

Korsuva™ (difelikefalin)



Pharmacy Coverage Policy

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Line of Business: Medicare, Commercial, Medicaid - Humana, Medicaid - Ohio

Policy Type: Prior Authorization

Page: 1 of 3

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Disclaimer Description Coverage Determination	Background Medical Terms References
Disclaimer	<p>State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at http://www.cms.hhs.gov/. The member's health plan benefits in effect on the date services are rendered must be used. 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. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise without permission from Humana.</p>
Description	<p>Korsuva (difelikefalin) is a kappa opioid receptor (KOR) agonist. The relevance of KOR activation to therapeutic effectiveness is not known.</p> <p>Korsuva (difelikefalin) is indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis (HD)</p> <p>CKD-aP is also known as uremic pruritus, and is local or general itching directly related to kidney disease without another comorbid condition to explain the itching</p> <p>Difelikefalin is available as a 65mcg/1.3ml solution for IV infusion</p>
Coverage Determination	<p>Please note the following regarding medically accepted indications:</p> <p>All reasonable efforts have been made to ensure consideration of medically accepted indications in this policy. Medically accepted indications are defined by CMS as those uses of a covered Part D drug that are approved under the federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of</p>

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the Act. These compendia guide review of off-label and off-evidence prescribing and are subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per CMS:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Truven Health Analytics Micromedex DrugDEX
- Elsevier/Gold Standard Clinical Pharmacology
- Wolters Kluwer Lexi-Drugs

Korsuva (difelikefalin) will require prior authorization. This agent may be considered medically necessary when the following criteria are met:

Chronic Kidney Disease associated Pruritus (CKD-aP)

Initial Review

Member must meet ALL of the following criteria:

- Diagnosis of Chronic Kidney Disease with associated pruritus (CKD-aP) also known as Uremic Pruritus
- Has undergone hemodialysis at least 3 times per week consistently for the previous 3 months

Continuation of Therapy

Member must meet ALL of the following criteria:

- Continues to undergo hemodialysis at least 3 times per week
- Reported efficacy that pruritus has decreased since initiation of Korsuva (difelikefalin) therapy

Korsuva (difelikefalin) will be approved for a 6 month duration or as determined through a clinical review for therapy initiation, and in plan year durations or as determined through clinical review for continuation of therapy.

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Coverage Limitations Korsuva (difelikefalin) therapy is not considered medically necessary for members with the following concomitant conditions:

- Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

Background

This is a prior authorization policy about Korsuva (difelikefalin)

CKD-aP is also known as uremic pruritus, and is local or general itching directly related to kidney disease without another comorbid condition to explain the itching. Data from the Dialysis Outcomes and Practice Patterns Study showed that CKD-aP affects approximately 70% of patients undergoing hemodialysis, with about 40% reporting moderate to severe pruritus. There are about 468K people in the United States receiving hemodialysis. The most common treatments used for CKD-aP are conventional antipruritic agents that have limited off-label clinical evidence. These agents include topical steroids and emollients, and systemic antihistamines, antidepressants, anticonvulsants, and opioid receptor modulators. Furthermore, it is estimated that a high proportion of patients with CKD-aP are currently not receiving treatment.

Provider Claims Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms pruritis; ckd; uremic pruritus; itch; Korsuva; IV; difelikefalin; hemodialysis

References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; URL: <http://www.clinicalpharmacology.com>. Updated Periodically
2. Lexi-Comp ASHP [database online]. Hudson, OH Lexi-comp, Inc.: URL <http://online.lexi.com>. Updated Periodically
3. Micromedex Healthcare Series: DRUGDEX. Thomson Micromedex, Greenwood Village, CO. Updated Periodically
4. Korsuva [package insert]. Stamford, CT: Cara Therapeutics. Revised August 2021