



Louisiana

Laser Treatment of Acne and Rosacea

Policy # 00162

Original Effective Date: 03/07/2005

Current Effective Date: 04/10/2023

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: Light Therapy for Psoriasis is addressed separately in medical policy 00131.

Note: Light Therapy for Vitiligo is addressed separately in medical policy 00699.

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 laser treatment of active acne to be **investigational.***

Based on review of available data, the Company considers laser treatment of rosacea to be **investigational.***

***Note:** The use of laser therapy, intense pulsed light therapy, electrosurgery, cryosurgery, and chemosurgery (i.e., epidermal/dermal chemical peels) for the treatment of acne scarring or effects associated with rosacea (e.g. erythema, telangiectasia, scarring) is not covered by the Company because it is considered a cosmetic service.*

Background/Overview

Acne

Acne is a very common disorder of the pilosebaceous follicles that primarily affects adolescents and young adults and may be classified as inflammatory or noninflammatory. Acne is characterized by comedones, nodules and eruptions of papules, pustules and nodulocystic lesions. Lesions are found in areas with the greatest concentration of sebaceous glands, i.e., the face, neck and upper part of the trunk. The four causal factors of acne are androgen-mediated sebaceous gland hyperplasia and excess sebum production; abnormal follicular keratinization, which results in plugging of the follicles, and comedo formation; proliferation of propionibacterium acnes (*P. acnes*) and

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inflammation resulting from the chemoattractant and proinflammatory byproducts of *P. acnes*. Genetic factors, diet and stress may also contribute to the development and severity of acne. Treatment of active acne usually consists of good skin care regimen, benzoyl peroxide, antibiotics and retinoids. Active acne is distinct from acne scarring, which may occur from tissue damage after inflammatory lesions subside.

Pulsed dye laser has been used in the treatment of acne scarring; however, more recently, lasers have been investigated for the treatment of active inflammatory acne. Laser therapy at various irradiation levels or fluences (e.g., low- and mid-level irradiation lasers and long-pulse diode lasers) has been used to destroy active acne lesions and enlarged sebaceous glands. Lasers are believed to improve active acne lesions by reducing the presence of *P. acnes*, which contain porphyrins that are destroyed by exposure to light of specific wavelengths (i.e., blue light of 405–420 nm). Lasers may also have anti-inflammatory effects (i.e., red light of 660 nm) that may improve active acne. Low-fluence pulsed dye lasers are less ablative and purpuric and may be preferred in active acne treatment to limit tissue damage and potential treatment-related scarring. Laser treatment of active acne lesions may also reduce potential acne scarring that can occur in severe cases.

Rosacea

Rosacea is characterized by episodic erythema, edema, papules, and pustules that occur primarily on the face but may also be present on the scalp, ears, neck, chest, and back. On occasion, rosacea may affect the eyes. Patients with rosacea tend to flush or blush easily. Because rosacea causes facial swelling and redness, it is easily confused with other skin conditions, such as acne, skin allergy, and sunburn.

Rosacea mostly affects adults with fair skin between the ages of 20 and 60 years and is more common in women, but often most severe in men. Rosacea is not life-threatening, but if not treated, it may lead to persistent erythema, telangiectasias, and rhinophyma (hyperplasia and nodular swelling and congestion of the skin of the nose). The etiology and pathogenesis of rosacea are unknown but may result from both genetic and environmental factors. Some theories on the causes of rosacea include blood vessel disorders, chronic *Helicobacter pylori* infection, Demodex folliculorum (mites), and immune system disorders.

While the clinical manifestations of rosacea do not usually impact the physical health status of the patient, psychological consequences from the most visually apparent symptoms (ie, erythema,

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papules, pustules, telangiectasias) may impact quality of life. Rhinophyma, an end-stage of chronic acne, has been associated with obstruction of nasal passages and basal cell carcinoma in rare, severe cases. The probability of developing nasal obstruction or basal or squamous cell carcinoma with rosacea is not sufficient to warrant the preventive removal of rhinophymatous tissue.

