Light Therapy for Psoriasis

Policy # 00131
Original Effective Date: 03/25/2002
Current Effective Date: 12/14/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Dermatologic Applications of Photodynamic Therapy is addressed separately in medical policy 00098.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider psoralen plus ultraviolet A (PUVA) for the treatment of severe, disabling psoriasis, which is not responsive to other forms of conservative therapy (e.g., topical corticosteroids, coal/tar preparations, and ultraviolet light), to be **eligible for coverage.****

Based on review of available data, the Company may consider the use of targeted phototherapy to be **eligible for coverage**** for the treatment of moderate to severe psoriasis comprising less than 20% body area for which narrowband ultraviolet B (NB-UVB) or psoralen plus ultraviolet A (PUVA) are indicated.

Based on review of available data, the Company may consider the use of targeted phototherapy to be **eligible for coverage**** for the treatment of mild to moderate psoriasis comprising less than 20% body area that is unresponsive to conservative treatment.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

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Based on review of available data, the Company may consider home ultraviolet light therapy to be **eligible for coverage.****

Patient Selection Criteria
Coverage eligibility may be considered for home ultraviolet light therapy when ALL of the following criteria are met:

- The device must be approved for home use by the Food and Drug Administration (FDA) and appropriate for the body surface and area treated; AND.
- The member has severe psoriasis, i.e. >10% body surface area (BSA) or if affecting hands, feet, genitalia can be <10%, with a history of frequent flares, with documented response to in-office phototherapy (as measured by BSA), for which narrowband ultraviolet B (NB-UVB) is prescribed and indicated; AND
- Long-term maintenance UV light treatment is planned and patient is unable to attend office-based treatment; AND
- The member is motivated, able to administer the treatment correctly, willing and able to keep records of treatments and attend regular follow-up visits with prescribing physician.

Note: Tanning beds are not eligible for coverage.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers targeted phototherapy as first line treatment of mild psoriasis to be **investigational.***

Based on review of available data, the Company considers targeted phototherapy for the treatment of generalized psoriasis or psoriatic arthritis to be **investigational.***

When Services Are Considered Not Medically Necessary

The use of home ultraviolet light therapy when patient selection criteria are not met is considered to be **not medically necessary.****

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Policy Guidelines

Disease severity is minimally defined by body surface area (mild psoriasis affects <5% of body surface area, moderate psoriasis affects 5%-10%, and severe disease affects >10% body surface area). However, lesion characteristics (eg, location and severity of erythema, scaling, induration, pruritus) and impact on quality of life are also taken into account (see references 1-3). For example, while a handprint is equal to approximately 1% body surface area, lesions on the hands, feet, or genitalia that cause disability may be classified as moderate-to-severe. The Psoriasis Area and Severity Index may be used as an outcome measure in clinical research. Clinical assessment of disease severity is typically qualitative.

Established treatments for psoriasis include the use of topical ointments and ultraviolet light ("light lamp") treatments. Lasers and targeted ultraviolet B lamps are considered equivalent devices; targeted ultraviolet devices are comparable with ultraviolet light panels for treatment purposes. First-line treatment of ultraviolet-sensitive lesions may involve around 6 to 10 office visits; treatment of recalcitrant lesions may involve around 24 to 30 office visits. Maintenance therapy or repeat courses of treatment may be required.

During psoralen plus ultraviolet A therapy, the patient needs to be assessed on a regular basis to determine the effectiveness of the therapy and the development of adverse effects. These evaluations are essential to ensure that the exposure dose of radiation is kept to the minimum compatible with adequate control of disease. Therefore, psoralen plus ultraviolet A is generally not recommended for home therapy.

Background/Overview

Treatment of Psoriasis

Topical therapy (eg, corticosteroids, vitamin D analogues) is generally considered first-line treatments of psoriasis, especially for mild disease. Phototherapy and systemic therapy are treatment options for patients with more extensive and/or severe disease and those who fail conservative treatment with topical agents. Phototherapy is available in various forms including exposure to natural sunlight, use of broadband ultraviolet B devices, narrowband ultraviolet B (NB-UVB) devices, targeted phototherapy, and psoralen plus ultraviolet A (PUVA). NB-UVB is an established treatment for psoriasis, based on efficacy and safety. This evidence review addresses two alternative

treatments: targeted phototherapy, which uses ultraviolet light that can be focused on specific body areas or lesions, and PUVA.

