



MASSACHUSETTS

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Medical Policy

Dermatologic Applications of Photodynamic Therapy

Table of Contents

- [Policy: Commercial](#)
- [Policy: Medicare](#)
- [Authorization Information](#)
- [Coding Information](#)
- [Description](#)
- [Policy History](#)
- [Information Pertaining to All Policies](#)
- [References](#)

Policy Number: 463

BCBSA Reference Number: 2.01.44

NCD/LCD: National Coverage Determination (NCD) for Treatment of Actinic Keratosis (250.4)

Related Policies

- Light Therapy for Psoriasis, #[698](#)
- Oncologic Applications of Photodynamic Therapy, Including Barrett's Esophagus, #[454](#)
- Photodynamic Therapy for Choroidal Neovascularization, #[599](#)

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

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 (eg 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.

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.

Photodynamic therapy as a technique of skin rejuvenation, hair removal, or other cosmetic indications is considered **NOT MEDICALLY NECESSARY**.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

Medical necessity criteria and coding guidance can be found through the link(s) below.

[National Coverage Determinations \(NCDs\)](#)

National Coverage Determination (NCD) for Treatment of Actinic Keratosis (250.4)

Note: To review the specific NCD, please remember to click “accept” on the CMS licensing agreement at the bottom of the CMS webpage.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for situations where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .
Medicare HMO Blue SM	Prior authorization is not required .
Medicare PPO Blue SM	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
96567	Photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa <u>with application and illumination/activation of photosensitive drug(s), per day</u>
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
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

HCPCS Codes

HCPCS codes:	Code Description
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J7308	Aminolevulinic hydrochloric acid for topical administration, 20%, single unit dosage form (354 mg)
J7309	Methyl aminolevulinate (MAL) for topical administration, 16.8%, 1 gram
J7345	Aminolevulinic acid HCl for topical administration, 10% gel, 10 mg

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT and HCPCS codes above if medical necessity criteria are met:

ICD- 10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
C44.01	Basal Cell Carcinoma Of Skin Of Lip
C44.111	Basal Cell Carcinoma Of Skin Of Unspecified Eyelid, Including Canthus
C44.112	Basal Cell Carcinoma Of Skin Of Right Eyelid, Including Canthus
C44.119	Basal Cell Carcinoma Of Skin Of Left Eyelid, Including Canthus
C44.211	Basal Cell Carcinoma Of Skin Of Unspecified Ear And External Auricular Canal
C44.212	Basal Cell Carcinoma Of Skin Of Right Ear And External Auricular Canal
C44.219	Basal Cell Carcinoma Of Skin Of Left Ear And External Auricular Canal
C44.310	Basal Cell Carcinoma Of Skin Of Unspecified Parts Of Face
C44.311	Basal Cell Carcinoma Of Skin Of Nose
C44.319	Basal Cell Carcinoma Of Skin Of Other Parts Of Face
C44.41	Basal Cell Carcinoma Of Skin Of Scalp And Neck
C44.510	Basal Cell Carcinoma Of Anal Skin
C44.511	Basal Cell Carcinoma Of Skin Of Breast
C44.519	Basal Cell Carcinoma Of Skin Of Other Part Of Trunk
C44.611	Basal Cell Carcinoma Of Skin Of Unspecified Upper Limb, Including Shoulder
C44.612	Basal Cell Carcinoma Of Skin Of Right Upper Limb, Including Shoulder
C44.619	Basal Cell Carcinoma Of Skin Of Left Upper Limb, Including Shoulder
C44.711	Basal Cell Carcinoma Of Skin Of Unspecified Lower Limb, Including Hip
C44.712	Basal Cell Carcinoma Of Skin Of Right Lower Limb, Including Hip
C44.719	Basal Cell Carcinoma Of Skin Of Left Lower Limb, Including Hip
C44.81	Basal Cell Carcinoma Of Overlapping Sites Of Skin
C44.91	Basal Cell Carcinoma Of Skin, Unspecified
D04.0	Carcinoma In Situ Of Skin Of Lip
D04.10	Carcinoma In Situ Of Skin Of Unspecified Eyelid, Including Canthus
D04.111	Carcinoma in situ of skin of right upper eyelid, including canthus
D04.112	Carcinoma in situ of skin of right lower eyelid, including canthus
D04.121	Carcinoma in situ of skin of left upper eyelid, including canthus
D04.122	Carcinoma in situ of skin of left lower eyelid, including canthus
D04.20	Carcinoma In Situ Of Skin Of Unspecified Ear And External Auricular Canal
D04.21	Carcinoma In Situ Of Skin Of Right Ear And External Auricular Canal
D04.22	Carcinoma In Situ Of Skin Of Left Ear And External Auricular Canal
D04.30	Carcinoma In Situ Of Skin Of Unspecified Part Of Face
D04.39	Carcinoma In Situ Of Skin Of Other Parts Of Face
D04.4	Carcinoma In Situ Of Skin Of Scalp And Neck
D04.5	Carcinoma In Situ Of Skin Of Trunk
D04.60	Carcinoma In Situ Of Skin Of Unspecified Upper Limb, Including Shoulder
D04.61	Carcinoma In Situ Of Skin Of Right Upper Limb, Including Shoulder
D04.62	Carcinoma In Situ Of Skin Of Left Upper Limb, Including Shoulder
D04.70	Carcinoma In Situ Of Skin Of Unspecified Lower Limb, Including Hip

