palifermin (Kepivance)

Commercial 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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

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)
2. Not being covered under the case rate

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