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5.21.008

Section:	Prescription Drug	**Effective Date:**	July 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	December 7, 2011
Subject:	Kepivance	**Page:**	1 of 4

Last Review Date: June 13, 2024

Kepivance

Description

Kepivance (palifermin)

Background
Kepivance (palifermin) 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 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 (1).

Limitation of Use:
The safety and efficacy of Kepivance have not been established in patients with non-hematologic malignancies. Kepivance was not effective in decreasing the incidence of severe mucositis in patients with hematologic malignancies receiving myelotoxic therapy in the setting

of allogeneic hematopoietic stem cell support. Kepivance is not recommended for use with melphalan 200 mg/m^2 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** 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

Same above

Rationale

Summary

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 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/m^2 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

1. Kepivance [package insert]. Stockholm, Sweden: Swedish Orphan Biovitrum AB (publ); July 2023.

Policy History

Date	Action
December 2011	New Policy
December 2012	Annual review and update
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
June 2020	Annual review and reference update
June 2021	Annual review
June 2022	Annual review
June 2023	Annual review. Changed policy number to 5.21.008
June 2024	Annual editorial review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.