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 (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).
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 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

**Diagnosis**

Patient must have the following:

Mild to moderate actinic keratoses on face or scalp

**AND ALL** of the following:

1. Inadequate treatment response, intolerance, or contraindication to at least **ONE** topical skin product (i.e. 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

**Diagnosis**

Patient must have the following:

- Actinic keratoses on face or scalp

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

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**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 and scalp are considered separate treatment sites

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

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**Rationale**

**Summary**
Ameluz gel and Levulan Kerastick are prescription medicines used on the skin for actinic keratoses on the face and scalp. 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

Policy History

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<td>June 2016</td>
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<tr>
<td>September 2016</td>
<td>Annual review</td>
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<tr>
<td>December 2016</td>
<td>Addition of Levulan Kerastick to the criteria and no dual therapy with</td>
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<td>another aminolevulinic acid agent</td>
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<td>March 2017</td>
<td>Annual editorial review</td>
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<td>Removal of inadequate treatment response, intolerance, or contraindica</td>
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<td>to a topical purine analog and topical antineoplastic and replaced</td>
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<td>to at least ONE topical skin product (i.e. imiquimod)</td>
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<td>September 2018</td>
<td>Annual review and reference update</td>
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<tr>
<td>April 2019</td>
<td>Revised continuation statements to clarify that face and scalp are</td>
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<td>June 2019</td>
<td>Annual review. Added reference for trial of topical therapies:</td>
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<td>Randomized Trial of Four Treatment Approaches for Actinic Keratosis</td>
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Keywords
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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.