D04.71	Carcinoma In Situ Of Skin Of Right Lower Limb, Including Hip
D04.72	Carcinoma In Situ Of Skin Of Left Lower Limb, Including Hip
D04.8	Carcinoma In Situ Of Skin Of Other Sites
D04.9	Carcinoma In Situ Of Skin, Unspecified
L57.0	Actinic Keratosis

Description

Photodynamic Therapy

PDT refers to light activation of a photosensitizer to generate highly reactive intermediaries, which ultimately cause tissue injury and necrosis. Two common photosensitizing agents are 5-aminolevulinic acid (5-ALA) and its methyl ester, methyl aminolevulinate. When applied topically, these agents pass readily through abnormal keratin overlying the lesion and accumulate preferentially in dysplastic cells. The agents 5-ALA and methyl aminolevulinate are metabolized by underlying cells to photosensitizing concentrations of porphyrins. Subsequent exposure to photoactivation (maximum absorption at 404 to 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, with generally acceptable cosmetic results. PDT with topical ALA has been investigated primarily as a treatment of actinic keratoses (AKs).

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 (AKs) and nonmelanoma skin cancers.

For individuals who have nonhyperkeratotic AKs on the face or scalp who receive PDT, the evidence includes randomized controlled trials (RCTs). The relevant outcomes are symptoms, change in disease status, quality of life (QOL), and treatment-related morbidity. Evidence from multiple RCTs has found that PDT improves the net health outcome in patients with nonhyperkeratotic AKs 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. The relevant outcomes are symptoms, change in disease status, QOL, and treatment-related morbidity. Systematic reviews of RCTs have found that PDT may not be as effective as surgery for superficial and nodular basal cell carcinoma. In the small number of trials available, PDT was more effective than a 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 RCTs. The relevant outcomes are symptoms, change in disease status, QOL, and treatment-related morbidity. 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. 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, QOL, 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 a systematic review. The relevant outcomes are symptoms, change in disease status, QOL, and treatment-related morbidity. The available RCTs have not consistently found significantly better outcomes with PDT compared with other interventions, and a meta-analysis did not find significantly better results with PDT vs placebo. Several trials have found that PDT is associated with high rates of adverse events leading to the cessation of treatment. Trials 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, QOL, 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 History

Date	Action
5/2020	BCBSA National medical policy review. Added new indication and medically necessary statement for nonhyperkeratotic actinic keratoses of the upper extremities. Effective 5/1/2020.
2/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
10/2018	Clarified coding information.
5/2018	Clarified coding information.
3/2018	New references added from BCBSA National medical policy.
1/2018	Clarified coding information.
1/2017	New references added from BCBSA National medical policy.
3/2016	New references added from BCBSA National medical policy.
6/2015	BCBSA National medical policy review. Superficial basal cell carcinoma changed to low-risk (ie superficial or nodular) basal cell carcinoma. Non-superficial basal cell carcinoma changed to high-risk basal cell carcinoma. Dermatologic Applications of Photodynamic Therapy transferred from policy #068, Plastic Surgery. Effective 6/1/2015.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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