Photodynamic Therapy for the Treatment of Actinic Keratoses and Other Skin Lesions

Policy Number: MM.02.016
Original Effective Date: 04/01/2008
Line(s) of Business: HMO; PPO; QUEST
Current Effective Date: 02/28/2014
Section: Medicine
Place(s) of Service: Office

I. Description

Photodynamic therapy (PDT) refers to light activation of a photosensitizer to generate highly reactive oxygen intermediaries, which ultimately cause tissue injury and necrosis. Healing occurs within 10 to 14 days, with generally acceptable cosmetic results. PDT with topical 5-aminolevulinic acid (ALA) has been investigated 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, acne vulgaris, mycoses, hidradenitis suppurativa, and superficial and nodular basal cell carcinoma. Potential cosmetic indications include skin rejuvenation and hair removal.

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, curettage (either alone or combined with electrodessication), and laser surgery. Non-surgical treatments include cryotherapy, topical chemotherapy (5-fluorouracil [5-FU]), chemexfoliation (also known as chemical peels), and dermabrasion. Topical treatments 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.

Basal cell carcinoma (BCC) is the most common cutaneous malignancy in humans and is most often found in light-skinned individuals. Although the tumors rarely metastasize, they can lead to significant local destruction and disfigurement. The most common forms of BCC are nodular BCC and superficial BCC. Bowen's disease is a squamous cell carcinoma (SCC) in situ with the potential for significant lateral spread. Metastases are rare, with less than 5% of cases advancing to invasive SCC. Lesions may appear on sun-exposed or covered skin. Excision surgery is the most common and preferred treatment for smaller non-melanoma skin lesions and those not in problematic areas, such as the face and digits. Other established treatments include topical 5-FU, imiquimod, and cryotherapy. Poor cosmesis resulting from surgical procedures and skin irritation induced by topical agents can be significant problems.
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 following indication: “The Levulan Kerastick for topical solution plus blue light illumination using the BLU-U Blue Light Photodynamic Therapy Illuminator is indicated for the treatment of non-hyperkeratotic actinic keratoses of the face and scalp.” As described in the package insert, the technique involves two steps starting with application of the ALA topical solution in the physician's office. The patient is told to return at which point the lesion is exposed to blue light.

Another variant of PDT for skin lesions is Metvixia® and the Aktilite CL128 lamp, each of which received FDA approval in July 2004. Metvixia® (Galderma, SA, Switzerland; PhotoCure ASA, Norway) consists of the topical application of methyl aminolevulinate (MAL) in contrast to ALA used in the Kerastick procedure, followed by exposure with the Aktilite CL 128 lamp, a red light source (in contrast to the blue light source in the Kerastick procedure). Broadband light sources (containing the appropriate wavelengths), intense pulsed light (IPL), pulsed dye lasers (PDL), and potassium titanyl phosphate (KTP) lasers have also been used. Metvixia 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.

II. Criteria/Guidelines

A. Photodynamic therapy is covered (subject to Limitations/Exclusions and Administrative Guidelines) for the treatment of:
   1. Nonhyperkeratotic actinic keratoses of the face and scalp
   2. Superficial basal cell skin cancer only when surgery and radiation are contraindicated
   3. Bowen’s disease (squamous cell carcinoma in situ) only when surgery and radiation are contraindicated.

III. Limitations/Exclusions

A. Photodynamic therapy is not covered for the treatment of other dermatologic applications, including but not limited to, acne vulgaris, non-superficial basal cell carcinomas, hidradenitis suppurativa, and mycoses, due to the lack of scientific evidence demonstrating improved health outcomes.

B. Photodynamic therapy as a treatment of rosacea or as a technique of skin rejuvenation, hair removal, or other cosmetic indication is not a covered benefit.

C. Photodynamic therapy for actinic keratoses is limited to use on nonhyperkeratotic lesions on the face and scalp. Use for hyperkeratotic lesions and use on other body areas is not covered due to the lack of scientific evidence demonstrating improved health outcomes.

IV. Administrative Guidelines

Precertification is not required for this service. Documentation supporting the medical necessity should be legible, maintained in the patient's medical record and must be made available to HMSA
Photodynamic Therapy for the Treatment of Actinic Keratoses and Other Skin Lesions

upon request. HMSA reserves the right to perform retrospective review using the above criteria to validate if services rendered met payment determination criteria.

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<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>96567</td>
<td>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 session</td>
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<table>
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<tr>
<th>HCPCS Code</th>
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<tr>
<td>J7308</td>
<td>Aminolevulinic acid HCl for topical administration, 20%, single unit dosage form (354 mg).</td>
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<tr>
<td>J7309</td>
<td>Methyl aminolevulinate (MAL) for topical administration, 16.8%, 1 gram</td>
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<tr>
<th>ICD-9-CM Code</th>
<th>Description</th>
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<tr>
<td>702.0</td>
<td>Actinic keratosis</td>
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ICD-10 codes are provided for your information. These will not become effective until 10/1/2014.

<table>
<thead>
<tr>
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<td>L57.0</td>
<td>Actinic Keratoses</td>
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V. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.
VI. References


