Light Therapy for Psoriasis

Policy # 00131
Original Effective Date: 03/25/2002
Current Effective Date: 11/16/2016

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.

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 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.*

Background/Overview
Light therapy for psoriasis includes both targeted phototherapy and photochemotherapy with PUVA. Targeted phototherapy describes the use of ultraviolet light that can be focused on specific body areas or lesions. Psoralen plus ultraviolet A uses a psoralen derivative in conjunction with long wavelength ultraviolet A (UVA) light (sunlight or artificial) for photochemotherapy of skin conditions.

Psoriasis is a common chronic immune-mediated disease characterized by skin lesions ranging from minor localized patches to complete body coverage. There are several types of psoriasis; most common is plaque psoriasis which is associated with red and white scaly patches on the skin. In addition to being a skin disorder, psoriasis can negatively impact many organ systems and is associated with an increased risk of...
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Cardiovascular disease, some types of cancer, and autoimmune diseases such as celiac disease and Crohn disease. Although disease severity is minimally defined by body surface area (mild psoriasis affects less than 5% of the body's surface area, moderate psoriasis affects 5% to 10%, and severe disease affects more than 10% body surface area), lesion characteristics (e.g., location and severity of erythema, scaling, induration, pruritus) and impact on quality of life are also taken into account.

Topical therapy (e.g., corticosteroids, vitamin D analogs) is generally considered to be first-line treatment 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 (BB-UVB) devices, NB-UVB devices, and PUVA. This policy addresses 2 treatments: PUVA and targeted phototherapy, i.e., use of ultraviolet light that can be focused on specific body areas or lesions.

**Targeted Phototherapy**

Potential advantages of targeted phototherapy include the ability to use higher treatment doses and to limit exposure to surrounding tissue. BB-UVB 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 erythrogenic and carcinogenic but not therapeutic. NB-UVB is more effective than BB-UVB 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, xenon chloride (XeCl) lasers 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. Typically, these patients have not been considered candidates for light box therapy, because the risks of exposing the entire skin to the carcinogenic effects of UVB light may outweigh the benefits of treating a small number of lesions. Newer XeCl laser devices are faster and more powerful than the original models, which may allow treatment of patients with more extensive skin involvement (10%-20% body surface area). The American Academy of Dermatology does not recommend phototherapy for patients with mild localized psoriasis whose disease can be controlled with topical medications. A variety of topical agents are available including steroids, coal tar, vitamin D analogs (e.g., calcipotriol, calcitriol), tazarotene, and anthralin.

**Psoralen Plus Ultraviolet A**

Psoralen Plus Ultraviolet A uses a psoralen derivative in conjunction with long wavelength 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 directly applying 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 U.S. Food and Drug Administration (FDA). Paint PUVA and soak PUVA are other forms of topical
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Application of psoralen and are often used for psoriasis localized to the palms and soles. In paint PUVA, 8-methoxypsoralen (8-MOP) in an 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.

Psoralen plus ultraviolet A has most commonly been used to treat severe psoriasis, for which there is no generally accepted first-line treatment. Each treatment option (e.g., systemic therapies such as methotrexate, phototherapy, biologic therapies, etc.) has associated benefits and risks. Common minor toxicities associated with PUVA include erythema, pruritis, irregular pigmentation, and gastrointestinal tract symptoms; these generally can be managed by altering the dose of psoralen or UV light. Potential long-term effects include photoaging and skin cancer, particularly squamous cell carcinoma (SCC) and possibly malignant melanoma. Psoralen plus ultraviolet A 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 cases.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
In 2001, an XeCl excimer laser (XTRAC™ by PhotoMedex) received 510(k) clearance from the U.S. FDA for the treatment of mild to moderate psoriasis. 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), and the European manufactured Excilite™ and Excilite µ™ XeCl lamps. FDA product code: FTC.

In 2010, the Levia Personal Targeted Phototherapy UVB device (Daavlin Co., Bryan, OH previously manufactured by Lerner Medical Devices, Los Angeles, CA) was cleared by FDA 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 e.g., Oxsoralen (Valeant Pharmaceuticals).

Centers for Medicare and Medicaid Services (CMS)
Ultraviolet light treatment is covered; targeted phototherapy is not specifically mentioned. There is no national coverage determination on PUVA.

Rationale/Source
This policy was updated regularly with searches of the MEDLINE database. Most recently, the literature was reviewed through November 11, 2015. Following is a summary of the literature to date.

