Anthem

Clinical UM Guideline

Subject: Ultraviolet Light Therapy Delivery Devices for Home Use
Guideline #: CG-DME-41
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Description

This document addresses the use of home ultraviolet light (UV) therapy to treat various skin conditions.

Note: Please see the following document that addresses the treatment of skin conditions:

- ANC.00007 Cosmetic and Reconstructive Services: Skin Related

Clinical Indications

Medically Necessary:

An in-home Ultraviolet B (UVB) light therapy delivery device is considered **medically necessary** when conditions A and B are met:

A. The treatment is for **one** of the following conditions:
   1. Atopic dermatitis, when topical treatment alone has failed; **or**
   2. Pityriasis lichenoides; **or**
   3. Pruritus of hepatic disease; **or**
   4. Pruritus of renal failure; **or**
   5. Psoriasis, when topical treatment alone has failed; **or**
   6. Cutaneous T-cell lymphoma including mycosis fungoides and Sézary syndrome.

   and

B. The treatment meets **all** of the following criteria:
   1. Treatment is conducted under a physician's supervision with regularly scheduled exams; **and**
   2. Treatment is expected to be long term (3 months or longer); **and**
   3. The individual meets **any** of the following:
      a. The individual is unable to attend office-based therapy due to a serious medical or physical condition (for example, confined to the home, leaving home requires special services or involves unreasonable risk); **or**
      b. Office-based therapy has failed to control the disease and it is likely that home-based therapy will be successful; **or**
      c. The individual suffers from severe psoriasis with a history of frequent flares which require immediate treatment to control the disease.

Not Medically Necessary:

An in-home UVB delivery device is considered **not medically necessary** for all other conditions not mentioned above, including but not limited to vitiligo, and when the criteria above are not met.

Home ultraviolet light therapy using ultraviolet A (UVA) light devices are considered **not medically necessary** for all indications.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

HCPCS	
E0691	Ultraviolet light therapy system, includes bulbs/lamps, timer and eye protection; treatment area 2 square feet or less [when specified as UVB]
E0692	Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 4 foot panel [when specified as UVB]
E0693	Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 6 foot panel [when specified as UVB]
E0694	Ultraviolet multidirectional light therapy system in 6 foot cabinet, includes bulbs/lamps, timer and eye protection [when specified as UVB]

ICD-10 Diagnosis	
C84.00-C84.09	Mycosis fungoides
C84.10-C84.19	Sézary disease
C86.6	Primary cutaneous CD30-positive T-cell proliferations
K73.0-K73.9	Chronic hepatitis, not elsewhere classified
K74.00-K74.69	Fibrosis and cirrhosis of liver
K75.0-K75.9	Other inflammatory liver diseases
L20.0-L20.9	Atopic dermatitis
L29.0-L29.9	Pruritus
L40.0-L40.9	Psoriasis
L41.0	Pityriasis lichenoides et varioliformis acuta
L41.1	Pityriasis lichenoides chronica
N03.0-N03.A	Chronic nephritic syndrome

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above for UVB therapy when criteria are not met or for all other diagnoses not listed; or when the code describes a procedure or situation designated in the Clinical Indications section as not medically necessary such as UVA therapy.

Discussion/General Information

Description of UV Light Therapy

UV light therapy is an established treatment for skin disorders that uses UV light alone, or in combination, with topical preparations or oral medications. UV therapy involves exposure of the individual's skin to ultraviolet A (UVA) or ultraviolet B (UVB) radiation using a specialized light source. As an alternative to UV therapy alone, some individuals respond to the Goeckerman or modified Goeckerman treatment, which is comprised of coal tar dressings in combination with exposure to UVB light.

UVB light can be categorized as wide-band (or broad-band) and narrow-band, which refers to the range of wavelengths included in the UV light source. The wide-band devices deliver full spectrum UVB light. The narrow-band devices deliver a very narrow range of the UV light spectrum, focusing on the specific wavelengths most effective for the treatment of disease. Narrow-band UVB (NB-UVB) light can be delivered with either a light bulb or with a hand-held laser device. UVB treatment is typically offered using a light "booth" or "light box" several times a week for as long as the condition persists, which may be for the lifetime of the individual. In most cases an individual must go to a doctor's office or other facility for treatments. However, UVB treatment is available for home use under certain circumstances and under strict physician supervision.

