AMELUZ GEL
(aminolevulinic acid)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Ameluz gel is a prescription medicine used on the skin for actinic keratoses. Actinic keratosis (AK), also called solar keratosis, which is a chronic (long-term) condition of the skin caused by a chemical reaction to ultraviolet (UV) rays. Actinic keratosis can be linked to the development of skin cancer (1).

Regulatory Status
FDA-approved indications: Ameluz gel porphyrin precursor, in combination with photodynamic therapy using BF-RhodoLED lamp, is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp (1).

Ameluz gel is contraindicated in patients with a history of porphyria and photodermatoses and should not be used (1).

Safety and effectiveness of Ameluz gel in pediatric patients under 18 years of age has not been established (1).

Summary
Ameluz gel is a prescription medicine used on the skin for actinic keratoses on the face and scalp. Actinic keratosis (AK), also called solar keratosis, which is a chronic (long-term) condition of the skin. It is caused by a chemical reaction to ultraviolet (UV) rays. AKs can be linked to the development of skin cancer. Safety and effectiveness of Ameluz gel in pediatric patients under 18 years of age has not been established (1).

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

References
1. Ameluz Gel [package Insert]. Wakefield, MA: Biofrontera Inc. May 2016