Assessment of efficacy for therapeutic interventions involves a determination of whether the intervention improves health outcomes. The optimal study design for a therapeutic intervention is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Nonrandomized
comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as selection bias (eg, noncomparability of treatment groups) and observation bias (eg, placebo effect).

**Targeted Phototherapy**

There are several systematic reviews of the literature on targeted phototherapy. Reviews differed in the type of study they included and in the comparison interventions. In a 2013 systematic review by Almutawa et al, PUVA was the comparison intervention and only evidence from RCTs was considered. The authors identified 3 RCTs comparing the efficacy of targeted ultraviolet B (UVB) phototherapy with PUVA for treatment of plaque psoriasis. Two of the 3 studies used an excimer laser (308-nm) as the source of targeted phototherapy, and the third study used localized NB-UVB light. There was heterogeneity among studies, and thus a random effects meta-analysis model was used. Using the random effects model, there was not a statistically significant difference between the 2 techniques in the proportion of patients with at least a 75% reduction in psoriasis. The pooled odds ratio (OR) was 3.48 (95% confidence interval [CI], 0.56 to 22.84). (The wide CI indicated a lack of precision in the efficacy estimate). The trials in the systematic review included a study by Neumann et al in which 10 patients were treated with a NB-UVB lamp or cream PUVA. The UVB lamp and PUVA-treated sides showed similar gradual clearing over the course of 20 treatments, reaching 64% clearance at the end of the 5-week treatment period. In another trial, Sezer et al conducted a left-to-right comparison of local NB-UVB versus PUVA paint (3 times per week for 9 weeks) in a cohort of 25 patients. The mean severity index improved by 61% with local NB-UVB and 85% with PUVA paint; 1 patient dropped out of the study because of a phototoxic reaction in the PUVA-paint-treated side.

In 2012, Mudigonda and colleagues published a systematic review of controlled studies comparing the 308-nm UVB excimer laser to non-targeted phototherapy for patients with localized psoriasis. The authors identified 3 prospective non-randomized studies comparing the 308-nm excimer laser to NB-UVB; no studies comparing the excimer laser with BB-UVB or PUVA were identified. Among the 3 studies was one by Goldinger and colleagues that compared the excimer laser to full body NB-UVB in 16 patients. At the end of 20 treatments, the psoriasis area and severity index (PASI) scores were equally reduced on the 2 sides, from a baseline of 11.8 to 6.3 for laser and from 11.8 to 6.9 for non-targeted NB-UVB. Another study, by Kollner and colleagues, included 15 patients with stable plaque psoriasis. The study compared the 308-nm laser, the 308-nm excimer lamp, and standard TL-01 lamps. One psoriatic lesion per patient was treated with each therapy (i.e., each patient received all 3 treatments). The investigators found no significant difference in the efficacy of the 3 treatments after 10 weeks. The mean number of treatments to achieve clearance of lesions was 24.

Another systematic review by Mudigonda and colleagues included non-controlled observational studies on targeted UVB phototherapy for treating psoriasis. This article was not limited to the 308-nm excimer laser as was the 2012 review, discussed above. In their review, the authors included case series with at least 7 patients. A total of 9 studies meeting the eligibility criteria were identified; sample sizes ranged from 7 to 124. The authors concluded that the 308-nm excimer laser, 308-nm excimer nonlaser, and non-excimer light devices are effective for treating localized psoriasis and are safer than whole-body phototherapy because uninvolved skin is spared. The review did not pool study findings, did not evaluate separately studies by severity of psoriasis.
A small 2014 sham-controlled RCT by Levin et al evaluated the Levia targeted NB-UVB device. Although the device can be used at home, in the trial, treatments were provided by experienced phototherapists in a clinical setting. The study included patients with bilateral plaque-type psoriasis who had symmetric target lesions 2 to 4 cm in diameter. The minimum target lesion score (TLS) was 6, indicating at least moderate severity. (TLS is a 12-point scale that incorporates erythema, lesion thickness, and scaling.) Patients received targeted phototherapy on a randomly selected side of the body and sham (visible light treatment) on the other side. Treatments were given 3 times weekly for 12 weeks. Seventeen (81%) of 21 randomized patients completed the study. The primary end point, percentage of lesions that were clear or almost clear (TLS ≤ 3) at week 12 did not differ significantly between groups. The end point was attained on 10 treated lesions and 7 sham lesions (p=0.118). Two of 3 prespecified secondary end points significantly favored active treatment. The percentage improvement in TLS was 43% on the treated side and 29% on the sham side (p=0.043). In addition, 12 lesions in the treated group and 7 in the placebo group had at least 50% improvement, as measured by TLS (p=0.020). However, percentage improvement in pruritus visual analog scale score, 62% on the treated side and 27% on the sham side, did not differ significantly between groups. The study had a relatively high dropout rate but because patients served as their own controls, this is not likely to be a major source of bias.

