Korsuva (difelikefalin)
PAM – 054

Iowa Medicaid Program	Prior Authorization	**Effective Date**	04/01/2022
Revision Number	3	**Last Reviewed**	04/18/2025
Reviewed By	Medicaid Medical Director	**Next Review**	04/17/2026
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	04/21/2023

Overview

Medication: [1]	difelikefalin
Brand Name:	Korsuva™
Pharmacologic Category:	kappa opioid receptor agonist
FDA-Approved Indication(s):	Indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis. • Limitation of Use: Korsuva™ has not been studied in patients on peritoneal dialysis and is not recommended for use in this population.
How Supplied:	Single-dose vial containing 65 mcg/1.3 mL (50 mcg/mL)
Dosage and Administration:	0.5 mcg/kg by intravenous bolus injection into the venous line of the dialysis circuit at the end of each hemodialysis treatment (Korsuva™ is removed by the dialyzer membrane and must be administered after blood is no longer circulating through the dialyzer).
Benefit Category:	Medical

Descriptive Narrative

Chronic kidney disease–associated pruritus (CKD-aP), defined as itch secondary to kidney disease and unexplained by alternate causes, is a common, yet underrecognized condition in patients with chronic kidney disease (CKD) and end-stage renal disease (ESRD). Several factors are thought to contribute to CKD-aP, including an immune-mediated response and nociceptive stimulation.

Real-world observational studies indicate that CKD-aP affects up to 80 percent of ESRD patients undergoing hemodialysis (HD), with 40 percent experiencing moderate to severe itch (the systemic pruritis does not originate from skin lesions, but rather is a persistent itch sensation that often leads to considerable mechanical skin damage due to a continuous and uncontrollable urge to scratch).[2] CKD-aP can negatively impact patients' mental and physical health-related quality of life (HRQoL) and is also associated with sleep

disturbance and depression.[3] Patients with CKD-aP have increased infective complications, experience more frequent hospitalizations, and have a higher rate of all-cause mortality (including higher rates of cardiovascular-related mortality and infection-related mortality), relative to patients without pruritis.

Chronic kidney disease-associated pruritis (CKD-aP) is also known as uremic pruritis. Before a diagnosis of CKD-aP can be made, other potential causes of pruritis must be ruled out. The following are some other common non-uremic causes of itch:

Primary Dermatologic Conditions	Systemic Conditions	
• Drug-induced hypersensitivity and other allergies • Contact dermatitis • Psoriasis • Dermatophytosis (tinea cruris, tinea pedis, tinea corporis) • Bullous pemphigoid • Infestations (e.g., bed bugs, scabies, lice)	• Cholestasis • Viral hepatitis • Primary biliary cirrhosis • Hematologic malignancy • Hodgkin's lymphoma	• Cutaneous T-cell lymphoma • Polycythemia vera • Post-herpetic neuralgia • HIV

Guidelines

Kidney Disease: Improving Global Outcomes (KDIGO) is a nonprofit organization developing and implementing evidence-based clinical practice guidelines in kidney disease. KDIGO was originally established in 2003 by the National Kidney Foundation, a U.S. foundation experienced in developing and implementing guidelines. In 2013 KDIGO became an independently incorporated non-profit foundation and is governed by an international volunteer Executive Committee.

KDIGO recommendations for CKD-Associated Pruritis:

Skin Care and Education:
- Apply emollients two to four times daily, especially after bathing.
- Encourage use of non-drying soap.
- Keep nails short and clean.
- Avoidance of scratching.

Topical Agents:
- Given minimal risk of toxicity, use prior to systemic therapies.
- E.g., capsaicin (for localized pruritis), pramoxine, corticosteroids.

Systemic Medications:
- Initiate gabapentin at lowest appropriate dose and titrate according to efficacy and side effects (adjust dosing based on level of renal function, if needed).
- Consider pregabalin if lack of efficacy with or intolerance to gabapentin.[4]

Criteria

Prior authorization is required.

