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Dermatologic Applications of Photodynamic Therapy Corporate Medical Policy

File Name: Dermatologic Applications of Photodynamic Therapy
File Code: 2.01.VT44
Origination: 08/2016
Last Review: 02/2024
Next Review: 02/2025
Effective Date: 03/01/2024

Description/Summary

Photodynamic therapy (PDT) refers to light activation of a photosensitizer to generate highly reactive intermediaries, which ultimately cause tissue injury and necrosis. Photosensitizing agents are being proposed for use with dermatologic conditions such as actinic keratoses and nonmelanoma skin cancers.

For individuals who have nonhyperkeratotic actinic keratoses on the face or scalp who receive PDT, the evidence includes randomized controlled trials (RCTs). Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity.

Evidence from multiple RCTs has found that PDT improves the net health outcome in patients with nonhyperkeratotic actinic keratoses on the face or scalp compared with placebo or other active interventions. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have nonhyperkeratotic AKs on the upper extremities who receive PDT, the evidence includes RCTs. The relevant outcomes are symptoms, change in disease status, QOL, and treatment-related morbidity. In two placebo controlled RCTs, significantly more patients had a complete clearance of AKs with ALA/PDT with blue light compared to placebo at 12 weeks, and a third found a significantly greater reduction in mean lesion count at 4 weeks. Two small RCTs compared ALA/PDT using red light to imiquimod or 5- fluorouracil and found similar efficacy between the active treatment groups after six months of follow-up. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have low-risk basal cell carcinoma who receive PDT, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Systematic reviews of RCTs have found that PDT may not be as effective as surgery for low-risk superficial and nodular basal cell carcinoma. In the small number of

trials available, PDT was more effective than placebo. The available evidence from RCTs has suggested that PDT has better cosmetic outcomes than surgery. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have squamous cell carcinoma in situ who receive PDT, the evidence includes meta-analyses and RCTs. The relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Meta-analyses and RCTs have found that PDT has similar or greater efficacy compared with cryotherapy and 5- fluorouracil. Additionally, adverse events and cosmetic outcomes appear to be better after PDT. Few RCTs have compared PDT with surgery or radiotherapy; as a result, conclusions cannot be drawn about PDT compared with these other standard treatments. Current guidance from the National Comprehensive Cancer Network notes that topical modalities, including PDT, may have lower cure rates than with surgical treatment. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have nonmetastatic invasive squamous cell carcinoma who receive PDT, the evidence includes observational studies and a systematic review of observational studies The relevant outcomes are overall survival, symptoms, change in disease status, quality of life, and treatment-related morbidity. Conclusions cannot be drawn from small, uncontrolled studies. RCTs are needed to determine the safety and efficacy of PDT for this condition. The evidence is insufficient to determine the effects of the technology on health outcomes.
For individuals who have acne who receive PDT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The available RCTs have not consistently found significantly better outcomes with PDT compared with other interventions, and meta- analyses did not find significantly better results with PDT versus placebo. Several trials have found that PDT is associated with high rates of adverse events leading to the cessation of treatment. Trials have tended to have relatively small sample sizes and used a variety of comparison interventions. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have noncancerous dermatologic skin conditions (eg, hidradenitis suppurativa, mycoses, port-wine stain) who receive PDT, the evidence includes case series, systematic reviews of uncontrolled series, and an RCT for port-wine stain. The relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. RCTs are needed to determine the safety and efficacy of PDT for these conditions. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy

Coding Information
Click the links below for attachments, coding tables & instructions.
Attachment I- Code Table & Instructions

When a service may be considered Medically Necessary

Photodynamic therapy may be considered **medically necessary** as a treatment of:

- Nonhyperkeratotic actinic keratoses of the face and scalp
- Nonhyperkeratotic actinic keratoses of the upper extremities
- Low-risk (e.g., superficial and nodular) basal cell skin cancer only when surgery and radiation are contraindicated
- Cutaneous squamous cell carcinoma in situ (Bowen disease) only when surgery and radiation are contraindicated

When a service is considered Investigational

Photodynamic therapy is considered **investigational** for other dermatologic applications, including, but not limited to, acne vulgaris, high-risk basal cell carcinomas, hidradenitis suppurativa and mycoses.