**Treatment-resistant Psoriatic Lesions**

The findings of several small studies suggest that targeted phototherapy can be effective for treatment-resistant lesions. One patch comparison reported effective clearing (PASI pre 6.2, PASI post 1.0) of treatment-resistant psoriatic lesions; 6 of the patients had previously received topical treatment, 5 had received conventional phototherapy, and 3 had received combined treatments including phototherapy. The same group reported that 12 of 13 subjects with "extensive and stubborn" scalp psoriasis (i.e., unresponsive to class I topical steroids used in conjunction with tar and/or zinc pyrithione shampoos for at least 1 month) showed clearing following treatment with the 308-nm laser. In an open trial from Europe, 44 of 54 patients with palmoplantar psoriasis resistant to combined phototherapy and systemic treatments were cleared of lesions with only 1 NB-UVB lamp treatment per week for 8 weeks.

**Section Summary**

Several small RCTs and other small non-RCTs in patients with moderate-to-severe psoriasis have found that targeted phototherapy has efficacy similar to whole body phototherapy or PUVA. Targeted phototherapy is presumed to be safer or at least no riskier than whole body phototherapy. Several nonrandomized studies have found that targeted phototherapy can improve health outcomes in patients with treatment-resistant psoriasis. One small sham controlled RCT evaluating a targeted NB-UVB device had mixed findings; the primary outcome was statistically nonsignificant.

**Psoralens Plus Ultraviolet A**

Several systematic reviews have been published. As previously noted, Almutawa et al conducted a pooled analysis of 3 RCTs, 2 of which used an excimer laser, and did not find a statistically significant difference in the efficacy of PUVA and targeted phototherapy in patients with plaque psoriasis. In 2012, an industry-sponsored systematic review by Archier and colleagues was published on psoralens with ultraviolet A and/or narrow-band UVB for treating psoriasis. Three RCTs were identified that directly compared PUVA to NB-UVB in patients with chronic plaque psoriasis. A pooled analysis of these studies found a significantly
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higher psoriasis clearance with PUVA compared to NB-UVB (OR: 2.79; 95% CI: 1.40 to 5.55). In addition, significantly more patients remained cleared at 6 months with PUVA compared to NB-UVB (OR: 2.73; 95% CI: 1.18 to 6.27).

A 2013 systematic review by Almutawa et al identified 8 RCTs that evaluated oral PUVA and reporting PASI-75 as an outcome measure. The mean percentage of patients achieving PASI-75 was 73% (95% CI, 56% to 88%). The mean clearance rate in 10 trials of PUVA monotherapy was 79% (95% CI, 68% to 88%). In 4 trials with bath PUVA monotherapy, the mean proportion of patients achieving PASI-75 was 47% (95% CI, 30% to 65%). The authors did not report outcomes in the control groups and thus conclusions cannot be drawn from this analysis on the relative efficacy of PUVA and other psoriasis treatments. A Cochrane review was published in 2013 on light therapy for psoriasis. However, that review is less useful for the analysis at hand because the authors combined results of studies using PUVA and BB-UVB, rather than reporting outcomes separately for these 2 treatment modalities.

Representative recent RCTs evaluating PUVA for treating psoriasis are described next:

In 2014, El-Mofty et al in Egypt published an RCT comparing PUVA and BB-UVB in 61 patients with psoriasis affecting at least 30% body surface area. Patients in the BB-UVB group were further randomized to 1 of 2 fixed doses: 10 or 15 J/cm² per session. A maximum of 48 treatment sessions were provided. Clinical outcomes were significantly better in the PUVA group than the BB-UVB groups. For example, complete clearance was obtained by 23 (77%) of 30 patients in the PUVA group, 5 (31%) of 16 patients in the 10 J/cm² UVA group, and 5 (33%) of 15 patients in the 15 J/cm² UVA group (p=0.020).

