Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 149.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Ameluz (aminolevulinic acid)

I. Policy:
Ameluz (aminolevulinic acid)

II. Purpose/Objective:
To provide a policy of coverage regarding Ameluz (aminolevulinic acid)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Ameluz (aminolevulinic acid) is a metabolic precursor of the photosensitizer protoporphyrin IX (PpIX). Photosensitization following local/topical application of aminolevulinic acid occurs through the metabolic conversion to PpIX. When exposed to light of appropriate wavelength and energy, accumulated PpIX produces a photodynamic reaction resulting in local cytotoxicity. Precancerous and cancerous cells exhibit a higher rate of porphyrin induction compared to normal cells.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Ameluz (aminolevulinic acid) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Must be prescribed by a dermatologist **AND**
- Medical record documentation of a diagnosis of actinic keratosis of mild-to-moderate severity on the face and/or scalp **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to topical fluorouracil **AND**
- Medical record documentation that Ameluz will be used in conjunction with the BF-RhodoLED lamp or RhodoLED XL lamp.

QUANTITY LIMIT: 2 grams per application (1 tube=2 grams)

AUTHORIZATION DURATION: Initial approval will be for a period of 3 months. One additional 3 month approval may be granted if there is medical record documentation that lesions have not completely resolved within 3 months after the initial treatment

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Ameluz [prescribing information]. Woburn, MA: Biofrontera Inc; December 2021.
2. Gupta AK. Paquet M. Network meta-analysis of the outcome 'participant complete clearance' in nonimmunosuppressed participants of eight interventions for actinic keratosis: a follow-up on a Cochrane review. British Association of Dermatologists. British Journal of Dermatology; 2013 Aug 1; 169(2):250-259 [cited 2023 Dec 26]. Available from: https://academic.oup.com/bjd/article-abstract/169/2/250/6615141?redirectedFrom=fulltext&login=false
3. Jansen MHE, Janneke, Kessels, et al. Randomized Trial of Four Treatment Approaches for Actinic Keratosis. New England Journal of Medicine (NEJM); 2019 Mar 7; 380:935-946 [cited 2023 Dec 26]. Available from: https://www.nejm.org/doi/10.1056/NEJMoa1811850?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

This policy will be revised as necessary and reviewed no less than annually.

Devised: 1/17/17

Revised: 10/31/17 (removed Medicaid), 10/30/18 (added Medicaid), 6/23/22 (Medicaid PARP statement), 7/8/22 (RhodoLED XL lamp per DHS), 6/6/23 (LOB carve out, Medicaid business segment), 12/30/23 (references added)

Reviewed: 10/31/17, 8/29/19, 8/26/20, 7/26/21, 5/29/24

MA UM Committee approval: 12/31/23