Targeted Phototherapy
Potential advantages of targeted phototherapy include the ability to use higher treatment doses and to limit exposure to surrounding tissue. Broadband ultraviolet B devices, which emit wavelengths from 290 to 320 nm, have been largely replaced by NB-UVB devices. NB-UVB devices eliminate wavelengths below 296 nm, which are considered erythemogenic and carcinogenic but not therapeutic. NB-UVB is more effective than broadband ultraviolet B and approaches PUVA in efficacy. Original NB-UVB devices consisted of a Phillips TL-01 fluorescent bulb with a maximum wavelength (lambda max) at 311 nm. Subsequently, an excimer (excited dimer) laser using xenon chloride (XeCl) and lamps were developed as targeted NB-UVB treatment devices; they generate monochromatic or very narrow band radiation with a lambda max of 308 nm. Targeted phototherapy devices are directed at specific lesions or affected areas, thus limiting exposure to the surrounding normal tissues. They may, therefore, allow higher dosages compared with a light box, which could result in fewer treatments to produce clearing. The original indication of the excimer laser was for patients with mild-to-moderate psoriasis, defined as involvement of less than 10% of the skin. Newer XeCl laser devices are faster and more powerful than the original models, which may allow the treatment of patients with more extensive skin involvement (10%-20% body surface area).

Psoralen Plus Ultraviolet A
PUVA uses a psoralen derivative in conjunction with long-wavelength ultraviolet A (UVA) light (sunlight or artificial) for photochemotherapy of skin conditions. Psoralens are tricyclic furocoumarins that occur in certain plants and can also be synthesized. They are available in oral and topical forms. Oral PUVA is generally given 1.5 hours before exposure to UVA radiation. Topical PUVA therapy refers to the direct application of the psoralen to the skin with subsequent exposure to UVA light. Bath PUVA is used in some European countries for generalized psoriasis, but the agent used (trimethylpsoralen) is not approved by the Food and Drug Administration (FDA). Paint PUVA and soak PUVA are other forms of topical application of psoralen and are often used for psoriasis localized to the palms and soles. In paint PUVA, 8-methoxypsoralen in ointment or lotion form is put directly on the lesions. With soak PUVA, the affected areas of the body are placed in a basin of water containing psoralen. With topical PUVA, UVA exposure is generally administered within 30 minutes of psoralen application.

PUVA has most commonly been used to treat severe psoriasis, for which there is no generally accepted first-line treatment. Each treatment option (eg, systemic therapies such as methotrexate, phototherapy, biologic therapies) has associated benefits and risks. Common minor toxicities associated with PUVA include erythema, pruritus, irregular pigmentation, and gastrointestinal tract symptoms; they generally can be managed by altering the dose of psoralen or ultraviolet light. Potential long-term effects include photoaging and skin cancer, particularly squamous cell carcinoma and possibly malignant melanoma. PUVA is generally considered more effective than targeted phototherapy for the treatment of psoriasis. However, the requirement of systemic exposure and the higher risk of adverse reactions (including a higher carcinogenic risk) have generally limited PUVA therapy to patients with more severe disease.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2001, XTRAC™‡ (PhotoMedex), a XeCl excimer laser, was cleared for marketing by the FDA through the 510(k) process for the treatment of mild-to-moderate psoriasis. The 510(k) clearance was subsequently obtained for a number of targeted UVB lamps and lasers, including newer versions of the XTRAC system (eg, XTRAC Ultra™‡), the VTRAC™‡ lamp (PhotoMedex), the BClear™‡ lamp (Lumenis), and the European manufactured Excilite™‡ and Excilite µ™‡ XeCl lamps. FDA product code: FTC.

In 2010, the Levia Personal Targeted Phototherapy®‡ UVB device (Daavlin; previously manufactured by Lerner Medical Devices) was cleared for marketing by the FDA through the 510(k) process for home treatment of psoriasis.

The oral psoralen products Oxsoralen-Ultra (methoxsalen soft gelatin capsules) and 8-MOP (methoxsalen hard gelatin capsules) have been approved by the FDA; both are made by Valeant Pharmaceuticals. Topical psoralen products have also received FDA approval (eg, Oxsoralen; Valeant Pharmaceuticals).

Rationale/Source

Light therapy for psoriasis includes phototherapy with ultraviolet B (UVB) light boxes, targeted phototherapy, and photochemotherapy with psoralen plus ultraviolet A (PUVA). Targeted phototherapy describes the use of ultraviolet light focused on specific body areas or lesions. PUVA

uses a psoralen derivative in conjunction with long-wavelength ultraviolet A light (sunlight or artificial) for photochemotherapy of skin conditions.

