MEDICAL POLICY

POLICY TITLE	DERMATOLOGIC APPLICATIONS OF PHOTODYNAMIC THERAPY
POLICY NUMBER	MP- 4.018

Original Issue Date (Created):	**7/1/2002**
Most Recent Review Date (Revised):	**6/1/2020**
Effective Date:	**9/1/2020**

I. POLICY

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

- Actinic keratoses of the face and scalp.
- 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.

Photodynamic therapy is considered **investigational** for other dermatologic applications, including, but not limited to, acne vulgaris, high-risk basal cell carcinomas, hidradenitis suppurativa, or mycoses. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Photodynamic therapy as a technique of skin rejuvenation, hair removal, or other cosmetic indications is considered **not medically necessary**.

Policy Guidelines

Surgery and radiation are the preferred treatments 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 compared with surgery or radiation.

Photodynamic therapy typically involves two (2) office visits: one to apply the topical aminolevulinic acid 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 two (2) treatments spaced a week apart; more than one (1) treatment series may be required.

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Cross-reference:

MP-1.004 Cosmetic and Reconstructive Surgery
MP-4.019 Oncological Applications of Photodynamic Therapy including Barrett's Esophagus
MP-2.046 Ultraviolet Light Therapies
MP-4.008 Photodynamic Therapy for Choroidal Neovascularization

II. PRODUCT VARIATIONS

TOP

This policy is only applicable to certain programs and products administered by Capital BlueCross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO: Refer to FEP Benefit Brochure for information on Lab, X-ray and Other Diagnostic Tests: https://www.fepblue.org/benefit-plans/benefit-plans-brochures-and-forms

Note **-** The Federal Employee Program (FEP) Service Benefit Plan does not have a medical policy related to these services.

III. DESCRIPTION/BACKGROUND

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Photodynamic Therapy

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 (MAL). When applied topically, these agents pass readily through abnormal keratin overlying the lesion and accumulate preferentially in dysplastic cells. The agent's 5-ALA and MAL 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.

Regulatory Status

In 1999, Levulan® Kerastick™, a topical preparation of ALA, in conjunction with illumination with the BLU-U™ Blue Light Photodynamic Therapy Illuminator, was approved by the U.S. Food and Drug Administration (FDA) for the treatment of nonhyperkeratotic actinic keratoses of the face and scalp. In 2018, the indication was expanded to include nonhyperkeratotic AKs of the upper extremities. The product is applied in the physician's office. FDA product code: MVF.

In 2016, the FDA approved Ameluz® (aminolevulinic acid hydrochloride) gel, 10% (BF-200 ALA; Biofrontera AG) in combination with PDT using BF-RhodoLED lamp, to be used for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. The treatment is to be administered by a health care provider.

A 5-ALA patch technology is available outside of the United States through an agreement between Intendis (now Bayer HealthCare) and Photonamic. The 5-ALA patch is not approved by the FDA.

Another variant of PDT for skin lesions is Metvixia® used with the Aktilite CL128 lamp, each of which received FDA approval in 2004. Metvixia® (Galderma, Switzerland; Photocure, Norway) consists of the topical application of MAL (in contrast to ALA used in the Kerastick™ procedure), followed by exposure with the Aktilite CL128 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 (FDA product code: ONF), pulsed dye lasers, and potassium-titanyl-phosphate lasers have also been used. Metvixia® is indicated for the treatment of nonhyperkeratotic actinic keratoses of the face and scalp in immunocompetent patients when used with lesion preparation (débridement using a sharp dermal curette) in the physician's office when other therapies are unacceptable or considered medically less appropriate. FDA product codes: GEX and LNK

IV. RATIONALE

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Summary of Evidence

For individuals who have nonhyperkeratotic actinic keratoses on the face or scalp who receive PDT, the evidence includes 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 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 RCTs. Relevant outcomes are symptoms, change in disease status, quality of life, 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. 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 a systematic review. 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 a meta-analysis 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 (e.g., hidradenitis suppurativa, mycoses, port wine stain) who receive PDT, the evidence includes case series and systematic reviews of uncontrolled series. 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.