Treatment

Rosacea treatment can be effective in relieving signs and symptoms. Treatment may include oral and topical antibiotics, isotretinoin, b-blockers, alpha₂-adrenergic agonists (e.g., oxymetazoline, clonidine), and anti-inflammatories. Patients are also instructed on various self-care measures such as avoiding skin irritants and dietary items thought to exacerbate acute flare-ups.

Nonpharmacologic therapy has also been tried in patients who cannot tolerate or do not want to use pharmacologic treatments. To reduce visible blood vessels, treat rhinophyma, reduce redness, and improve appearance, various techniques have been used such as laser and light therapy, dermabrasion, chemical peels, surgical debulking, and electrosurgery. Various lasers used include low-powered electrical devices and vascular light lasers to remove telangiectasias, carbon dioxide lasers to remove unwanted tissue from rhinophyma and reshape the nose, and intense pulsed lights that generate multiple wavelengths to treat a broader spectrum of tissue.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Acne

A number of laser and focused light devices have received marketing clearance for the treatment of acne via the FDA's 510(k) mechanism. These include lasers that emit light at 1320nm (Candela SmoothbeamTM† and CoolTouch[®])‡; intense pulsed light systems, which emit light in the range of 590 to 1200nm (Radiancy ClearTouchTM‡, MED flash II and Ellispse I²PL)‡; pulsed dye lasers (ICN Photonics NLite System); and lasers or high-intensity light devices, which emit violet or blue (around 414nm) and red (around 633nm) light (AuraTM, Clearlight and Dermillume)‡. The specific indications for these devices vary; Candela Smoothbeam is indicated solely for the treatment of acne on the back, others are indicated for the treatment of inflammatory acne or for mild to moderate acne with no location specified. In 2006, a thermal device (ThermaClearTM)‡ was cleared for marketing

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for the “treatment of individual acne pimples in persons with mild to moderate inflammatory acne” in both a practitioner’s office environment and a consumer home-use environment.

Rosacea

Several laser and light therapy systems have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process for various dermatologic indications, including rosacea. For example, rosacea is among the indications for:

- Vbeam laser system (Candela)
- Stellar M22TM laser system (Lumenis)
- excel VT[®], excel V[®], and xeo[®] laser systems (Cutera)
- Harmony[®] XL multi-application platform laser device (Alma Lasers, Israel)
- UV-300 Pulsed Light Therapy System (New Star Lasers)
- CoolTouch[®] PRIMA Pulsed Light Therapy System (New Star Lasers).

FDA product code: GEX.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Acne

Two systematic reviews of light therapies for treatment of active acne were identified. Both reviews included studies on photodynamic therapy, as well as light and laser therapy. Neither review conducted any pooled analyses of laser treatment studies due to heterogeneity between studies (e.g. different wavelengths of light were used). The two systematic reviews had similar assessments of the literature. Hamilton and colleagues identified 10 randomized controlled trials (RCTs) comparing light therapy to placebo and 3 RCTs comparing light therapy to topical treatment of acne. The authors commented that studies of light therapy tended to be small (all had fewer than 50 participants), of short duration and of variable quality, and that a few compared light therapy to conventional treatment. They concluded: “our review found only limited or no benefit is given by

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light therapies alone...Further trials comparing light therapy with usual treatment, using a larger effect size in the power calculations, would be helpful to determine the usefulness of light therapy in treating acne.” The other systematic review by Haedersdal and colleagues included 11 RCTs on light treatments (other than photodynamic therapy) and stated that that most of the studies had suboptimal methods. For example, few studies described their randomization method and most had large losses to follow-up without intention to treat analysis. The authors state, “Based on the present best available evidence, we conclude that optical treatments with lasers, light sources and PDT possess the potential to improve inflammatory acne on a short-term basis with the most consistent outcomes for PDT. We recommend that patients are informed of the existing evidence, which denotes that optical treatments for acne today are not included among first-line treatments” There is no separate conclusion focusing on laser therapy. The systematic reviews identified a number of side effects from optical treatments, and these include pain, erythema, edema, crusting, hyperpigmentation, and pustular eruptions.

