SmartHealth Ascension

Palifermin

(Kepivance®) J2425 (50mcg)

Covered with prior authorization

Kepivance® (Palifermin) may be authorized when the following criteria are met:

- Individual has a diagnosis of hematologic malignancy; **AND**
- Individual is receiving or scheduled to receive myelotoxic therapy; **AND**
- Individual is receiving hematopoietic cell transplantation; **AND**
- The regimen the member is to receive is predicted to result in a high incidence of WHO Grade 3 or higher mucositis.

Exclusion criteria:
Requests may not be approved for the following:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

Initial authorization approval is up to 12 months.

Reauthorization approval is up to 12 months.

Reauthorization Criteria
Palifermin is considered medically necessary for continued use when initial criteria are met.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Kepivance® (**Palifermin)** is a mucocutaneous epithelial human growth factor indicated to decrease the incidence and duration of severe oral mucositis in patients with hematologic malignancies receiving myelotoxic therapy in the setting of autologous hematopoietic stem cell support. Kepivance® is indicated as supportive care for preparative regimens predicted to result in ≥ WHO Grade 3 mucositis in the majority of patients.

References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
2. Kepivance® [package insert]. Stockholm, Sweden: Swedish Orphan Biovitrum AB; July 2017.

Criteria History/ Revision Information:

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.