In 2011, Amirnia and colleagues published a study from Iran in which 88 patients with moderate plaque psoriasis were randomized to receive PUVA or topical steroids. Treatment was continued for 4 months or until clearance was achieved. Clearance was defined as disappearance of at least 90% of baseline lesions. All patients in both groups achieved clearance within the 4-month treatment period. Recurrence (defined as a resurgence of at least 50% of the baseline lesions) occurred significantly more often in the topical steroid group (9 of 44, 20.5%) than in the PUVA group (3 of 44, 6.8%), (p=0.007).

In 2009, Sivanesan and colleagues published a double-blind RCT evaluating the efficacy of 8-MOP PUVA treatment in patients 18 years and older with moderate to severe psoriasis affecting at least 10% of their body surface area. The study included 40 patients, 30 randomly assigned to receive PUVA and 10 to receive UVA plus placebo psoralens. After a washout period of 2 weeks for topical psoriasis medications and 4 weeks for phototherapy and systemic therapies, patients were treated 3 times a week for 12 weeks. A total of 28 patients completed the study, 21 in the PUVA group and 7 in the UVA plus placebo group. The primary outcome was at least a 75% improvement in the PASI score (PASI 75). In an intention-to-treat analysis with the last observation carried forward to analysis at 12 weeks, 19 of 30 (63%) in the PUVA group and 0 of 10 (0%) in the UVA with placebo group achieved at least a 75% improvement in the PASI 7 score (p<0.001). In the per protocol analysis, 18 of 21 (86%) in the PUVA group and 0 of 7 (0%) in the placebo group achieved PASI 75. There were no serious adverse effects. The study found a dramatic treatment benefit with PUVA compared to UVA plus placebo; however, there was substantial drop-out and no long-term follow-up.
Two RCTs from India compared outcomes after treatment with oral methoxsalen PUVA and NB-UVB. In 2011, Chauhan and colleagues included 51 patients with plaque psoriasis involving greater than 20% of their body surface area. Patients received treatment with NB-UVB or PUVA 3 times a week. Treatment continued until greater than 75% clearance was attained or for a maximum of 16 weeks. A total of 43 of 51 (84%) patients completed the study. Marked improvement (>75% clearance) was seen in 17 of 21 (90.9%) study completers in the NB-UVB group and 18 of 22 (81.8%) in the PUVA group; p>0.05. The mean time to achieve results was also similar in the 2 groups, a mean of 9.9 weeks with each treatment. A 2010 study by Dayal and colleagues randomly assigned 60 patients with chronic plaque psoriasis to receive twice weekly PUVA (n=30) or twice weekly NB-UVB phototherapy (n=30). After the 3-month treatment period, all patients in both groups had at least 75% clearance of psoriasis or complete clearance. The PASI score did not differ significantly between groups (mean of 1.39 in the PUVA group and 1.61 in the NB-UVB group). The mean number of treatments to achieve clearance, however, was significantly higher in the NB-UVB group than the PUVA group, 16.4 and 12.7, respectively.

Section Summary
Randomized controlled trials and systematic reviews of RCTs have found that PUVA is at least as effective as NB-UVB for patients with moderate to severe psoriasis. A 2014 RCT found that PUVA was more effective than BB-UVA.

Home Treatment
No studies were identified that compared home-based PUVA to office-based PUVA. A 2010 review of various types of home phototherapies for psoriasis did not discuss any studies on PUVA delivered at home.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in December 2015 did not identify any ongoing or unpublished trials that would likely influence this review.

Summary of Evidence
The evidence for targeted phototherapy in patients who have mild psoriasis is limited. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Based on this review, evidence is lacking for the use of targeted phototherapy for the first-line treatment of mild psoriasis. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for targeted phototherapy in patients who have moderate-to-severe psoriasis includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The literature supports the use of targeted phototherapy for the treatment of moderate-to-severe psoriasis comprising less than 20% body surface area for which narrowband ultraviolet B or photochemotherapy with psoralen plus ultraviolet A (PUVA) are indicated, and for the treatment of mild-to-moderate localized psoriasis that is unresponsive to conservative treatment. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.
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The evidence for PUVA in patients who have moderate-to-severe psoriasis includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Evidence from RCTs suggests that office-based PUVA is at least as effective as narrowband ultraviolet B and broadband ultraviolet A for patients with moderate-to-severe psoriasis. In addition, PUVA for severe treatment-resistant psoriasis is well-accepted and is recommended by the American Academy of Dermatology. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

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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
03/29/2004 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
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
11/04/2010 Medical Policy Committee review
11/03/2011 Medical Policy Committee review
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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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
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

Next Scheduled Review Date: 11/2017

Coding

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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. 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
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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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