Key individual RCTs with at least 40 participants are described as follows:

Seaton et al., 2003: This trial was a double-blind RCT of 41 adults with mild to moderate facial inflammatory acne (i.e., Leeds acne severity score of between 2 and 7). Patients were randomized to receive a single low fluence pulsed dye laser treatment or sham treatment. At 12 weeks, Leeds acne scores fell from 3.8 to 1.9 in the treatment group and from 3.6 to 3.5 in the control group. Total lesion counts fell by 53% and 9% and inflammatory lesion counts fell by 49% and 10% in the laser treatment group and control group, respectively. While the authors reported statistically significant improvements, they concluded that “laser treatment should be further explored as an adjuvant or alternative to daily conventional pharmacological treatments.”

Orringer et al., 2004: The article reported on a single-blind, split-face RCT of 40 patients (aged 13 years or older with a Leeds acne score of two or greater) who were randomized to receive either one or two sessions of pulsed dye laser treatment (3 J/cm² fluence) to half of the face with the opposite, non-treated side serving as the control. At 12 weeks, changes in lesion counts (including pustules, comedones, macules, cysts, and papules) and mean Leeds acne scores were not significantly different for the treated versus untreated sides of the face. The authors concluded that “...additional well designed studies are needed before the use of pulse dye laser becomes a part of acne therapy.”

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Orringer et al., 2007: This RCT assessed the efficacy of a 1320-nm laser (CoolTouch II) in 46 patients in a split-face design. Laser treatment was given once every three weeks, with blinded evaluation by a panel of three dermatologists (from photographs taken at 7 and 14 weeks). Thirty patients completed the 14-week assessment (35% dropout); data were carried forward to adjust for subjects who may have dropped out of the study due to lack of effect. The authors report that the treated side remained unchanged at 0.22 cysts (10 total cysts in 46 subjects) while the untreated side increased from 0.27 to 0.70 cysts. Subjective patient reports (of 37 who completed at least the 7-week assessment; not blinded to treatment) favored the treated side over the control side for a decrease in acne (59%) and oily skin (54%). No differences were found between the treated and un-treated sides in the number of papules, pustules, open comedones, or closed comedones at 14 weeks.

Laheta, 2009: This study included 45 patients with mild to moderate acne who were randomly assigned to one of three groups (15 patients per group). Group A received pulsed dye laser therapy (3 J/cm² fluence) every two weeks for six sessions; Group B applied topical treatment with 0.1% tretinoin cream every evening and 5% benzoyl peroxide gel every morning; and Group C underwent chemical peeling using trichloroacetic acid 25%. An assessor blinded to treatment group evaluated outcomes; 41 patients were included in the analysis. There was no significant difference between groups in the acne severity score (0=no acne to 10=severe acne) at the end of the 3-month treatment period. Mean scores were 0.56 ± 0.57 for Group A, 0.65 ± 0.47 for Group B, and 0.68 ± 0.50 for Group C ($p=0.38$). The analysis of disease severity did not adjust for baseline scores, and standard deviations were large due to the small number of participants in each group. The degree of clinical response (marked or moderate) and side effects (trace, mild, or moderate) also did not differ significantly between the three groups. The proportion of patients with moderate side effects was 23% in Group A, 15% in Group B, and 13% in Group C (overall p -value=0.95).

Summary

Due to the small sample sizes of the published trials, lack of long-term follow-up, small number of studies on any particular type of laser, and paucity of studies comparing light therapy to standard acne treatments, the evidence is insufficient to draw conclusions about the impact of laser treatments on health outcomes in patients with active acne. Therefore, the technology is considered investigational.

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Rosacea

Rosacea is a chronic, inflammatory skin condition without a known cure; the goal of treatment is symptom management. Nonpharmacologic treatments, including laser and light therapy as well as dermabrasion, which are the focus of this evidence review, are proposed for patients who do not want to use or are unresponsive to pharmacologic therapy.