V. DEFINITIONS

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CHEMOSURGERY is the destruction of tissue by the use of chemical compounds.

CRYOSURGERY is the use of extremely cold probes to destroy unwanted, cancerous, or infected tissue.

ELECTRODESSICATION is the destruction of cells by application of electrical energy similar to, but to a lesser intensity than, electrocoagulation.

HYPERKERATOSIS refers to hypertrophy of the corneous layer of the skin.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes®								
96567	96573	96574						

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HCPCS Codes	Description
J7308	Aminolevulinic acid HCl for topical administration, 20%, single unit dosage form (354 mg)
J7309	Methyl aminolevulinate (MAL) for topical administration, 16.8%, 1 g
J7345	Aminolevulinic acid HCL for topical administration, 10% gel, 10 mg

ICD-10-CM Diagnosis Codes	Description
C44.01	Basal cell carcinoma of skin of lip
C44.111	Basal cell carcinoma of skin of unspecified eyelid, including canthus
C44.1121	Basal cell carcinoma of skin of right upper eyelid, including canthus
C44.1122	Basal cell carcinoma of skin of right lower eyelid, including canthus
C44.1191	Basal cell carcinoma of skin of left upper eyelid, including canthus
C44.1192	Basal cell carcinoma of skin of left lower 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
D04.0	Carcinoma in situ of skin of lip
D04.10	Carcinoma in situ of skin of unspecified eyelid, including canthus
D04.11	Carcinoma in situ of skin of right eyelid, including canthus
D04.121	Carcinoma in situ of the 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

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ICD-10-CM Diagnosis Codes	Description
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

IX. REFERENCES

TOP

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X. POLICY HISTORY

TOP

MP 4.018	**CAC 9/30/03**
	CAC 5/31/05
	CAC 2/28/06
	CAC 2/27/07
	CAC 3/25/08
	CAC 11/25/08
	CAC 1/26/10
	7/30/10 Administrative update. Added clarification of red light therapy.
	CAC 4/26/11 Consensus review.
	CAC 2/28/12 Adopt BCBSA. Policy title revised to "Dermatologic Applications of Photodynamic Therapy and now is specific to photodynamic therapy for treatment of dermatologic conditions. Surgical excision, chemosurgical destruction, cryosurgery, curettage, and electrodessication for treatment of actinic keratosis have been removed from the policy with this change. FEP variation revised.
	CAC 3/26/13 Consensus review. References updated but no changes to the policy statements. Codes reviewed.
	CAC 1/28/14 Consensus review. Rationale section added. No change to policy statements. References updated.
	CAC 1/27/15 Consensus review. References and rationale updated. No changes to the policy statements.
	CAC 1/26/16 Consensus review. No change to policy statements. References and rationale reviewed. Changed LCD number from L27527 to L34938 due to Novitas update to ICD 10. Coding reviewed.

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	1/1/17 Administrative update. Product variation section reformatted.
	CAC 3/28/17 Consensus review. In medically necessary statement, superficial basal cell carcinoma changed to low-risk (i.e., superficial or nodular) basal cell carcinoma. In investigational statement, non-superficial basal cell carcinoma changed to high-risk basal cell carcinoma. No change to intent of statements. References and rationale updated. Coding Reviewed.
	1/1/18 Administrative update. Medicare variations removed from Commercial Policies. Added new codes J7345, 96573, and 96574; effective 1/1/18.
	1/15/18 Consensus review. No change to policy statements. References and rationale updated.
	7/1/18 Administrative update. Diagnosis codes updated.
	10/1/18 Administrative update. Removed deleted ICD-10 codes and added new ICD-10 codes effective 10/1/18.
	1/14/19 Consensus review. Minor edits to the policy statement do not change intent. Background and references updated. Rationale condensed.
	2/3/20 Minor review. Criteria updated to include nonhyperkeratitic actinic keratoses of the upper extremities. Updated Regulatory Status (FDA indications), summary of evidence and added FEP PPO note. Coding reviewed, removed diagnosis code D04.12 and added D04.121 and D04.112. Effective 6/1/2020.
	6/1/20 Minor review. Revised medically necessary criteria: requirement that actinic keratosis be “non-hyperkeratotic” was removed.

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