
Medical Policy



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Joint Medical Policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information.

Category: Medicine
***Current Policy Effective Date: 9/1/07**

Title: Photodynamic Therapy for Treatment of Actinic Keratoses and Other Skin Lesions

Procedure Code(s): J7308, 96567

Description/Background

Actinic keratoses are rough, scaly, or wart-like premalignant growths on sun-exposed skin that are very common in older individuals with fair complexions, with a prevalence of >80% in fair-skinned people over the age of 60.

The available treatments for actinic keratoses can generally be divided into surgical and non-surgical methods. Surgical treatments used to treat one or a small number of dispersed individual lesions include excision, cryosurgery, curettage (either alone or combined with electrodesiccations) and laser surgery. Non-surgical treatments include topical chemotherapy (fluorouracil or masoprocol creams), chemexfoliation (also known as chemical peels) and dermabrasions. These methods are generally used in patients with multiple lesions and the involvement of extensive areas of skin. Under some circumstances, combinations of different treatment methods may be used.

Photodynamic therapy using 5-aminolevulinic acid (5-ALA) in conjunction with the BLU-U™ Blue Light Photodynamic Therapy Illuminator is another treatment option for actinic keratoses. Photodynamic therapy refers to light activation of a photosensitizer to generate highly reactive oxygen intermediaries, which ultimately cause tissue injury and necroses. 5-ALA is a precursor of porphyrins, which, when given orally, is widely used in other photodynamic therapy applications. When applied topically, 5-ALA in aqueous solution passes readily through the abnormal keratin overlying the lesion and is metabolized by the underlying cells to photosensitizing concentrations of porphyrins. Subsequent exposure to photoactivation causes

erythema, severe burning and pain, ultimately destroying the actinic keratosis. Healing occurs within 10 to 14 days, with acceptable cosmetic results. While photodynamic therapy with topical ALA is used primarily as a treatment of actinic keratoses, it has also been investigated as a treatment of other superficial dermatologic lesions, such as Bowen's disease and superficial and nodular basal cell carcinoma. Potential cosmetic indications include skin rejuvenation and hair removal.

In 1999, Levulan® Kerastick™, a topical preparation of ALA, in conjunction with illumination with the BLU-U™ Blue Light Photodynamic Therapy Illuminator, received approval by the U.S. Food and Drug Administration (FDA) for the treatment of non-hyperkeratotic actinic keratoses of the face and scalp. Another variant of photodynamic therapy for skin lesions is Metvix and the CureLight BroadBand (Model CureLight 01), each of which received FDA approval in July 2004.

Metvix® (PhotoCure ASA, Norway) consists of the topical application of methyl aminolevulinate (in contrast to ALA used in the Kerastick procedure) followed by exposure with the CureLight BroadBand, a proprietary red light source (in contrast to the blue light source in the Kerastick procedure). Metvix is indicated for the treatment of non-hyperkeratotic actinic keratoses of the face and scalp in immunocompetent patients when used in conjunction with lesion preparation (debridement using a sharp dermal curette) in the physician's office when other therapies are unacceptable or considered medically less appropriate.

Metvix also sought FDA approval for the treatment of basal cell carcinomas. However, the indication for basal cell carcinomas was not approved by the FDA.

CPT/HCPCS Level II Codes and Description *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

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| J7308 | Aminolevulinic acid HCl for topical administration, 20%, single unit dosage form (354 mg) |
| 96567 | Photodynamic therapy by external application of light to destroy premalignant and/or malignant lesions of the skin and adjacent mucosa (e.g., lip) by activation of photosensitive drug(s), each phototherapy exposure session |

Other codes (investigational, not medically necessary, etc.):

N/A

Diagnoses/Medical Conditions

Actinic Keratosis

Medical Policy Statement

Photodynamic therapy with topical aminolevulinic acid and exposure to red or blue light is a safe and effective nonsurgical treatment of non-hyperkeratotic actinic keratoses of the face and scalp. It may be considered a useful therapeutic or diagnostic option when indicated.

Photodynamic therapy with topical ALA or methyl aminolevulinate and exposure to blue or red light is considered investigational for other dermatologic applications, including, but not limited to, acne vulgaris, squamous cell carcinoma, basal cell carcinoma, hidradenitis suppurativa, mycoses or Bowen's disease. It has not been scientifically demonstrated to be as safe and effective as conventional treatment.

Photodynamic therapy as a technique of skin rejuvenation, hair removal, or other cosmetic indications is considered not medically necessary. Its primary purpose is usually to improve appearance or self esteem, not to treat or cure a specific disease state or improve function.

Rationale

Based on the available published data, photodynamic therapy with aminolevulinic acid is an effective nonsurgical technique of treating actinic keratoses. However, no data confirm that treatment effectiveness is equivalent or superior to other widely available nonsurgical approaches. While photodynamic therapy can be directed at individual lesions, 5-FU is commonly used in patients with a large number of lesions (i.e., full face therapy). This technique requires the application of 5-FU twice daily for 3 to 4 weeks followed by a further 2 to 4 weeks of healing time. Therefore, the patient population treated with photodynamic therapy may be different than those typically treated with topical 5-FU, and with limited treatment time, photodynamic therapy may represent a convenience. Similar to photodynamic therapy, cryotherapy with liquid nitrogen is used to treat patients with a small number of discrete lesions. However, cryotherapy may result in a large blister with a subsequent delay in healing time. In addition, pigmentary changes and scarring may occur. Data are inadequate regarding photodynamic therapy of other dermatologic lesions, including basal cell carcinoma, squamous cell carcinoma, acne vulgaris, hidradenitis suppurativa, mycoses or Bowen's disease.

