

palifermin (Kepivance)**Medical Benefit Drug Policy**Place of Service

Ambulatory Center Only

Drug Details**USP Category:** DENTAL AND ORAL AGENTS**Mechanism of Action:** Human keratinocyte growth factor (KGF) that targets epithelial cells to encourage epithelial cell proliferation, differentiation, migration, and upregulation.**HCPCS:**

J2425:Injection, palifermin, 50 micrograms

How Supplied:

5.16 mg lyophilized powder in single-use vials

Condition(s) listed in policy *(see coverage criteria for details)*

- Severe Oral Mucositis in Patients with Hematologic Malignancies receiving Myelotoxic Therapy followed by Autologous Hematopoietic Stem Cell Support

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria**The following condition(s) require Prior Authorization/Preservice.****Severe Oral Mucositis in Patients with Hematologic Malignancies receiving Myelotoxic Therapy followed by Autologous Hematopoietic Stem Cell Support****Meets medical necessity if all the following are met:**

1. Patients is to receive myelotoxic therapy (chemotherapy or radiation) prior to hematopoietic stem cell support (bone marrow transplant)

Covered Doses:

Up to 60 mcg/kg given by intravenous injection for 3 consecutive days before and 3 consecutive days after myelotoxic therapy, for a total of 6 doses

Coverage Period:

Cover one cycle only (6 doses)

ICD-10:

K12.31, K12.33

References

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Kepivance (palifermin) Prescribing Information. Swedish Orphan Biovitrum AB, Stockholm, Sweden: 7/2023.

Review History

Date of Last Annual Review: 2Q2025

Changes from previous policy version:

- No clinical change to policy following annual review.

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*