UVA light is offered in conjunction with a photosensitizer called psoralen, and this combined approach may be referred to as photochemotherapy. Photosensitizers can be applied directly to the skin or taken orally and make the skin more sensitive to ultraviolet light. Photochemotherapy is used for more severe cases of skin diseases that fail to respond to topical therapy. One type of photochemotherapy known as PUVA (Psoralen with UVA) involves the topical or oral administration of psoralen (a potent photosensitizing drug), followed by exposure to varying doses of UVA light. The use of drugs and the higher risk of adverse reactions, including a higher risk of skin cancer, have generally limited PUVA therapy to the office setting.

However, the use of UVA and UVB light therapy carries a significant risk of sunburn and increased skin cancer risk. The supervision of a physician is needed to make sure that the dose of UV light delivered to the treatment area is in the therapeutic range but does not exceed safe levels. Skin cancer, skin typing or phototesting is usually performed prior to treatment to determine the appropriate radiation dose. While high doses of UV light may result in faster clearing of the lesions, the normal skin surrounding lesions cannot tolerate such exposure and the risk of skin cancer is increased. Multiple sessions over 3 or more months are often required to produce clearing of skin lesions. During UV light therapy, individuals need regular medical assessments to evaluate the effectiveness of the therapy and to monitor for the development of side effects such as "sun burn" and pruritus (itching), skin cancer, photoaging, and liver or kidney disease.

UVB home therapy devices

The majority of individuals undergoing UV treatment can be treated in the office. However, some individuals require treatments at a frequency that makes office visits overly burdensome. Home therapy with UVB light is an alternative. Concerns regarding over-exposure to unsafe levels of UVB radiation in the home setting have been addressed with the evolution of integrated security features such as keys, pass codes, etc. As with UVB therapy performed in the office, routine clinical evaluation should be conducted on home therapy individuals to ensure that exposure is kept to the minimum level compatible with adequate control of disease and the prevention of complications.

Atopic dermatitis (AD)

The initial treatment of AD typically consists of topical and non-pharmacological therapies as well as modifications in individual environments or occupations. Phototherapy is limited to those whose symptoms are not adequately controlled by the initial treatment modalities. There are numerous treatment protocols, but in general, individuals are dosed according to their minimal erythema dose and/or Fitzpatrick skin type. The AAD (2014) notes "Phototherapy can be administered on a scheduled but intermittent basis over time, or more continuously as maintenance therapy, for patients with refractory or chronic disease."

Cutaneous T-cell lymphoma (CTCL)

Non-Hodgkin lymphoma includes two types of cutaneous lymphomas, T-cell lymphomas (CTCLs) and B-cell lymphomas (CBCLs), with CTCLs accounting for the majority of cutaneous lymphomas. According to the National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines (CPGs) in Oncology® for Primary Cutaneous Lymphomas, Mycosis Fungoides (MF) accounts for 50% to 70% of CTCL cases and Sézary syndrome (SS) accounts for less than 5% of CTCL cases (2023). MF is considered an indolent malignancy and generally is associated with a slow progression while the median survival of SS is only 32 months from diagnosis (Trautinger, 2006). While CTCLs develop in the skin, the disease can progress and involve other areas such as lymph nodes, blood or visceral organs. Prognosis and treatment are dependent upon several factors including, but not limited to extent and type of skin involvement, overall stage, whether extracutaneous disease is present and peripheral blood involvement (NCCN, 2023).

Mycosis Fungoides and Sézary syndrome

Ultraviolet light therapy is an established treatment of MF and therapies have included UVB (broad-band and narrow-band) and UVA treatments (Hodak, 2015). Phototherapy can be used at various stages of MF, either alone or in combination with systemic therapy (Hodak, 2015). The 2023 NCCN CPGs for Primary Cutaneous Lymphomas include a 2A indication for UVB therapy for patch/thin plaques in MF/SS with limited/localized or generalized skin involvement. In addition, NCCN includes a 2A indication for UVB in stage III MF/SS, noting that while generalized skin directed therapies may not be well tolerated in this population, phototherapy can be used successfully.

