Korsuva™ (difelikefalin)

Humana

Pharmacy Coverage Policy

Effective Date: July 27, 2022
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Line of Business: Medicare, Commercial, Medicaid - Humana, Medicaid - Ohio
Policy Type: Prior Authorization

Disclaimer

Description

Korsuva (difelikefalin) is a kappa opioid receptor (KOR) agonist. The relevance of KOR activation to therapeutic effectiveness is not known.

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

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

Difelikefalin is available as a 65mcg/1.3ml solution for IV infusion

Coverage Determination

Please note the following regarding medically accepted indications:

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

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.

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