Mass General Brigham
Health Plan

Dermatological Agents
Ameluz (aminolevulinic acid)
Levulan (aminolevulinic acid)
Effective 10/01/2024

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		
Notes	Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview

Ameluz, in combination with photodynamic therapy (PDT) using BF-RhodoLED® or RhodoLED® XL lamp, a narrowband, red light illumination source, is indicated for lesion-directed and field-directed treatment of actinic keratoses (AKs) of mild-to-moderate severity on the face and scalp.

Levulan for topical solution plus blue light illumination using the BLU-U Blue Light Photodynamic Therapy Illuminator is indicated for the treatment of minimally to moderately thick actinic keratoses of the face, scalp, or upper extremities.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met:

Ameluz (aminolevulinic acid)

1. Diagnosis of mild to moderate actinic keratosis on face and/or scalp
2. Member is ≥ 18 years of age
3. Prescriber is a dermatologist or consult notes from a dermatologist are provided
4. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following:
    a. topical fluorouracil
    b. topical imiquimod
    c. cryosurgery

5. Requested agent will be used in conjunction with photodynamic therapy
6. Inadequate response, adverse reaction, or contraindication to Levulan used in conjunction with photodynamic therapy

Levulan (aminolevulinic acid)

1. Diagnosis of mild to moderate actinic keratosis on face, scalp, and/or upper extremities
2. Member is ≥ 18 years of age
3. Prescriber is a dermatologist or consult notes from a dermatologist are provided
4. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following:
    a. topical fluorouracil
    b. topical imiquimod
    c. cryosurgery
5. Requested agent will be used in conjunction with photodynamic therapy

Continuation of Therapy

New flares of diagnosis must meet initial criteria.

Continuation of same episodes: Prescriber provides documentation of medical necessity (lesions have not completely resolved) for use beyond 12 weeks (3 months) for AK.

Limitations

1. Initial approvals and reauthorizations will be granted up to 12 weeks (3 months).

References

1. Ameluz® [package insert on the internet]. Wakefield (MA): Biofrontera Inc.; 2021 Dec.
2. Levulan Kerastick® [package insert on the internet]. Wilmington (MA): DUSA Pharmaceuticals.; 2018 March.
3. Serra-Guillén C, Nagore E, Hueso L, et al. A randomized pilot comparative study of topical methyl aminolevulinate photodynamic therapy versus imiquimod 5% versus sequential application of both therapies in immunocompetent patients with actinic keratosis: clinical and histologic outcomes. J Am Acad Dermatol 2012; 66:131.
4. Hadley J, Tristani-Firouzi P, Hull C, et al. Results of an investigator-initiated single-blind split-face comparison of photodynamic therapy and 5% imiquimod cream for the treatment of actinic keratoses. Dermatol Surg 2012; 38:722.
5. Sotiriou E, Apalla Z, Maliamani F, et al. Intraindividual, right-left comparison of topical 5-aminolevulinic acid photodynamic therapy vs. 5% imiquimod cream for actinic keratoses on the upper extremities. J Eur Acad Dermatol Venereol 2009; 23:1061.
6. Patel G, Armstrong AW, Eisen DB. Efficacy of photodynamic therapy vs other interventions in randomized clinical trials for the treatment of actinic keratoses: a systematic review and meta-analysis. JAMA Dermatol 2014; 150:1281.
7. Jansen MHE, Kessels JPHM, Nelemans PJ, et al. Randomized Trial of Four Treatment Approaches for Actinic Keratosis. N Engl J Med 2019; 380:935.

Review History
09/11/24 – Created for P&T. Adopted MH criteria. Ameluz and Levulan will now require PA through medical benefit. Effective 10/1/24.