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 Last P&T Approval/Version: 07/26/2023
 Next Review Due By: 07/2024
 Policy Number: C23743-A

Korsuva (difelikefalin)

PRODUCTS AFFECTED

Korsuva (difelikefalin)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:

Pruritus associated with chronic kidney disease (CKD-aP)

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review.

A. PRURITUS ASSOCIATED WITH CHRONIC KIDNEY DISEASE (CKD-aP):

1. Documented diagnosis of chronic kidney disease
AND
2. Documentation of moderate-to-severe pruritus that impairs member's quality of life (e.g., sleep disruptions, fatigue, or depression) [DOCUMENTATION REQUIRED]
AND
3. Prescriber attests that the member has been receiving hemodialysis at least 3 times weekly for at

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least 3 months

AND

4. Prescriber attests or clinical reviewer has found that the member is not receiving peritoneal dialysis
AND
5. Documentation of inadequate response after trial of 4 weeks, serious side effects, or contraindication to ONE of the following: gabapentinoids (e.g., gabapentin, pregabalin), oral antihistamine (e.g., diphenhydramine), topical analgesic (e.g., pramoxine), topical emollient

CONTINUATION OF THERAPY:

A. PRURITUS ASSOCIATED WITH CHRONIC KIDNEY DISEASE (CKD-aP):

1. Documentation of member's positive clinical response as demonstrated by improvement in pruritus symptoms
AND
2. Prescriber attests or clinical reviewer has found that the member is not receiving peritoneal dialysis
AND
3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a nephrologist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

The recommended dose of Korsuva is 0.5 mcg/kg at the end of each hemodialysis treatment based on the member's target dry body weight.

Target Dry Body Weight Range (kg)	Injection Volume (mL)
36 – 44	0.4
45 – 54	0.5
55 – 64	0.6
65 – 74	0.7
75 – 84	0.8
85 – 94	0.9
95 – 104	1
105 – 114	1.1
115 – 124	1.2
125 – 134	1.3
135 – 144	1.4
145 – 154	1.5
155 – 164	1.6
165 – 174	1.7
175 – 184	1.8
185 – 194	1.9
195 – 204	2

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PLACE OF ADMINISTRATION:

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Intravenous

DRUG CLASS:

Uremic Pruritis Agents

FDA-APPROVED USES:

Indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX:

None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Chronic kidney disease associated pruritus (CKD-aP), or uremic pruritus, is a chronic itching disorder in patients with CKD that is not associated with a primary dermatologic condition. CKD-aP has been associated with poorer quality of life in patients including poor sleep quality, fatigue, and depression. Patients in the later stages of CKD are more likely to be impacted by the condition. CKD-aP is estimated to affect 40-50% of CKD patients on hemodialysis, which is about 223,000-279,000 people in the United States.

There are no formal treatment guidelines for CKD-aP as the typical treatments are not backed by robust clinical evidence. Some therapies that have demonstrated to reduce pruritus symptoms include gabapentin or pregabalin, topical emollients, topical analgesics, oral antihistamines, and altering the hemodialysis dose. Korsuva (difelikefalin) is currently the only FDA-approved therapy indicated for the treatment of moderate-to-severe CKD-aP in adults on hemodialysis. Korsuva is a kappa opioid receptor (KOR) agonist which shows activity by activating the receptors on peripheral neurons and immune cells.

Korsuva received approval from the FDA based on a Phase 3, randomized, multi-center, double-blind, placebo-controlled trial (KALM-1). Adult patients with moderate-to-severe CKD-aP undergoing dialysis at least 3 times weekly for at least 3 months were randomized 1:1 to receive injections of Korsuva (n=189) or placebo (n=188) after each dialysis session. Patients were permitted to continue stable doses of antihistamines, glucocorticoids, opioids, gabapentin, and pregabalin to treat their pruritus. However, patients were excluded if any new anti-pruritic agent was initiated during the trial. The primary endpoint KALM-1 was at least a 3-point improvement from baseline in the weekly mean WI-NRS score at week 12. The WI-NRS is a validated 11-point scale to assess patient-reported severity of itching in the past 24 hours. The endpoint was observed in 51.9% of the treatment group and 30.9% of the placebo group (RR 1.65; 95% CI 1.26-2.14; p<0.001).

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The safety profile for Korsuva is mild and was similar to those who received placebo. The most common adverse events were diarrhea, dizziness, nausea, and gait disturbances. The drug label includes warnings for dizziness, somnolence, mental status changes, and gait disturbances. Patients 65 years and older were more likely to experience somnolence than younger patients. Before receiving Korsuva, patients should be advised to avoid driving or operating heavy machinery.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Korsuva are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. There are no contraindications listed in the manufacturer's labeling.

OTHER SPECIAL CONSIDERATIONS:

None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J0879	Injection, difelikefalin, 0.1 microgram, (for esrd on dialysis)

AVAILABLE DOSAGE FORM:

Korsuva SOLN 65MCG/1.3ML single-dose vial

REFERENCES

1. Korsuva (difelikefalin) [prescribing information]. Stamford, CT: Cara Therapeutics, Inc and Vifor, Inc; December 2021.
2. Fishbane S, Jamal A, Munera C, Wen W, Menzaghi F, et al. A Phase 3 Trial of Difelikefalin in Hemodialysis Patients with Pruritis; 2020 Jan 16; New England Journal of Medicine. 382:222-232
3. Hercz D, Jiang SH, Webster AC. Interventions for itch in people with advanced chronic kidney disease. Cochrane Database Systemic Review. 2020 Dec 7;12:CD011393
4. Shirazian, S., Aina, O., Park, Y., Chowdhury, N., Leger, K., Hou, L., ... & Mathur, V. S. (2017). Chronic kidney disease-associated pruritus: impact on quality of life and current management challenges. *International journal of nephrology and renovascular disease*, 10, 11.
5. Simonsen B, Komenda P, Lerner B, Shaw J, Tangri N, Rigatto C, et. Al. Treatment of Uremic Pruritis: A Systemic Review. American Journal of Kidney Diseases (2017) 70(5), 638–655. <https://doi.org/10.1053/j.ajkd.2017.05.018>

Drug and Biologic Coverage Criteria

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Prescriber Requirements Drug Class Coding/Billing Information Available Dosage Forms References	Q3 2023
Initial version created	Q2 2022