



**Prior Authorization Approval Criteria**  
*Department of Pharmacy Services*

**Generic Name:** Palifermin

**Brand Name:** Kepivance®

**Medication Class:** Keratinocyte Growth Factor

**FDA Approved Uses:**

- decrease the incidence and duration of severe oral mucositis in patients with hematologic malignancies receiving myelotoxic therapy requiring hematopoietic stem cell support

**Available Dosage Forms:** injection, lyophilized powder for reconstitution (6.25mg)

**Usual Dose:** 60 mcg/kg/d for 3 consecutive days before & after myelotoxic therapy (6 doses total)

- Pre-myelotoxic therapy: Administer first 3 doses prior to myelotoxic therapy, with the 3rd dose given 24-48 hours before therapy begins
- Post-myelotoxic therapy: The last 3 doses should be administered after myelotoxic therapy, with the first of these doses after but on the same day of hematopoietic stem cell infusion and at least 4 days after the most recent dose of palifermin.

**Duration of Therapy:** Treatment to be given 3 days before and 3 days after myelotoxic therapy

**Approximate cost per course of therapy** (based on ASP 7/20/06): \$129

**Criteria for Use:** *(bullet points below are all inclusive unless otherwise noted)*

- Clinically diagnosed with oral mucositis with hematologic malignancies receiving myelotoxic therapy requiring hematopoietic stem cell support

**Cautions:**

- Safety and efficacy have not been established with nonhematologic malignancies or in children

**Monitoring:** BP, allergic reactions, edema, serum lipase and amylase levels

**Contraindications:** Hypersensitivity to palifermin, *E. coli*-derived proteins

**Not Approved if:** Above criteria is not met or patient is hypersensitive to palifermin

P&T Approval: \_\_\_\_\_ Date: \_\_\_\_\_