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5.90.021

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Topical Products	**Original Policy Date:**	June 3, 2016
Subject:	Aminolevulinic Acid	**Page:**	1 of 5

Last Review Date: March 7, 2025

Aminolevulinic Acid

Description

Ameluz Gel, Levulan Kerastick (aminolevulinic acid)

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).

Related policies
Aldara, Solaraze, Zyclara

Policy

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

Ameluz gel may be considered **medically necessary** if the conditions indicated below are met.

Ameluz gel may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

Ameluz
1. Actinic keratoses (AK) on face or scalp
    a. Mild to moderate AK

Levulan
1. Actinic keratosis (AK) on face or scalp
    a. Minimally to moderately thick AK
2. Actinic keratoses (AK) of the upper extremities

AND ALL of the following for **ALL** indications:
1. Inadequate treatment response, intolerance, or contraindication to at least **ONE** topical skin product (e.g., imiquimod)
2. Used in combination with the BF-RhodoLED lamp (if using Ameluz gel) **OR** in combination with the BLU-U Blue Light Photodynamic Therapy (PDT) Illuminator (if using Levulan Kerastick)
3. **NO** history of porphyria

4. **NO** history of photodermatoses
5. **NO** dual therapy with another aminolevulinic acid agent

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Actinic keratoses (AK) on face or scalp
2. Levulan **only:** Actinic keratoses AK) of the upper extremities

AND ALL of the following for **ALL** indications:

1. Re-evaluation of lesion(s) for improvement
2. A minimum of 3 months have elapsed since initial treatment for the requested site
3. Used in combination with the BF-RhodoLED lamp (if using Ameluz gel) **OR** in combination with the BLU-U Blue Light Photodynamic Therapy (PDT) Illuminator (if using Levulan Kerastick)
4. **NO** dual therapy with another aminolevulinic acid agent

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 3 months of Levulan Kerastick or Ameluz gel

Prior – Approval *Renewal* Limits

Duration 3 months of Levulan Kerastick or Ameluz gel

*One renewal only per site – face, scalp, and upper extremities are considered separate treatment sites

**Continuation of therapy for the same site must be completed with the same aminolevulinic acid agent

Rationale

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

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.

Policy History

Date	Action
June 2016	Addition to PA
September 2016	Annual review
December 2016	Addition of Levulan Kerastick to the criteria and no dual therapy with another aminolevulinic acid agent
March 2017	Annual editorial review Removal of inadequate treatment response, intolerance, or contraindication to a topical purine analog and topical antineoplastic and replaced with inadequate treatment response, intolerance, or contraindication to at least **ONE** topical skin product (i.e. imiquimod)
June 2017	Annual review Related Medical Policy 2.01.44

September 2018	Annual review and reference update
April 2019	Revised continuation statements to clarify that face and scalp are separate sites and continuation must be with the same aminolevulinic acid agent
June 2019	Annual review. Added reference for trial of topical therapies: Randomized Trial of Four Treatment Approaches for Actinic Keratosis
September 2020	Annual review
March 2021	Annual editorial review and reference update. Separated Ameluz and Levulan indications based on package inserts
March 2022	Annual review and reference update
March 2023	Annual review. Changed policy number to 5.90.021
September 2023	Annual review
March 2024	Annual review. Per SME, changed verbiage of continuation to “A minimum of 3 months have elapsed since initial treatment for the requested site”
September 2024	Annual review and reference update
March 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.