Due to the low incidence of MF, there is a dearth of appropriately powered randomized controlled trials (RCTs) and most recommendations are generally based upon small studies, case series or expert opinion. Olsen and colleagues reported on the results of three studies which included home broad-based UVB therapy which consisted of a total of 109 individuals who presented with stage 1A or 1B MF. Home treatments included daily phototherapy while office-based treatments were carried out 3 times per week. A total of 58 individuals received home-based therapy, with 48 of these 58 individuals receiving only home-based therapy and the remaining 10 individuals receiving home therapy after office-based therapy. The authors noted that maintenance regimens within the studies varied and likely affected response duration. Relapse was uncommon while individuals were on maintenance phototherapy (2/18), but was more common once maintenance phototherapy was discontinued (12/23). The authors found that

individuals using home-based phototherapy were much more likely to continue maintenance phototherapy than individuals who received office-based phototherapy.

Pityriasis lichenoides

UVB has also been recommended as a treatment for several other conditions. Pityriasis lichenoides is a rare collection of skin disorders that have been reported to progress to cutaneous lymphoma or an ulceronecrotic presentation, both of which carry a significant risk of mortality. Treatment is difficult and aggressive approaches are usually recommended. According to one source, the use of UVB phototherapy has been the most successful treatment method and is considered first-line therapy (Khachemoune, 2007).

Pruritus of hepatic or renal disease

Pruritus of hepatic disease and renal failure are difficult to treat. Management is primarily focused on the treatment of the underlying symptoms such as pain and itching. Several treatment options are currently used, and UVB phototherapy has become widely accepted as an important tool in the management of these conditions (Wang, 2010).

Psoriasis

Koek and colleagues (2009) conducted a randomized controlled single-blind trial comparing office-based UVB treatment with home therapy for individuals with plaque or guttate psoriasis. This study involved 196 subjects who were evaluated through the initial therapy, with the first 105 subjects followed for an additional 12 months post-treatment. The authors reported that both treatments provided significant improvement from baseline, with home therapy being non-inferior to office-based treatment as measured by the psoriasis area and severity index (PASI) and the self-administered psoriasis area and severity index (SAPASI). No significant differences between groups were reported with regard to total cumulative radiation dose or short-term side effects.

Unrue and colleagues (2019) conducted a multicenter, prospective, open-label, interventional study to assess the treatment efficacy, adherence, and satisfaction of an ultraviolet home phototherapy system. The study included 8 participants with stable plaque psoriasis. Matched control and study lesions were assessed on each participant. All participants that completed the 10-week study experienced an improvement in the treated lesions with a mean improvement of 57% in Psoriasis Severity Index (PSI; $p<0.0001$ compared to baseline, and $p<0.0002$ compared to the control lesions). Control lesions did not significantly change in PSI over the study period with a mean change of 9% ($p=0.1411$). No adverse events were reported. Participant treatment adherence was 96%. The results indicate that the home phototherapy system was a safe and effective monotherapy to manage plaque psoriasis in this group of participants.

The Joint American Academy of Dermatology – National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy (2019) included the following recommendation:

> Recommend No. 1.8
> Home NB-UVB phototherapy is recommended for appropriate patients with generalized plaque psoriasis as an alternative to in-office NB-UVB phototherapy. (Strength of recommendation: B; Level of evidence: I)

In 2022, Cohen and colleagues performed a systematic review of the use of home-based devices for the treatment of skin conditions. A total of 4 RCTs evaluating home UVB phototherapy for psoriasis were included (Franken, 2015; Koek, 2009; Paul, 1983; Unrue, 2019). Conflicting evidence was identified for the efficacy of home-based UVB compared to traditional clinic-based administration. Three studies reported either significant improvements in PASI or PSI scores with home UVB use compared to controls, or non-inferiority of home therapy to office-based treatment. However, a study by Paul and colleagues (1983) showed the opposite outcome: while 90% of subjects who were treated in a clinic with phototherapy experienced complete clearance of psoriasis lesions, only 40% of subjects treated at home achieved the same result. Similar to the American Academy of Dermatology – National Psoriasis Foundation guidelines, the review gave a grade of recommendation of B for home phototherapy (UVB) devices for psoriasis.

