Palifermin (Kepivance®)

Place of Service
Ambulatory Center Only

HCPCS: J2425 per 50 mcg

Conditions listed in Policy (*see criteria for details*)

- Severe oral mucositis in patients with hematologic malignancies receiving myelotoxic therapy followed by autologous hematopoietic stem cell support

AHFS therapeutic class: recombinant human keratinocyte growth factor (rHuKGF)

Mechanism of action: Kepivance (palifermin) is a human keratinocyte growth factor (KGF) produced by recombinant DNA technology in *Escherichia coli (E coli)* that targets epithelial cells to encourage epithelial cell proliferation, differentiation, migration, and upregulation.

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Kepivance® (palifermin) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Severe oral mucositis in patients with hematologic malignancies receiving myelotoxic therapy followed by autologous hematopoietic stem cell support

1. Patients is to receive myelotoxic therapy (chemotherapy or radiation) prior to hematopoietic stem cell support (bone marrow transplant), **AND**
2. Not being covered under the case rate

Covered Doses
60 mcg/kg/day IV bolus for 3 consecutive days before and 3 consecutive days after myelotoxic therapy, for a total of 6 doses

Coverage Period
Cover one cycle (6 doses) only

ICD-10:
K12.31, K12.33

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Kepivance® (palifermin) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Myelotoxic therapy for diagnoses not indicated under prior authorization

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How Supplied:
5.16 mg lyophilized powder in single-use vials
6.25 mg lyophilized powder in single-use vials (obsolete date 10/6/2023)

Do not administer within 24 hours before, during, or within 24 hours after myelotoxic chemotherapy due to risk of increased severity and duration of oral mucositis

Pre-myelotoxic therapy:
The first 3 doses should be administered prior to myelotoxic therapy, with the third dose 24 to 48 hours before myelotoxic therapy.

Post-myelotoxic therapy:
The last 3 doses should be administered post-myelotoxic therapy; the first of these doses should be administered after, but on the same day of hematopoietic stem cell infusion and at least 4 days after the most recent administration of Kepivance®.

Studies have not been performed in patients undergoing subsequent cycles of myelotoxic therapy for stem cell support.

Use not recommended with melphalan 200 mg/m^2 as a conditioning regimen

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Kepivance® (palifermin) [Prescribing Information]. Stockholm, Sweden: Swedish Orphan Biovitrum AB; 12/2019.

(7) Policy Update

Date of last revision: 4Q2023
Date of next review: 2Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.