Korsuva (difelikefalin acetate)

Override(s)	Approval Duration
Prior Authorization	Initial requests: 3 months Continuation requests: 12 months

Medications
Korsuva (difelikefalin acetate) Intravenous Injection

APPROVAL CRITERIA

Initial requests for Korsuva (difelikefalin acetate) may be approved if the following criteria are met:

I. Individual has a diagnosis of chronic kidney disease; **AND**
II. Individual is receiving hemodialysis at least 3 times per week; **AND**
III. Individual is using for moderate to severe pruritus associated with hemodialysis (CKD-aP); **AND**
IV. Individual has a trial and inadequate response, or intolerance to one (1) other pruritus therapy, such as antihistamines, glucocorticoids, and gabapentin (*or* pregabalin) (Fishbane 2020); **AND**
V. Individual has received optimal dialysis treatment in the last 3 months defined as **one** of the following on different dialysis days (Fishbane 2020):
   A. Two (2) single-pool Kt/V measurements greater than or equal to 1.2
   B. Two (2) urea reduction ratio measurements greater than or equal to 65%
   C. One (1) pool Kt/V measurement greater than or equal to 1.2 **and** one (1) urea reduction ratio measurement greater than or equal to 65%.

Continuation requests for Korsuva (difelikefalin acetate) may be approved if the following criteria are met:

I. Individual continues to receive hemodialysis at least 3 times per week; **AND**
II. Individual has received optimal dialysis treatment in the last 3 months defined as **one** of the following
on different dialysis days:
   A. Two (2) single-pool Kt/V measurements greater than or equal to 1.2
   B. Two (2) urea reduction ratio measurements greater than or equal to 65%
   C. One (1) pool Kt/V measurement greater than or equal to 1.2 **and** one (1) urea reduction ratio measurement greater than or equal to 65%; **AND**
III. There is confirmation of clinically significant improvement or stabilization in pruritus (CKD-aP) from baseline.

Requests for Korsuva (difelikefalin acetate) may not be approved for the following:

I. Individual is using for pruritus associated with peritoneal dialysis.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 15, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Fishbane S, Jamal A, Munera C, Wen W, Menzaghi F; KALM-1 Trial Investigators. A Phase 3 Trial of Difelikefalin in Hemodialysis Patients with Pruritus. N Engl J Med. 2020 Jan 16;382(3):222-232. doi: 10.1056/NEJMoa1912770. Epub 2019 Nov 8. PMID: 31702883. Available at: https://www.nejm.org/doi/pdf/10.1056/NEJMoa1912770?articleTools=true. Accessed July 5, 2022.
5. Hercz D, Jiang SH, Webster AC. Interventions for itch in people with advanced chronic kidney disease. Cochrane Database Syst Rev. 2020 Dec 7;12(12):CD011393. doi: 10.1002/14651858.CD011393.pub2. PMID: 33283264; PMCID: PMC8094883.
6. KDOQI Clinical Practice Guideline for Hemodialysis Adequacy: 2015 Update. National Kidney Foundation. https://doi.org/10.1053/j.ajkd.2015.07.015. Available at https://www.ajkd.org/article/S0272-6386(15)01019-7/fulltext. Accessed on July 19, 2022.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.