Medical Policy Position Summary (Non-clinical summary statement for customer use)

In photodynamic therapy (PDT), the physician applies a photosensitizing agent, such as twenty percent topical aminolevulinic acid hydrochloride, directly onto the patient's lesions to treat premalignant cells such as non-hyperkeratotic actinic keratosis and malignant cells. The patient is sent home and scheduled to return within the time frame required for the light treatment to activate the photosensitive drug. The lesions are irradiated with a photodynamic therapy illuminator for a standard number of minutes. The exposure time does not depend on the number of lesions. The blue light exposure causes a cytotoxic

reaction with the topical agent that was applied to the lesions, killing the existing cells and preventing the spread of the suspect or malignant cells.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Inclusions:

Photodynamic therapy with topical ALA and exposure to blue light may be considered medically necessary as a treatment of non-hyperkeratotic actinic keratoses of the **face and scalp** only.

Exclusions: Photodynamic therapy with topical ALA and exposure to blue light is considered investigational for other dermatologic applications, including, but not limited to, acne vulgaris, squamous cell carcinoma, basal cell carcinoma, hidradenitis suppurativa, mycoses or Bowen's disease.

Related Policies

N/A

Medicare Information

Actinic keratoses (AKs), also known as solar keratoses, are common, sun-induced skin lesions that are confined to the epidermis and have the potential to become a skin cancer. Various options exist for treating AKs. Clinicians should select an appropriate treatment based on the patient's medical history, the lesion's characteristics, and on the patient's preference for a specific treatment. Commonly performed treatments for AKs include cryosurgery with liquid nitrogen, topical drug therapy, and curettage. Less commonly performed treatments for AK include dermabrasion, excision, chemical peels, laser therapy and photodynamic therapy (PDT).

An alternative approach to treating AKs is to observe the lesions over time and remove them only if they exhibit specific clinical features suggesting possible transformation to invasive squamous cell carcinoma (SCC). Medicare covers the destruction of actinic keratoses without restrictions based on lesion or patient characteristics.

Transmittal number 127, Manual section number 35-101.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicaid Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

References

- Blue Cross Blue Shield Association, "Photodynamic Therapy with Topical 5-Aminolevulinic Acid for the Treatment of Actinic Keratoses," *Medical Policy Reference Manual*, #2.01.44, Issue Date 1:2003, last update 7/20/06.
- CMS National Coverage Decision, "Treatment of Actinic Keratosis", Policy # DERM-009, Effective date 11/26/2001
- *Hayes Medical Technology Directory*, "Photodynamic Therapy for Actinic Keratoses," Lansdale, PA: HAYES, Inc., May 23, 2004. Update search October 15, 2006.
- *Hayes Medical Technology Directory*, "Photodynamic Therapy for Barrett's Esophagus and Esophageal Cancer," Lansdale, PA: HAYES, Inc., February 6, 2002. Update search: January 28, 2007.
- Nestor, Mark S., MD, PhD, "The Use of Photodynamic Therapy for Treatment of Acne Vulgaris,' *Dermatologic Clinics*, Volume 25, Issue 1, January 2007.
- Nootheti, Pavan K., MD and Mitchel P. Goldman, MD, "Aminolevulinic Acid-Photodynamic Therapy for Photorejuvenation," *Dermatologic Clinics*, Volume 25, Issue 1 January 2007.
- Piacquadio D, J., "Photodynamic therapy with aminolevulinic acid topical solution and visible blue light in the treatment of multiple actinic keratoses of the face and scalp: investigator-blinded, phase 3, multicenter trials," *Arch Dermatol*, January 2004, Volume 140, Number 1, pp. 41-46.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through May 14, 2007, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
2/16/04	2/16/04	3/12/04	Joint medical policy established
9/1/07	7/3/07	08/29/07	Routine maintenance; policy retired

Next Review Date: This is an established policy and no longer subject to routine review.

Pre-Consolidation Medical Policy History

Original Policy Date		Comments
BCN	N/A	Revised: N/A
BCBSM	N/A	Revised: N/A

BLUE CARE NETWORK
POLICY: PHOTODYNAMIC THERAPY FOR TREATMENT OF
ACTINIC KERATOSES AND OTHER SKIN LESIONS

I. Coverage Determination:

BCN covers photodynamic therapy with topical aminolevulinic acid and exposure to red or blue light as a nonsurgical treatment of actinic keratoses of the face and scalp. It is considered investigational (and therefore not covered) for other dermatologic applications.

Photodynamic therapy as a technique of skin rejuvenation, hair removal, or other cosmetic indications is considered not medically necessary. BCN does not cover procedures that are primarily cosmetic in nature.

II. Benefit Information:

Covered as a treatment of keratoses of the **face and scalp** only.

III. Benefit Exclusions:

Photodynamic therapy with topical ALA and exposure to blue light is considered investigational for other dermatologic applications, including but not limited to the treatment of acne, squamous cell carcinoma, basal cell carcinoma and Bowen's disease.

IV. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Appropriate copayments will apply.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Payment is based on BCN payment rules, individual certificate benefits and certificate riders.

V. Effective Date:

Policy updated: 9/1/07
Joint policy effective date: 2/16/04
Supersedes benefit information of: N/A