When a service is considered a Benefit Exclusion

Photodynamic therapy as a technique of skin rejuvenation, hair removal or cosmetic indications is considered **a benefit exclusion and, therefore, not covered**.

Policy Guidelines

Surgery or radiation is the preferred treatment for low-risk basal cell cancer and Bowen disease. If photodynamic therapy is selected for these indications because of contraindications to surgery or radiation, patients and physicians need to be aware that it may have a lower cure rate in comparison with surgery or radiation.

Photodynamic therapy typically involves 2 office visits: one to apply the topical ALA and a second visit to expose the patient to blue light. The second physician office visit, performed solely to administer blue light, should not warrant a separate Evaluation and Management CPT® code. Photodynamic protocols typically involve 2 treatments spaced a week apart; more than 1 treatment series may be required.

Reference Resources

1. Blue Cross and Blue Shield Association Medical Policy MPRM 2.01.44 - Dermatologic Applications of Photodynamic Therapy. Last Reviewed 01/2024. Accessed 02/2024.
2. Photodynamic Therapy. UpToDate. Literature review current through 01/2024. Accessed 02/2024.

Related Policies

Light Therapy for Dermatologic Conditions

Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer's benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical

practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member's contract/employer benefit plan language takes precedence.

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non- compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval is required and benefits are subject to all terms, limitations and conditions of the subscriber contract.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member's benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member's benefit.

Coverage varies according to the member's group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member's employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

08/2016	New policy. Adoption of BCBSA MPRM# 2.01.44
08/2017	Updated references. Updated related policy section.
01/2018	Updated descriptor on 96567 code and added 96573 & 96574 effective 01/01/2018.
01/2019	Updated to reflect the updated BCBSA medical policy MPRM #2.01.44. No changes to policy statement. Codes 96573 & 96574 changed to require prior approval.

02/2020	Updated to reflect the updated BCBSA medical policy MPRM #2.01.44. Added new indication and medical necessity statement for nonhyperkeratotic actinic keratoses of the upper extremities. Updated references.
03/2021	Policy Reviewed. References reviewed. MPRM 2.01.44 unchanged. No change to policy statement. Minor formatting changes.
03/2022	Policy Reviewed. References reviewed. No change to policy statement.
02/2023	Policy Reviewed. References updated. No change to policy statement.
02/2024	Policy Reviewed. Minor grammatical edits. References updated. No changes to policy statement.

Eligible providers

Qualified healthcare professionals practicing within the scope of their license(s).

Approved by BCBSVT Medical Directors

Tom Weigel, MD, MBA
Vice President & Chief Medical Officer

Tammaji P. Kulkarni, MD
Senior Medical Director

Attachment I
Coding Table & Instructions

The following codes will be considered as Medically Necessary when applicable criteria have been met.			
Code Type	**Number**	**Brief Description**	**Policy Instructions**
CPT®	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 per day	Prior Approval Required
CPT®	96573	Photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa with application and illumination/activation of photosensitizing drug(s) provided by a physician or other qualified health care professional, per day	Prior Approval Required

CPT®	96574	Debridement of premalignant hyperkeratotic lesion(s) (ie, targeted curettage, abrasion) followed with photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa with application and illumination/ activation of photosensitizing drug(s) provided by a physician or other qualified health care professional, per day	Prior Approval Required
HCPCS	J7308	Aminolevulinic acid hydrochloric acid for topical administration, 20%, single unit dosage form (354 mg)	
HCPCS	J7309	Methyl aminolevulinate (MAL) for topical administration, 16.8%, 1 gram	