RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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