Summary of Evidence

For individuals who have rosacea who receive nonpharmacologic treatment (e.g., laser therapy, light therapy, dermabrasion), the evidence includes systematic reviews and several small, randomized, split-face design trials. Relevant outcomes are symptoms, change in disease status, and treatment-related morbidity. The systematic reviews reported favorable effects on erythema and telangiectasia with several laser types, including intense pulsed light (IPL), pulsed dye lasers, and neodymium-doped yttrium aluminum garnet (Nd:YAG) lasers. However, the systematic reviews did not pool results from individual studies and the studies differed in the specific lasers being compared. Overall, the systematic review results were insufficient to establish whether any laser type is more effective and safe than others. The randomized controlled trials (RCTs) evaluated laser and light therapy. One RCT compared combination laser and pharmacologic therapy with pharmacologic therapy alone and 2 RCTs compared combination laser and pharmacologic therapy with laser therapy alone, but the lack of an arm evaluating laser therapy alone against established pharmacologic therapy does not allow a direct assessment on the efficacy of laser or light treatment compared with alternative treatments. No trials assessing other nonpharmacologic treatments were identified. There is a need for RCTs that compare nonpharmacologic treatments with placebo controls and with pharmacologic treatments. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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American Acne and Rosacea Society

In 2014, the American Acne and Rosacea Society issued consensus recommendations on the management of rosacea. The Society stated that lasers and intense pulsed light (IPL) devices could improve certain clinical manifestations of rosacea that have not responded to medical therapy. The recommendations indicated that these therapies would have to be repeated intermittently to sustain improvement.

In 2016, the American Acne and Rosacea Society issued updated consensus recommendations on the management of rosacea. The update focused on how medical and device therapies are used--whether concurrently or in a staggered fashion--noting that there is a lack of evidence to justify either use. The Society's consensus recommendation on rosacea management correlated with clinical manifestations observed at the time of presentation is summarized in Table 1:

Table 1. Recommendations on Use of Lasers and Intense Pulsed Light Devices for the Management of Rosacea

Condition	Recommendation	Grade ^a
Persistent central facial erythema without papulopustular lesions	IPL, potassium titanyl phosphate crystal laser, or pulsed dye laser	B
Diffuse central facial erythema with papulopustular lesions	“While the data on the use of IPL, potassium titanyl phosphate or pulsed dye laser are limited for papulopustular lesions, these options are useful to treat erythema”	NR
Granulomatous rosacea	<ul style="list-style-type: none">Intense pulsed dye laser“No current standard of treatment; limited data based on case reports”	C
Phymatous Rosacea	<ul style="list-style-type: none">“Surgical therapy for fully developed phymatous changed (carbon dioxide laser, erbium-doped [YAG] laser, electrosurgery, dermabrasion)”	C

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	<ul style="list-style-type: none">• “Treatment selection dependent on stage of development (early or fibrotic) and extent of inflammation (active or burnt out)”	
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IPL: intense pulsed light, YAG: yttrium aluminum garnet; NR: not reported.

^a Grade A: Criteria not described in recommendation; Grade B: Systematic review/meta-analysis of lower-quality clinical trials or studies with limitations and inconsistent findings; lower-quality clinical trial; Grade C: Consensus guidelines; usual practice, expert opinion, case series—limited trial data

Rosacea Consensus Panel

In 2017, the Rosacea Consensus panel, comprised of international experts including representatives from the U.S., published recommendations for rosacea treatment. The panel agreed that treatments should be based on phenotype. IPL and pulsed dye laser were recommended for persistent erythema, but not for transient erythema. IPL and lasers were also recommended for telangiectasia rosacea.

The panel updated their recommendations on rosacea treatment in 2019, agreeing that lasers were recommended for persistent centrofacial erythema. They also noted that “use of IPL and vascular lasers in darker skin phototypes requires consideration by a healthcare provider with experience..., as it can result in dyspigmentation.” The panel also acknowledged that combining treatments could benefit patients with more severe rosacea and multiple rosacea features; however “there remains an ongoing need for more studies to support combination treatment use in rosacea.”