Korsuva™ is considered medically necessary when **ALL** of the following are met:

1. Documented diagnosis of chronic kidney disease (CKD); **AND**
2. Member has been receiving optimal hemodialysis at least three (3) times weekly for at least three months (Korsuva™ is not indicated for pruritis associated with peritoneal dialysis); **AND**
3. Member is 18 years of age or older; **AND**
4. Documentation that member has moderate-to-severe pruritis associated with hemodialysis (CKD-aP); **AND**
5. Pruritis is not attributed to a cause other than end stage renal disease or its complications (e.g., pruritic dermatological disease, cholestatic liver disease); **AND**
6. Member has a trial and inadequate response to one other pruritis therapy [e.g., topical agents, glucocorticoids, and gabapentin (or pregabalin)] after a minimum 4-week trial (unless clinically significant adverse effects occurred, or all therapies are contraindicated); **AND**
7. Prescribed by, or in consultation with, a nephrologist; **AND**
8. The regimen prescribed is within the FDA-approved labeling (0.5 mcg/kg administered after each dialysis session).

Korsuva™ is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Documentation of positive clinical response to therapy, as demonstrated by clinically significant improvement or stabilization in pruritis (CKD-aP) from baseline; **AND**
3. Member continues to receive optimal hemodialysis at least three (3) times weekly; **AND**
4. Prescribed by, or in consultation with, a nephrologist; **AND**
5. The regimen prescribed is within the FDA-approved labeling (0.5 mcg/kg administered after each dialysis session).

Approval Duration and Quantity Limits

	Initial Authorization	Subsequent Authorization(s)
Approval Duration	6 months	12 months
Quantity Limits	0.5 mcg/kg administered at the end of each dialysis treatment	

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
J0879	Injection, difelikefalin, 0.1 mcg, (for ESRD on dialysis)

ICD-10	Description
L29.8	Other pruritis
L29.9	Pruritis, unspecified
N18.5	Chronic kidney disease, stage 5
N18.9	Chronic kidney disease, unspecified

NDC (Strength)	Labeler	Dosage	Pkg Size	Pkg Qty	Units/ Pkg
59353-0065-01 (65 mcg/1.3 mL [50 mcg/ml] single-dose vial)	Cara Therapeutics, Inc. (59353)	0.1 mcg	1	EA	65
59353-0065-12 (65 mcg/1.3 mL [50 mcg/ml] single-dose vial; carton of 12 vials)	Cara Therapeutics, Inc. (59353)	0.1 mcg	12	EA	780

Compliance

1. Should conflict exist between the policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Korsuva™ prescribing information (04/2024). Cara Therapeutics, Inc.: Stamford, CT. Available online: www.korsuva.com/hcp. Accessed March 3, 2025.

[2] NDA/BLA Multi-disciplinary Review and Evaluation NDA 214916. Korsuva (difelikefalin) solution. FDA – Division of Dermatology and Dentistry. Review completion date August 20, 2021. Available online at www.accessdata.fda.gov. Accessed March 2, 2023.

[3] Kim D, Pollock C. Epidemiology and burden of chronic kidney disease-associated pruritus. Clin Kidney J. 2021 Oct 14;14(Suppl 3):i1-i7. PMID: 34987777.

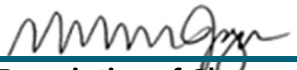
[4] CKD-associated Pruritis. KDIGO: Kidney Disease, Improving Global Outcomes. September 2019. Available online at kdigo.org/wp-content/uploads/2019/09/1.-Combs-CKD_Itch__KDIGO2019.pdf.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
04/18/2025	CAC	Annual review. Updated labeler name to Cara Therapeutics, Inc. (59353) in Coding and Product Information section.	3
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
04/19/2024	CAC	Annual review. Added vial strength to Coding and Product Information section.	2
Signature William (Bill) Jagiello, DO			
Change Date	**Changed By**	**Description of Change**	**Version**
04/21/2023	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee