



Status

Active

## Medical and Behavioral Health Policy

Section: Medicine

Policy Number: II-46

Effective Date: 05/19/2014

Blue Cross and Blue Shield of Minnesota medical policies do not imply that members should not receive specific services based on the recommendation of their provider. These policies govern coverage and not clinical practice. Providers are responsible for medical advice and treatment of patients. Members with specific health care needs should consult an appropriate health care professional.

## PHOTODYNAMIC THERAPY FOR SKIN CONDITIONS

**Description:** Photodynamic therapy (PDT) refers to light activation of a photosensitizer to generate highly reactive oxygen intermediaries, which ultimately cause tissue injury and necrosis. When applied topically, the photosensitizing agent 5-aminolevulinic acid (5-ALA) or its methyl ester, methyl aminolevulinate (MAL), passes readily through the abnormal keratin overlying the lesion and accumulates preferentially in dysplastic cells. 5-ALA and MAL are metabolized by the underlying cells to photosensitizing concentrations of porphyrins. Subsequent exposure to photoactivation (maximum absorption at 404–420 nm and 635 nm) generates reactive oxygen species that are cytotoxic, ultimately destroying the lesion. PDT can cause erythema, burning, and pain. Healing occurs within 10 to 14 days.

PDT has been investigated as a treatment of actinic keratoses and as a treatment of other superficial dermatologic lesions such as superficial and nodular basal cell carcinoma, Bowen's disease, acne vulgaris, mycoses, and hidradenitis suppurativa. Cosmetic indications include skin rejuvenation and hair removal.

The scope of this policy does not include other forms of light therapy, such as targeted phototherapy or photochemotherapy, used to treat skin conditions. Targeted phototherapy describes the use of ultraviolet light that can be focused on specific body areas or lesions. Photochemotherapy uses a phototoxic agent (e.g., a psoralen derivative) in conjunction with long wavelength ultraviolet A (UVA) light (sunlight or artificial) to treat certain skin conditions. See the Cross Reference section for more information on policies related to phototherapy and photochemotherapy for treatment of skin conditions.

Levulan® Kerastick™, a topical preparation of ALA, received approval by the U.S. Food and Drug Administration (FDA) in conjunction with illumination with the BLU-U™ Blue Light

Photodynamic Therapy Illuminator for the treatment of non-hyperkeratotic actinic keratoses of the face and scalp. A topical preparation of MAL (Metvixia® - PhotoCure ASA, Norway) and the Aktelite CL128 lamp have received FDA approval 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.

Skin conditions addressed in this policy include, but are not limited to, the following:

**Acne vulgaris:** This is a common condition in which the sebaceous glands in the skin become inflamed, producing comedones, swelling and papules.

**Actinic keratoses:** Rough, scaly or warty premalignant growths on sun-exposed skin. These commonly occur in older individuals, particularly those with fair complexions. In some cases, actinic keratoses may progress to squamous cell carcinoma.

**Basal cell carcinoma:** Most often found in light-skinned individuals, basal cell carcinoma is the most common of the cutaneous malignancies. Although the tumors rarely metastasize, they can be locally invasive if left untreated leading to significant local destruction and disfigurement. Nodular and superficial basal cell carcinoma are the most prevalent forms.

**Bowen's disease:** A squamous cell carcinoma in situ, Bowen's disease has the potential for significant lateral growth. Metastases are rare, with less than 5% of cases advancing to invasive squamous cell carcinoma.

**Hidradenitis suppurativa:** The disease is characterized by the development of recurrent, boil-like nodular lesions and deep pus-containing abscesses that may eventually rupture through the [skin](#). The underlying cause of hidradenitis suppurativa is unknown.

**Mycoses:** These are fungal infections usually confined to the outer layers of skin. Examples of skin mycoses include ringworm and athlete's foot. These may also be referred to as tinea.

**Sebaceous gland hyperplasia:** A common condition in adults, sebaceous hyperplasia papules are benign with no known potential for malignant transformation.

**Policy:**

- I. Photodynamic therapy may be considered **MEDICALLY NECESSARY** for the treatment of the following conditions:
  - A. Actinic keratoses;
  - B. Superficial basal cell skin cancer only when surgery and radiation are contraindicated;
  - C. Bowen's disease (squamous cell carcinoma in situ) only when surgery and radiation are contraindicated.
- II. Photodynamic therapy is considered **INVESTIGATIVE** for all other dermatologic applications, including but not limited to:
  - A. Acne vulgaris

- B. Non-superficial basal cell carcinomas
- C. Sebaceous gland hyperplasia
- D. Hidradenitis suppurativa
- E. Mycoses

III. Photodynamic therapy as a technique for hair removal and skin rejuvenation is considered **COSMETIC**.

**Coverage:**

Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member's summary plan description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

**Coding:**

*The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.*

**CPT:**

96567 Photodynamic therapy by external application of light to destroy pre-malignant and/or malignant lesions of the skin and adjacent mucosa (e.g., lip) by activation of photosensitive drug(s), each phototherapy exposure session

**HCPCS:**

J7308 Aminolevulinic acid HCl for topical administration, 20%, single unit dosage form (354 mg)

J7309 Methyl aminolevulinic acid (mal) for topical administration, 16.8%, 1 gram

**Policy History:**                    **Developed March 9, 2005**

**Most recent history:**  
Reviewed February 9, 2011  
Reviewed February 8, 2012  
Reviewed February 13, 2013  
Revised March 12, 2014

**Cross Reference:**                Non Pharmacologic Treatment of Rosacea, II-08  
Non Pharmacologic Treatment of Acne, II-33  
Phototherapy for the Treatment of Psoriasis, II-39

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