J-Code for LEVULAN® KERASTICK® (aminolevulinic acid HCl) for topical solution, 20%

LEVULAN KERASTICK is assigned

J-Code: J7308

At this time there is no other single-unit dosage product that is described by this HCPCS code J7308. In order to ensure compliance, please note that the J-Code J7308 cannot be used for the following:

- Any other topical formulation or product for PDT which includes:
  - Any other concentration/formulation of aminolevulinic acid
  - Formulations for distribution and re-sale provided by compounding pharmacies

Sample CMS-1500* Claim Form (Physician Office)

ELECTRONIC CLAIMS (ANSI 5010 837P)

Product ID Qualifier	Enter **N4** in this Field	2410	LIN02
National Drug Code	Enter 11-digit NDC billing format **67308010101**	2410	LIN03
National Drug Code Unit Count	Enter Quantity (number of NDC units) **1**	2410	CTP04
Unit of Measurement	Enter NDC unit of measure as **UN**	2410	CTP05

Box 19: If billing two or more sticks add a comment on the claim in Box 19

Box 21: ICD Indication: Enter "L57.0" for ICD-10

Box 24: 24D: Enter appropriate HCPCS and CPT® codes

19 ADDITIONAL CLAIM INFORMATION
2 sticks for treatment of arms per label indication

20 OUTSIDE LAB? ☐ YES ☐ NO $ CHARGES

21 DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to s ICD ind.
A. L57.0 B. C. D.
E. F. G. H.
I. J. K. K.

22 RESUBMISSION CODE ORIGINAL REF. NO.

23 PRIOR AUTHORIZATION NUMBER

24 A DATE(S) OF SERVICE FROM MM DD YY	TO MM DD YY	B PLACE OF SERVICE	C EMG	D PROCEDURES, SERVICES OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E DIAGNOSIS POINTER	F $ CHARGES	G DAYS OR UNITS	H Family Plan	I ID QUAL	J RENDERING PROVIDER ID #
03 01 18		11				A		1		NPI	9999999999
N467308010101 UN1											
03 01 18		11		J7308		A		2		NPI	

IMPORTANT SAFETY INFORMATION

LEVULAN® KERASTICK® (aminolevulinic acid HCl) for topical solution, 20%, 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 or scalp, or actinic keratosis of the upper extremities.

Please see Important Safety Information on reverse.
Please see full Prescribing Information enclosed.

CPT®: Current Procedural Terminology. CPT® is a registered trademark of the American Medical Association.

LEVULAN® KERASTICK®
(aminolevulinic acid HCl)
for topical solution, 20%
+ BLU-U®
Blue Light Photodynamic Therapy
Illuminator Model 4170

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Contraindicated in patients with cutaneous photosensitivity at wavelengths of 400–450 nm, porphyria, or known allergies to porphyrins, and in patients with known sensitivity to any of the components of the LEVULAN KERASTICK topical solution.

Application of LEVULAN KERASTICK topical solution should involve lesions on the face or scalp, or upper extremities. Multiple lesions can be treated within a treatment region, but multiple treatment regions should not be treated simultaneously.

Do not apply to the eyes or to mucus membranes. Irritation may be experienced if LEVULAN KERASTICK topical solution is applied to eyes or mucous membranes. Treatment of upper extremities is approved after an incubation time of 3 hours under occlusion. Excessive irritation may be experienced if this product is applied under occlusion longer than 3 hours.

Transient amnestic episodes have been reported during postmarketing use of LEVULAN KERASTICK in combination with BLU-U Blue Light Photodynamic Therapy Illuminator. Inform patients and their caregivers that LEVULAN KERASTICK in combination with PDT may cause transient amnestic episodes. Advise them to contact the healthcare provider if the patient develops amnesia after treatment.

After LEVULAN KERASTICK topical solution has been applied, the treatment site will become photosensitive and patients should avoid exposure of the photosensitive treatment sites to sunlight or bright indoor light (e.g., examination lamps, operating room lamps, tanning beds, or lights at close proximity) for 40 hours. To avoid unintended photosensitivity, LEVULAN KERASTICK topical solution should be applied by a qualified health professional to no more than 5 mm of perilesional skin surrounding each target actinic keratosis lesion.

Advise patients to wear a wide-brimmed hat or similar head covering of light-opaque material or a long-sleeved shirt and/or gloves to shade the treated actinic keratoses from sunlight or other bright light sources until at least 40 hours after the application of LEVULAN KERASTICK topical solution. Sunscreens will not protect against photosensitivity reactions caused by visible light. The patient should be advised to reduce light exposure if the sensations of stinging and/or burning are experienced.

LEVULAN KERASTICK topical solution has not been tested on patients with inherited or acquired coagulation defects.

It is possible that concomitant use of other known photosensitizing agents such as St. John's wort, griseofulvin, thiazide diuretics, sulfonylureas, phenothiazines, sulfonamides and tetracyclines might increase the photosensitivity reaction of actinic keratoses treated with the LEVULAN KERASTICK topical solution.

During light treatment, both patients and medical personnel should be provided with blue blocking protective eyewear as specified in the BLU-U Blue Light Photodynamic Therapy Illuminator Operating Instructions.

The most common local adverse reactions (incidence ≥ 10%) were erythema, edema, stinging/burning, scaling/crusting, itching, erosion, hypo/hyperpigmentation, oozing/vesiculation/crusting, scaling and dryness.

In clinical trials, severe stinging and/or burning was reported by at least 50% of face and scalp patients and 9% of upper extremity patients at some time during treatment. However, less than 3% of subjects receiving treatment for face or scalp lesions discontinued light treatment because of stinging/burning. No subjects discontinued light treatment in the trial for upper extremity lesions.

Please refer to the full Prescribing Information linked here for complete discussion of the risks associated with LEVULAN KERASTICK (aminolevulinic acid HCl) for topical solution, 20%.

Please see full Prescribing Information enclosed.

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