Topical Photosensitizers used with PDT for Actinic Keratoses and Certain Skin Cancers

FIRST COAST SERVICE OPTIONS
MAC - PART A/B
LOCAL COVERAGE DETERMINATION

LCD Database ID Number
L33414

Contractor Name
First Coast Service Options, Inc.

Contractor Number
09101 – Florida
09201 – Puerto Rico/Virgin Islands
09102 – Florida
09202 – Puerto Rico
09302 – Virgin Islands

Contractor Type
MAC – Part A and B

LCD Title
Topical Photosensitizers used with PDT for Actinic Keratoses and Certain Skin Cancers

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CMS National Coverage Policy
Language quoted from CMS National Coverage Determination (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:
CMS Manual System, Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 50
Actinic keratoses (AKs) are a premalignant condition of thick, scaly, or crusty patches of skin. They are more common in fair-skinned people and associated with years of exposure to ultraviolet light, such as sunlight. Various modalities are used in the treatment of actinic keratosis, one of which is photodynamic therapy (PDT). PDT treatment involves the use of photochemical reactions mediated through the interaction of photosensitizing agents, light, and oxygen for the treatment of malignant or benign diseases. PDT is a 2-step process. The first step involves administration of the photosensitizer, and the second step involves the activation of the photosensitizer in the presence of oxygen with a specific wavelength of light directed toward the target tissue. Because the photosensitizer is preferentially absorbed by hyperproliferative tissue and the light source is directly targeted on the lesional tissue, PDT achieves dual selectivity, minimizing damage to adjacent healthy structures.

The most commonly used topical photosensitizers in PDT are aminolevulinic acid HCL (ALA) and methyl aminolevulinate (MAL). Both ALA and MAL are approved by the Food and Drug Administration (FDA) for the treatment of AKs on the face and scalp. The use of these drugs is not indicated for treatment of AKs located on areas other than the face or scalp.

The following topical photosensitizer drugs for PDT for AKs are covered when used on the face or scalp for the following approved FDA indications:

- Levlun® Kerastick® (ALA) for topical solution, 20%, a porphyrin precursor, 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.
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Levulan® Kerastick® (ALA) topical solution, 20% should be used by a qualified health professional. The first step in Levulan® Kerastick® PDT for AKs is application of this topical solution to the face or scalp in the physician’s office (or other appropriate outpatient setting). After application of Levulan® Kerastick® (ALA) topical solution, the patient will receive blue light treatment, which is the second and final step in the treatment and lasts for approximately 17 minutes. For treated lesions that have not completely resolved after 8 weeks, a second treatment may be administered.

- Metvixia (MAL) Cream, 16.8% for topical use, a porphyrin precursor, in combination with the Aktilite CL 128 lamp, a narrowband, red light illumination source, is indicated for treatment of thin and moderately thick, non-hyperkeratotic, non-pigmented actinic keratoses of the face and scalp in immunocompetent patients when used in conjunction with lesion preparation in the physician’s office.

Metvixia (MAL) Cream 16.8% for topical use is to be used only by physicians in the physician’s office (or other appropriate outpatient setting). Physicians should be knowledgeable about PDT and familiar with the Aktilite Operators Manual prior to use of Metvixia Cream. Two treatment sessions one week apart should be administered. Multiple lesions on the face and/or scalp may be treated during the same treatment session, and lesion response should be assessed 3 months after the last treatment session. Use of Metvixia Cream without subsequent red light illumination is non-covered.

In addition to the above approved FDA indications for Levulan® Kerastick® (ALA) topical solution, 20%, and Metvixia (MAL) Cream, 16.8% topical use, the following compendia listed off-label indications for treatment of Basal cell carcinoma and Squamous cell carcinoma in situ (Bowen’s disease) will also be considered medically reasonable and necessary for both drugs when used as photosensitizers with approved light source when other therapies are considered medically less appropriate, and if the therapy is one that meets, but does not exceed, the patient’s medical need; and is at least as beneficial as an existing and available medically appropriate alternative.

**Type of Bill Code**

013x Hospital Outpatient

085x Critical Access Hospital

**Revenue Codes**

0636 Pharmacy – drugs requiring detailed coding

**CPT/HCPCS Codes**

J7308 Aminolevulinic acid HCL for topical administration, 20%, single unit dosage form (354 mg) [Levulan Kerastick]

J7309 Methyl aminolevulinate (MAL) for topical administration, 16.8%, 1 gram [Metvixia Cream]

**ICD-10 Codes that Support Medical Necessity**

C44.00 – C44.89 Other and unspecified malignant neoplasm of skin

D04.0 – D04.8 Carcinoma in situ of skin

L57.0 Actinic keratosis

**Diagnoses that Support Medical Necessity**

See ICD-10 Codes that Support Medical Necessity
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ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Associated Information

Documentation Requirements

Medical record documentation maintained by the physician must substantiate the medical need for the PDT treatment used. The type and size of lesion treated with PDT must be documented. The medical record must be made available upon request.

PDT treatment for skin lesions using topical solution Levulan® Kerastick® (ALA), or topical Metvixia (MAL) Cream, 16.8% as photosensitizers are covered when used for FDA and off-labeled indications outlined under the “Indications and Limitations of Coverage and/or Medical Necessity” section above. Other indications for these drugs will not be covered.

When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary under Section 1862(a)(1) of the Social Security Act.

Utilization Guidelines

Levulan® Kerastick® (ALA) topical solution, 20% may be administered a second time with PDT for lesions that have not completely resolved after 8 weeks.

Metvixia (MAL) Cream 16.8% for topical use should be administered in two treatment sessions one week apart. Multiple lesions may be treated during the same treatment session using a total of not more than 1 gram (half tube) of Metvixia Cream.

Sources of Information and Basis for Decision

FCSO reference LCD number(s) – L31805


Clinical Pharmacology Compendia. Aminolevulinic Acid (Levulan Kerastick), 2009.


Food and Drug Administration (FDA) product label for Levulan® Kerastick® (aminolevulinic acid HCl) for topical solution 20%. Revised 2010.
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Food and Drug Administration (FDA) product label for Metvixia (methyl aminolevulinate) Cream, 16.8% for topical use. Revised 2008.


Other Medicare contractors


**Start Date of Comment Period**

N/A

**End Date of Comment Period**

N/A

**Start Date of Notice Period**

04/01/2014

**Original**

This LCD replaces all previous LCD versions (refer to “Sources of Information and Basis for Decision” section of the LCD) and publications on this subject to comply with ICD-10-CM based on Change Request 8112. The effective date of this LCD is based on date of service.

**Related Documents**

N/A

**LCD Attachments**

Coding Guidelines