Vitiligo

In 2021, Ashraf and colleagues published the results of a systematic review of three RCTs addressing home-based phototherapy for vitiligo. Two studies compared home-based with institution-based phototherapy, and one study compared home-based phototherapy with placebo. A total of 195 participants were included. The primary outcome was effectiveness of home-based phototherapy in achieving repigmentation; secondary outcomes were adverse effects of treatment, relapse rates and cost comparisons of institution- vs. home-based phototherapy. Therapy regimes varied between studies with four different types of NB-UVB devices used. Variable rates of repigmentation were achieved across studies but there was no significant difference in repigmentation rates between the groups. Adherence to treatment schedules was significantly better in home-based groups although adverse effects were also significantly higher in groups with home-based treatment vs. institution-based treatment (5% vs. 0% and 26% vs. 10%; two trials, 166 participants; RR 4.69, 95% confidence interval [CI], 2.16–10.21; $p<0.0001$). These adverse effects included excessive hyperpigmentation, blistering and enlargement of vitiligo patches. No data were reported on long-term maintenance of treatment benefits. The authors concluded that “data were insufficient to form conclusions on effectiveness” of home-based treatment and that it would be difficult to recommend home-based treatment in clinical practice due to the higher risk of adverse events.

Thomas and colleagues (2021) reported the results of the Home Interventions and Light therapy for the treatment of Vitiligo Trial (Hi-Light Vitiligo Trial), an RCT which evaluated the comparative safety and effectiveness of a topical corticosteroid (TCS) and handheld NB-UVB therapy for the management of active limited vitiligo. The trial compared TCS (mometasone furoate 0.1% ointment) alone, NB-UVB alone, and TCS combined with NB-UVB. The primary outcome was treatment success at 9 months at a target patch assessed using the participant-reported Vitiligo Noticeability Scale. Target patch treatment success was noted in 17% (TCS alone), 22% (NB-UVB alone), and 27% (combination treatment) of participants. An adjusted between-group difference of 10.9% (95% CI, 1.0% to 20.9%; $p=0.032$; number needed to treat = 10) showed that combination treatment was superior to TCS alone. NB-UVB alone was not superior to TCS with an adjusted between-group difference of 5.2% (95% CI, 4.4% to 14.9%; $p=0.29$; number needed to treat = 19). Participants with greater than 75% adherence to treatment were more likely to achieve treatment success but experienced a loss of effects once treatment stopped. The results showed that combination therapy was more likely to produce improved treatment response. However, combination therapy was only successful in about one quarter of participants. Although 517 participants were randomized, primary outcome data was only available for 370 participants. Attrition rates were similar in all three treatment arms. Most attrition occurred in the first 3 months of follow-up. Many leaving the trial said they did so because they could not commit the time required for the treatment. The high attrition rate left this trial insufficiently powered to provide precise confidence limits for the outcomes.

In 2020, Liu and colleagues published the results of a randomized pilot trial to determine the efficacy and safety of narrowband UVB phototherapy at home compared to hospital management of limited new-onset vitiligo. A total of 100 individuals with new-onset vitiligo (< 3 months) and < 5% body surface area involvement were randomized to either a home-based or a hospital-based treatment group and administered UVB phototherapy 3 times a week. At study-end (8 weeks), home- and hospital-based treatment showed similar efficacy but the frequency of adverse events, such as painful erythema, burning, blistering, and excessive hyperpigmentation, were

increased in the home-based cohort. The authors noted that some in the home cohort intentionally extended their treatments in an effort to increase efficacy and recommended that attention be paid to avoid overexposure.

A prospective cohort trial enrolled 94 individuals with non-segmental vitiligo to evaluate the efficacy and safety of home and outpatient narrowband UVB therapy. Over a period of 6 months, 48 participants received treatment at home while 46 received outpatient treatment. Primary outcomes included efficacy, quality of life and adverse events. Overall, results were similar at 6 months between groups with higher efficacy seen on some measures for the outpatient group (Zhang, 2019). Further investigation in the setting of a randomized trial is warranted to more firmly determine the benefits of NB-UVB as a home-treatment for non-segmental vitiligo.

