/kg intravenously three times per week (570 billable units (57 mcg) three times weekly)

Guideline

INITIAL APPROVAL CRITERIA

1. **Uremic Pruritis associated with Chronic Kidney Disease (CKD)** - Approve if the patient meets the following criteria (A, B, C, D **AND** E)

- A. Patient is \geq 18 years of age; **AND**
- B. Diagnosis of end-stage renal disease (ESRD) receiving hemodialysis 3 times per week for at least 3 months; **AND**
- C. Patient has Moderate-to severe pruritus associated with CKD; **AND**
- D. Previous trial of a conventional therapy, such as a topical agent (e.g. glycerol/paraffin emulsion), oral antihistamine, gabapentin, or pregabalin; **AND**
- E. Prescribed by or in consultation with a Nephrologist.

RENEWAL CRITERIA:

- 1. Member is responding positively to therapy, as determined by the prescriber; **AND**
- 2. Member has not experienced unacceptable toxicity from the drug

Dosing/Administration:

The recommended dosage of Korsuva is 0.5 mcg/kg administered by intravenous bolus injection into the venous line of the dialysis circuit at the end of each HD treatment. Korsuva is supplied in single-use vials; any unused drug remaining after injection must be discarded. Vials must be stored at 20°C-25°C (68°F to 77°F) with excursions permitted to 15°C-30°C (59°F to 86°F). Korsuva must be administered within 60 minutes of syringe preparation; prepared syringes can be stored at ambient temperature 20°C-25°C (68°F to 77°F) until dosing.

Applicable Procedure Codes

Code	Description
J0879	Injection, difelikefalin, 0.1 microgram, (for esrd on dialysis)

Applicable NDCs

Code	Description
59353-0065-01	Korsuva 50mcg/1mL, 1.3mL
59353-0065-12	Korsuva 50mcg/1mL, 1.3mL(12s)

ICD-10 Diagnoses

Code	Description
L29.8	Other pruritis
N18.5	Chronic kidney disease, stage 5
N18.6	End stage renal disease

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/7/2024	Annual Review: No criteria changes

EmblemHealth & ConnectiCare	6/13/2023	Annual Review: Removed code: L29.9, added codes N18.5 and N18.6
EmblemHealth & ConnectiCare	5/12/2022	NEW POLICY

References

1. Korsuva™ [package insert]. Stamford, CT: Cara Therapeutics Inc; December 2021. Accessed April 12, 2022.
2. Korsuva. IBM Micromedex [database online]. Cara Therapeutics Inc (per FDA), Stamford, CT, 2021. Available at: <https://www.micromedexsolutions.com>. Updated March 8th, 2022. Accessed April 12, 2022.
3. Korsuva. Lexicomp [database online]. Stamford, CT: Cara Therapeutics Inc. Available at <https://online.lexi.com>. Accessed April 12, 2022
4. Korsuva. IPD Analytics. Available at: <http://secure.ipdanalytics.com>. Accessed on April 12, 2022