Protocol

Light Therapy for Vitiligo

(20186)

Medical Benefit		**Effective Date**: 07/01/18	**Next Review Date**: 05/19
Preauthorization	Yes	**Review Dates**: 05/18	

Preauthorization is required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With vitiligo	Interventions of interest are: • Targeted phototherapy	Comparators of interest are: • Topical medications • Narrow-band ultraviolet B light box therapy	Relevant outcomes include: • Change in disease status • Quality of life • Treatment-related morbidity
Individuals: • With vitiligo who have not responded to conservative therapy	Interventions of interest are: • Psoralen plus ultraviolet A (photochemotherapy)	Comparators of interest are: • Topical medications • Narrow-band ultraviolet B light box therapy	Relevant outcomes include: • Change in disease status • Quality of life • Treatment-related morbidity

DESCRIPTION

Vitiligo is an idiopathic skin disorder that causes depigmentation of sections of skin, most commonly on the extremities. Topical corticosteroids, alone or in combination with topical vitamin D_3 analogues, are common first-line treatments for vitiligo. Alternative first-line therapies include topical calcineurin inhibitors, systemic steroids, and topical antioxidants. Treatment options for vitiligo recalcitrant to first-line therapy include, among others, ultraviolet B light box therapy and psoralen plus ultraviolet A (PUVA). Targeted phototherapy is also being evaluated.

SUMMARY OF EVIDENCE

For individuals who have vitiligo who receive targeted phototherapy, the evidence includes systematic reviews of randomized controlled trials (RCTs). Relevant outcomes are change in disease status, quality of life, and treatment-related morbidity. The studies tend to have small sample sizes, and few were designed to isolate the effect of laser therapy. Two meta-analyses were attempted; however, results from a meta-analysis could not be verified because the selected studies were not available in English, and one estimate was imprecise due to the small number of studies and participants. There is a lack of clinical trial evidence that compares this technique with more conservative treatments or no treatment/placebo. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have vitiligo who have not responded to conservative therapy who receive PUVA (photo-chemotherapy), the evidence includes systematic reviews and RCTs. Relevant outcomes are change in disease status, quality of life, and treatment-related morbidity. There is some evidence from randomized studies, mainly

those published before 1985, that PUVA is more effective than placebo for treating vitiligo. When compared with narrowband ultraviolet B in meta-analyses, results have shown that patients receiving narrowband ultraviolet B experienced higher rates of repigmentation than patients receiving PUVA, though the differences were not statistically significant. Based on the available evidence and clinical guidelines, PUVA may be considered in patients with vitiligo who have not responded adequately to conservative therapy. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

POLICY

Psoralen plus ultraviolet A for the treatment of vitiligo that is not responsive to other forms of conservative therapy (e.g., topical corticosteroids, coal/tar preparations, ultraviolet light) may be considered **medically necessary.**

Narrow-band ultraviolet B (UVB) for the treatment of vitiligo that is not responsive to other forms of conservative therapy (e.g., topical corticosteroids, coal/tar preparations) may be considered **medically necessary**.

Targeted phototherapy using methods other than UVB is considered **investigational** for the treatment of vitiligo.

POLICY GUIDELINES

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 side effects. These evaluations are essential to ensure that the exposure dose of radiation is kept to the minimum compatible with adequate control of the disease. Therefore, psoralen plus ultraviolet A is generally not recommended for home therapy.

BACKGROUND

VITILIGO

Vitiligo is an idiopathic skin disorder that causes depigmentation of sections of skin, most commonly on the extremities. Depigmentation occurs because melanocytes are no longer able to function properly. The cause of vitiligo is unknown; it is sometimes considered an autoimmune disease. The most common form of the disorder is nonsegmental vitiligo in which depigmentation is generalized, bilateral, symmetrical, and increases in size over time. In contrast, segmental vitiligo, also called asymmetric or focal vitiligo, covers a limited area of skin. The typical natural history of vitiligo involves stepwise progression with long periods in which the disease is static and relatively inactive, and relatively shorter periods in which areas of pigment loss increase.

Treatment

There are numerous medical and surgical treatments aimed at decreasing disease progression and/or attaining repigmentation. Topical corticosteroids, alone or in combination with topical vitamin D_3 analogues, are common first-line treatments for vitiligo. Alternative first-line therapies include topical calcineurin inhibitors, systemic steroids, and topical antioxidants. Treatment options for vitiligo recalcitrant to first-line therapy include, among others, light box therapy with narrow-band ultraviolet B (NB-UVB) and PUVA.

Targeted phototherapy with handheld lamps or lasers is also being evaluated. Potential advantages of targeted phototherapy include the ability to use higher treatment doses and to limit exposure to surrounding tissue. Original UVB devices consisted of a Phillips TL-01 fluorescent bulb with a maximum wavelength (lambda max) of 311 nm. Subsequently, xenon chloride lasers and lamps were developed as targeted UVB treatment devices; they generate monochromatic or very narrowband 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.

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 psoralen to the skin with subsequent exposure to UVA light. With topical PUVA, UVA exposure is generally administered within 30 minutes of psoralen application.

REGULATORY STATUS

In 2001, XTRAC™ (PhotoMedex), a xenon chloride (XeCl) excimer laser, was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for the treatment of skin conditions such as vitiligo. The 510(k) clearance has subsequently been obtained for a number of targeted UVB lamps and lasers, including newer versions of the XTRAC system including the XTRAC Ultra™, the VTRAC™ lamp (PhotoMedex), the BClear™ lamp (Lumenis), the 308 excimer lamp phototherapy system (Quantel Medical), MultiClear Multiwavelength Targeted Phototherapy System, Psoria-LightTM, and the Excilite™ and Excilite µ™ XeCl lamps. The intended use of all of these devices includes vitiligo among other dermatologic indications. Some light-emitting devices are handheld. FDA product code: GEX.

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 (e.g., Oxsoralen® [Valeant]).

RELATED PROTOCOLS

Dermatologic Applications of Photodynamic Therapy

Light Therapy for Psoriasis

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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