Shan and colleagues (2014) published the results of UVB home phototherapy for vitiligo in a prospective uncontrolled trial (n=93). Treatments were administered 3 times each week at variable dosages. Follow-up was conducted every 3 months up to 1 year to evaluate repigmentation and any complications. At 1 year of follow-up, 35 subjects (38%) achieved excellent repigmentation, 16 (17%) achieved good repigmentation, 15 (16%) showed moderate repigmentation, 16 (17%) had poor repigmentation, and 11 (12%) had no repigmentation. A total of 25 (27%) individuals discontinued treatment due to poor repigmentation. This study was hampered by several design limitations, including a lack of randomization, and lack of appropriate comparator groups.

Eleftheriadou (2014) conducted a pilot trial to determine the feasibility of conducting a multicenter RCT to assess the safety and effectiveness of home hand-held NB-UVB phototherapy compared with topical treatments for repigmentation of vitiligo. Results showed that a larger RCT evaluating home hand-held phototherapy is feasible and acceptable to participants and healthcare providers. This trial was not intended as an efficacy trial.

While there is increasing evidence supporting the benefits of home-based UVB phototherapy, this treatment has not been generally accepted as standard treatment for vitiligo.

UVA home therapy devices

The use of UVA as a home therapy has not been shown to be safe and effective when compared to the other alternatives, such as office or facility-based treatment UVA therapy or UVB therapy. The AAD (2014) notes that given the limited number of head-to-head trials, there is no definitive recommendation regarding which form of phototherapy is more effective. UVA therapy requires the concurrent use of photosensitizers, which greatly increase the risk of complications. UVB therapy does not involve the use of photosensitizers.

Definitions

Atopic dermatitis: The most common of many types of eczema; atopic dermatitis is a skin disease characterized by areas of severe itching, redness, scaling, and loss of the surface of the skin; when the eruption has been present for a prolonged time, chronic changes occur due to the constant scratching and rubbing.

Mycosis fungoides (Cutaneous T-cell lymphoma): A type of non-Hodgkin's lymphoma cancer that first appears on the skin.

Pityriasis lichenoides: A skin disorder of children and young adults that is characterized by a rash of unknown cause, which usually goes away on its own.

Plaque: A broad, raised area on the skin.

Pruritus: The medical term for itching.

Psoriasis: A genetic, systemic, inflammatory, chronic disorder, characterized by scaly, erythematous patches, papules, and plaques that are often pruritic (itchiness). It is commonly located over the surfaces of the elbows, knees, scalp, and around or in the ears, navel, genitals or buttocks, but may appear elsewhere. It can be altered by environmental factors and may be associated with other inflammatory disorders such as psoriatic arthritis, inflammatory bowel disease, and coronary artery disease. The major manifestation of psoriasis is chronic inflammation of the skin that may be disfiguring, painful and severely pruritic and may cause significant quality of life issues. Psoriasis is a chronic disease that waxes and wanes during an individual's lifetime, the severity of which changes by treatment initiation and cessation. Some individuals can undergo spontaneous remissions.

Vitiligo: A skin disorder that causes loss of pigmentation (skin color) in blotches. The disorder affects the skin on any part of the body, including the hair, inside of the mouth, and eyes.

Ultraviolet (UV) light: Also known as UV light. This is a form of light invisible to the human eye that naturally comes from the sun but can also be produced by artificial light sources such as tanning lamps. Three types of UV light exist: ultraviolet A (UVA), ultraviolet B (UVB), and ultraviolet C (UVC).

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion/General Information, References, and Websites for Additional Information sections.
Revised	08/11/2022	MPTAC review. Updated Discussion/General Information, References, and Websites for Additional Information sections. Administrative edits made to Clinical Indications: removed the word ‘the’ and hyphenated two words.
Reviewed	08/12/2021	MPTAC review. Updated Discussion/General Information and References sections.
Reviewed	08/13/2020	MPTAC review. Updated Discussion/General Information and References sections. Reformatted Coding section and updated with 10/01/2020 ICD-10-CM changes to add N03.A.
Reviewed	08/22/2019	MPTAC review. Updated Discussion and References sections.
Reviewed	09/13/2018	MPTAC review.
New	11/02/2017	MPTAC review.
New	11/01/2017	Hematology/Oncology Subcommittee review. Initial document development. Moved content of DME.00036 Ultraviolet Light Therapy Delivery Devices for Home Use to new clinical utilization management guideline document with the same title.