For individuals who have mild localized psoriasis who receive targeted phototherapy, there is little evidence. The relevant outcomes are symptoms, change in disease status, quality of life (QOL), and treatment-related morbidity. The evidence is lacking on the use of targeted phototherapy as the first-line treatment of mild psoriasis. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have mild psoriasis that is resistant to topical medications who receive targeted phototherapy, the evidence includes small within-subject studies. The relevant outcomes are symptoms, change in disease status, QOL, and treatment-related morbidity. The available pre-post studies have shown that targeted phototherapy can improve mild localized psoriasis (<10% body surface area) that has not responded to topical treatment. Targeted phototherapy is presumed to be safer or at least no riskier than whole body phototherapy, due to risks of exposing the entire skin to the carcinogenic effects of UVB light. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have moderate-to-severe localized psoriasis who receive targeted phototherapy, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. The relevant outcomes are symptoms, change in disease status, QOL, and treatment-related morbidity. Systematic reviews of small RCTs and non-RCTs in patients with moderate-to-severe psoriasis have found that targeted phototherapy has efficacy similar to whole-body phototherapy and supports the use of targeted phototherapy for the treatment of moderate-to-severe psoriasis comprising less than 20% of body surface area for which narrowband UVB or phototherapy with PUVA are indicated. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have generalized psoriasis who receive PUVA, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, change in disease status, QOL, and treatment-related morbidity. RCTs and systematic reviews of RCTs have found that PUVA is more effective than narrowband UVB, topical steroids, or ultraviolet A without psoralens in patients with generalized psoriasis. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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Supplemental Information

Practice Guidelines and Position Statements

American Academy of Dermatology – National Psoriasis Foundation
The AAD and NPF joint guidelines (2019) on the management and treatment of psoriasis with phototherapy give strong recommendations for the use of targeted UVB (Table 1).

Table 1. AAD-NPF Strength of Recommendations for Targeted UVB

No.	Recommendation	Strength
3.1	Targeted UVB phototherapy, including excimer laser, excimer light, and targeted NB-UVB light, for use in adults with localized plaque psoriasis, for individual lesions, or in patients with more extensive disease	A
3.2	For maximal efficacy, treatment with targeted UVB phototherapy for adults with localized plaque psoriasis should be carried out 2-3 times/wk rather than once every 1-2 wk	A
3.3	The starting dose for targeted UVB phototherapy for adults with localized plaque psoriasis can be determined on the basis of the MED or by a fixed-dose or skin phototype protocol	A
3.4	An excimer laser is more efficacious than an excimer light, which is more efficacious than localized NB-UVB light for the treatment of localized plaque psoriasis in adults	B
3.5	Recommend targeted UVB phototherapy, including excimer laser and excimer light, for use in adults with plaque psoriasis, including palmoplantar psoriasis	A
3.6	Excimer laser may be combined with topical corticosteroids in the treatment of plaque psoriasis in adults	B
3.7	Recommend excimer laser in the treatment of scalp psoriasis in adults	B

Table adapted from Elmets et al (2019).
NB-UVB: narrowband ultraviolet B; UVB: ultraviolet B.

The guidelines state of home NB-UVB therapy that evidence shows similar results regarding efficacy, quality of life, and side effects between patients with mild-to-severe psoriasis who received home treatments and those who received treatments at hospitals. In addition, home treatment was found to significantly lessen the burden on patients who had to travel to a phototherapy center.

American Academy of Dermatology
The American Academy of Dermatology (2010) guidelines on the management of psoriasis recommended that patients with psoriasis who are compliant could, under dermatologist supervision, be considered appropriate candidates for home ultraviolet B therapy. Targeted phototherapy was recommended for patients with mild, moderate, or severe psoriasis with less than 10% involvement of the body surface area. Systemic psoralen plus ultraviolet A was indicated in adults with generalized psoriasis resistant to topical therapy.

National Psoriasis Foundation
The National Psoriasis Foundation (2017) published consensus guidance based on a task force review of the literature on the treatment for psoriasis involving skinfolds (inverse or intertriginous) psoriasis. The treatment guidance for intertriginous or genital psoriasis stated: "....here is anecdotal evidence demonstrating the strong clinical efficacy of biologic treatment; with limited knowledge on the effects of biologics on intertriginous or genital psoriasis." The guidance on inverse psoriasis is provided in Table 2.

Table 2. Recommendations on Treatment of Inverse Psoriasis

Line of Therapy	Recommendation
First-line therapy	Low potency topical steroids for periods less than 2-4 wks
	Other topical therapies to consider are tacrolimus, pimecrolimus, calcitriol, or calcipotriene to avoid steroid side effects with long-term treatment
Second- and third-line therapies	Antimicrobial therapy, emollients, and tar-based products
	Axillary involvement can be treated with botulinum toxin injection to reduce perspiration and inhibit inflammatory substance release
	Excimer laser therapy or systemic agents

The National Psoriasis Foundation (2017) also published recommendations based on a review of the literature on the treatment for psoriasis in solid organ transplant patients. Because organ transplant patients are excluded from randomized controlled trials, there are limited data. The recommendations were based on case series (see Table 3).

