

5.90.21

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Topical Products	Original Policy Date:	June 3, 2016
Subject:	Aminolevulinic Acid	Page:	1 of 5

Last Review Date: March 12, 2021

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 indication (Ameluz): 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).

FDA-approved indication (Levulan Kerastick): The 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 (2).

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).

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Topical Products	Original Policy Date:	June 3, 2016
Subject:	Aminolevulinic Acid	Page:	2 of 5

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** in patients 18 years of age or older with actinic keratoses (AK) and if the conditions indicated below are met.

Ameluz gel is considered **investigational** in patients less than 18 years of age and 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:

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)

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Topical Products	Original Policy Date:	June 3, 2016
Subject:	Aminolevulinic Acid	Page:	3 of 5

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:

1. Re-evaluation of lesion(s) for improvement
2. A minimum of 3 months since last therapy
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

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Topical Products	Original Policy Date:	June 3, 2016
Subject:	Aminolevulinic Acid	Page:	4 of 5

**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.; August 2020.
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

5.90.21

Section:	Prescription Drugs	Effective Date:	April 1, 2021
Subsection:	Topical Products	Original Policy Date:	June 3, 2016
Subject:	Aminolevulinic Acid	Page:	5 of 5

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.