Kepivance

**Description**

Kepivance (palifermin)

**Background**

Kepivance is a recombinant human keratinocyte growth factor that works at the cellular level to help protect patients with hematologic malignancies undergoing high-dose chemotherapy and/or radiation followed by autologous bone marrow transplant from severe oral mucositis. Kepivance reduces the incidence and duration of severe oral mucositis in these patients by protecting the epithelial cells that line the mouth and throat from the damage caused by chemotherapy and radiation and by stimulating the growth and development of new epithelial cells to build up the mucosal barrier (1).

**Regulatory Status**

FDA-approved indication: Kepivance 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 requiring 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 (1).

**Limitation of Use:**

The safety and efficacy of Kepivance have not been established in patients with non-hematologic malignancies. Kepivance is not recommended in patients receiving allogeneic hematopoietic stem cell support or for use with melphalan 200 mg/m² as a conditioning regimen (1).
Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Kepivance may be considered **medically necessary** in patients with severe oral mucositis or in patients at risk of developing ≥ WHO Grade 3 mucositis and if the conditions indicated below are met.

Kepivance may be considered **investigational** for all other indications.

**Prior-Approval Requirements**

**Diagnosis**

Patient must have the following:

Severe oral mucositis or at risk of developing ≥ WHO Grade 3 mucositis

AND ALL of the following:

1. Hematologic malignancy (non-Hodgkin’s lymphoma, Hodgkin’s lymphoma, acute myelogenous leukemia (AML), acute lymphoblastic leukemia (ALL), chronic lymphocytic leukemia (CLL), chronic myelogenous leukemia (CML), acute monocytic leukemia (AMoL), or multiple myeloma)
2. Receiving or scheduled to receive myelotoxic therapy
3. Scheduled autologous hematopoietic stem cell transplantation

**Prior – Approval Renewal Requirements**

Same as above

**Policy Guidelines**

**Pre - PA Allowance**

None
Prior - Approval Limits
Duration 12 months

Prior – Approval Renewal Limits
Duration 12 months

Rationale

Summary
Kepivance 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 requiring 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. The safety and efficacy of Kepivance have not been established in patients with non-hematologic malignancies. Kepivance is not recommended for use in patients receiving allogeneic hematopoietic stem cell support or with melphalan 200 mg/m² as a conditioning regimen (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Kepivance while maintaining optimal therapeutic outcomes.

References
March 2014  Annual editorial review and reference update
   Addition to criteria requirement: patients at risk of development in WHO grade 3 mucositis or greater; defined approvable hematologic malignancy as: non-Hodgkin’s lymphoma, Hodgkin’s lymphoma, acute myelogenous leukemia (AML), acute lymphoblastic leukemia (ALL), chronic lymphocytic leukemia (CLL), chronic myelogenous leukemia (CML), acute monocytic leukemia (AMoL), or multiple myeloma

June 2015  Annual editorial review and reference update

June 2016  Annual editorial review
   Policy number change from 5.04.08 to 5.21.08

June 2017  Annual editorial review and reference update
   Addition to criteria requirement: only recommended in patients with autologous hematopoietic stem cell transplantation

June 2018  Annual review

June 2019  Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective July 1, 2019.