



AMINOLEVULINIC ACID

Ameluz Gel, Levulan Kerastick (aminolevulinic acid)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Ameluz gel and Levulan Kerastick are prescription medicines used on the skin for actinic keratoses. Actinic keratosis (AK), also called solar keratosis, 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 (1-2).

Regulatory Status

FDA-approved indications: (1-2)

- 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.
- Levulan Kerastick for Topical Solution, a porphyrin precursor, plus blue light illumination using the BLU-U Blue Light Photodynamic Therapy (PDT) Illuminator is indicated for the treatment of minimally to moderately thick actinic keratoses of the face or scalp, or actinic keratoses of the upper extremities.

Ameluz gel and Levulan Kerastick are contraindicated in patients with a history of porphyria and photodermatoses and should not be used (1-2).

Frequently prescribed and studied field-directed treatment approaches include topical therapies, such as fluorouracil cream or imiquimod cream (3).

Safety and effectiveness of Ameluz gel and Levulan Kerastick topical solution in pediatric patients under 18 years of age has not been established (1-2).

Summary

Ameluz gel and Levulan Kerastick are prescription medicines used on the skin for actinic keratoses. Actinic keratosis (AK), also called solar keratosis, 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



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

References

1. Ameluz Gel [package insert]. Woburn, MA: Biofrontera Inc.; October 2024.
2. Levulan Kerastick [package insert]. Billerica, MA: Sun Pharmaceutical Industries, Inc.; February 2020.
3. Maud, H.E., et al. Randomized Trial of Four Treatment Approaches for Actinic Keratosis. March 7, 2019. N Engl J Med 380:10, 935-46.