Table 3. Recommendations on Treatment of Psoriasis for Solid Organ Transplant Patients

Line of Therapy	Recommendation
First-line therapy for mild-to-moderate psoriasis	Topical therapy
First-line therapy for moderate-to-severe psoriasis	• Acitretin with narrowband ultraviolet light or • Narrowband ultraviolet light or • Acitretin
Second-line therapy	Increasing the current anti-rejection drug dose
Severe psoriasis or refractory cases	Systemic or biologic therapies

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
Ultraviolet light treatment is covered; targeted phototherapy is not specifically mentioned. There is no national coverage determination on psoralen plus ultraviolet A.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 4.

Table 4. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03180866[a]	Evaluation of Efficacy, Duration of Remission and Safety of a Light and Occlusive Patch Therapy for Plaque Psoriasis	32	Mar 2018 (unknown; updated 06/08/17)
NCT02999776[a]	An Observer Partially-blinded, Lesion-randomized, Intra-patient Controlled, 3-arm, Phase I Study to Assess Safety and Efficacy of Laser-assisted Topical Etanercept Administration in Patients With Mild to Moderate Plaque Psoriasis	30	Jun 2018 (unknown; updated 12/21/16)
Unpublished			
NCT02294981	A Randomized Clinical Trial to Determine Whether a Novel Plaque-based Dosimetry Strategy Can Improve the Speed of Response to Treatment in Patients With Plaque Psoriasis (Photos)	30	Jun 2017 (terminated; updated 12/10/18)[b]

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.
[b] Protocol was changed to make it easier for treating doctors. No safety concerns.

References

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Policy History

Original Effective Date: 03/25/2002
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03/21/2002	Medical Policy Committee/ review
03/25/2002	Managed Care Advisory Council approval.
06/24/2002	Format revision. No substance change to policy
03/08/2004	Medical Director review
03/16/2004	Medical Policy Committee review. Format revision. Phototherapy medical policy deleted. Policy specific to ultraviolet light and laser treatment of skin conditions formulated.
03/29/2004	Manage Care Advisory Council approval
03/01/2005	Medical Director review
03/15/2005	Medical Policy Committee review
04/04/2005	Managed Care Advisory Council approval
11/02/2005	Medical Director review

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11/15/2005	Medical Policy Committee review. Format revision. FDA approval information added. Updated coverage eligibility to include use of UVB in treatment of psoriasis.
01/26/2006	Quality Care Advisory Committee approval
05/03/2006	Medical Director Review
05/17/2006	Medical Policy Committee Review. UVB has been removed from policy.
04/04/2007	Medical Director review
04/18/2007	Medical Policy Committee approval. Coverage eligibility unchanged.
11/07/2007	Medical Director review
11/15/2007	Medical Policy Committee approval. Replaced policy including title changed from Ultraviolet Light, Including Laser Therapy, for Skin Conditions.
11/05/2008	Medical Director review
11/18/2008	Medical Policy Committee approval. Targeted phototherapy for the first line treatment of mild psoriasis and generalized psoriasis or psoriatic arthritis is now considered to be investigational.
11/12/2009	Medical Policy Committee approval
11/18/2009	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/04/2010	Medical Policy Committee review
11/16/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/03/2011	Medical Policy Committee review
11/16/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/01/2012	Medical Policy Committee review
11/28/2012	Medical Policy Implementation Committee approval. Title changed from Targeted Phototherapy for Psoriasis to Light Therapy for Psoriasis. Added new eligible for coverage statement. “PUVA for the treatment of severe, disabling psoriasis, which is not responsive to other forms of conservative therapy (e.g., topical corticosteroids, coal/tar preparations, and ultraviolet light), is considered to be eligible for coverage.”
11/07/2013	Medical Policy Committee review
11/20/2013	Medical Policy Implementation Committee approval. No change to coverage.
11/06/2014	Medical Policy Committee review

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11/21/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/29/2015	Medical Policy Committee review
11/16/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/03/2016	Medical Policy Committee review
11/16/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
11/02/2017	Medical Policy Committee review
11/15/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/08/2018	Medical Policy Committee review
11/21/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/06/2019	Coding update
11/07/2019	Medical Policy Committee review
11/13/2019	Medical Policy Implementation Committee approval. Added "When Services May Be Eligible for Coverage" and a "When Services Are Not Medically Necessary" sections for home ultraviolet light box therapy.
11/05/2020	Medical Policy Committee review
11/11/2020	Medical Policy Implementation Committee approval. Removed "box" from ultraviolet light box therapy to read ultraviolet light therapy in the eligible for coverage and not medically necessary statements. Coverage eligibility unchanged.
08/19/2021	Verbiage adjusted

Next Scheduled Review Date: 11/2021

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	96912, 96913, 96920, 96921, 96922
HCPCS	E0691, E0692, E0693, E0694
ICD-10 Diagnosis	L40.0-L40.9

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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