National Rosacea Society

In 2019, the National Rosacea Society Executive Committee published an expert consensus document on management options for rosacea.³⁵ This document endorses treatment goals of an Investigator Global Assessment score of 0 and normalization of skin tone and color due to the notable impact of rosacea on patient quality of life. Light devices are discussed as treatment options along with medications, skin care, and lifestyle interventions. Based on weak evidence, IPL, pulsed dye lasers, and potassium titanyl phosphate lasers are listed as moderately effective treatment options for persistent erythema, particularly due to telangiectasia. Both IPL and potassium titanyl phosphate are described as having at least some efficacy for flushing. Nonpharmacologic interventions that are listed as more highly effective treatment options for non-inflamed phymas (based on weak evidence)

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include carbon dioxide lasers, erbium lasers, cold steel, electrosurgery, and radiofrequency; these same interventions are listed for use in combination with other treatment modalities for inflammatory phymas. Carbon dioxide lasers, erbium lasers, cold steel, electrosurgery, and radiofrequency carry a risk of post-inflammatory hyperpigmentation and should only be provided by appropriately trained individuals.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT04889703	A Pilot Study Testing the Effects of Chemical Peels in Patients With Rosacea	20	May 2024
NCT05592548	Rosacea Treatment Using Non-thermal (Cold) Atmospheric Plasma Device	10	Jun 2023

NCT: national clinical trial.

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Policy History

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12/07/2004	Medical Director review
12/14/2005	Medical Policy Committee review
03/07/2005	Managed Care Advisory Council approval
09/07/2005	Medical Director review
09/20/2005	Medical Policy Committee review. Laser treatment for scar revision removed from policy.
09/22/2005	Quality Care Advisory Council approval
07/07/2006	Medical Policy Committee approval. Format revision, including addition of FDA and/or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
07/10/2007	Medical Director review
07/18/2007	Medical Policy Committee approval. No change to coverage eligibility.
07/02/2009	Medical Director review
07/22/2009	Medical Policy Committee approval. No change to coverage eligibility.
07/01/2010	Medical Policy Committee Director approval.
07/21/2010	Medical Policy Implementation Committee approval. No change to coverage.
07/07/2011	Medical Policy Committee Director approval.
07/20/2011	Medical Policy Implementation Committee approval. No change to coverage.
10/12/2011	Coding correction.
06/28/2012	Medical Policy Committee Director approval.

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07/27/2012	Medical Policy Implementation Committee approval. No change to coverage.
06/27/2013	Medical Policy Committee Director approval.
07/17/2013	Medical Policy Implementation Committee approval. No change to coverage.
07/10/2014	Medical Policy Committee Director approval.
07/16/2014	Medical Policy Implementation Committee approval. No change to coverage.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
09/03/2015	Medical Policy Committee Director approval.
09/23/2015	Medical Policy Implementation Committee approval. No change to coverage.
09/08/2016	Medical Policy Committee Director approval.
09/21/2016	Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
09/07/2017	Medical Policy Committee Director approval.
09/20/2017	Medical Policy Implementation Committee approval. No change to coverage.
09/06/2018	Medical Policy Committee Director approval.
09/19/2018	Medical Policy Implementation Committee approval. No change to coverage.
09/05/2019	Medical Policy Committee Director approval.
09/11/2019	Medical Policy Implementation Committee approval. No change to coverage.
09/03/2020	Medical Policy Committee Director approval.
09/09/2020	Medical Policy Implementation Committee approval. No change to coverage.
09/02/2021	Medical Policy Committee Director approval.
09/08/2021	Medical Policy Implementation Committee approval. No change to coverage.
02/09/2022	Coding Update
09/01/2022	Medical Policy Committee Director approval.
09/14/2022	Medical Policy Implementation Committee approval. No change to coverage.
03/02/2023	Medical Policy Committee Director approval.
03/08/2023	Medical Policy Implementation Committee approval. No change to coverage. Added intense pulsed light therapy to the note as not covered.

Next Scheduled Review Date: 03/2024

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 2022

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by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

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

Code Type	Code
CPT	96920 Delete codes effective 3/1/2022: 17110, 17111 Add codes effective 05/01/2023: 17106, 17107, 17108
HCPCS	No codes
ICD-10 Diagnosis	L70.0-L70.9, L71.0-L71.9, L73.0 Delete ICD-10 Dx effective 03/14/2022: L90.5

*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:

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- 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 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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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