



Louisiana

Percutaneous Tibial Nerve Stimulation

Policy # 00415

Original Effective Date: 04/16/2014

Current Effective Date: 07/13/2020

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

Note: Botulinum Toxins is addressed separately in medical policy 00012.

Note: Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence is addressed separately in medical policy 00095.

Note: Sacral Nerve Neuromodulation/Stimulation is addressed separately in medical policy 00108.

Note: Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT) is addressed separately in medical policy 00144.

Note: Transanal Radiofrequency Treatment of Fecal Incontinence is addressed separately in medical policy 00571.

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 maintenance therapy using monthly percutaneous tibial nerve stimulation (PTNS) for individuals following a 12-week initial course of PTNS that resulted in improved urinary dysfunction meeting treatment goals to be **eligible for coverage**.**

When Services May Be Eligible for Coverage

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

- *Benefits are available in the member's contract/certificate, and*

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- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider percutaneous tibial nerve stimulation (PTNS) for an initial 12-week course for individuals with non-neurogenic urinary dysfunction including overactive bladder (OAB) symptoms present for at least 3 months to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility will be considered for PTNS for an initial 12-week course for individuals with non-neurogenic urinary dysfunction including OAB symptoms present for at least 3 months if both criteria are met:

- Failed behavioral therapy following an appropriate duration of 8 to 12 weeks without meeting treatment goals; and
- Failed pharmacologic therapy, e.g., oral anti-muscarinics and/or transdermal oxybutynin, following 4 to 8 weeks of treatment without meeting treatment goals.

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 the use of percutaneous tibial nerve stimulation (PTNS) when patient selection criteria are not met to be **investigational**.*

Based on review of available data, the Company considers percutaneous tibial nerve stimulation (PTNS) for all other indications, to be **investigational***, including but not limited to the following.

- Neurogenic bladder dysfunction;
- Fecal incontinence.

Policy Guidelines

Patients may be considered to have failed behavioral therapies following an appropriate duration of 8 to 12 weeks without meeting treatment goals (Gormley et al [2015]).

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Patients may be considered to have failed pharmacologic therapies following 4 to 8 weeks of treatment without meeting treatment goals (Gormley et al [2015]).

Annual evaluation by a physician may be performed to ensure efficacy is continuing for maintenance percutaneous tibial nerve stimulation treatments.

Background/Overview

Voiding Dysfunction

Common causes of non-neurogenic voiding dysfunction are pelvic floor neuromuscular changes (eg, from pregnancy, childbirth, surgery), inflammation, medication (eg, diuretics, anticholinergics), obesity, and psychogenic factors. Overactive bladder is a non-neurogenic voiding dysfunction characterized by urinary frequency, urgency, urge incontinence, and nonobstructive retention.

Neurogenic bladder dysfunction is caused by neurologic damage in patients with multiple sclerosis, spinal cord injury, detrusor hyperreflexia, or diabetes with peripheral nerve involvement. The symptoms include overflow incontinence, frequency, urgency, urge incontinence, and retention.

Treatment

Approaches to the treatment of incontinence differentiate between urge incontinence and stress incontinence. Conservative behavioral management such as lifestyle modification (eg, dietary changes, weight reduction, fluid management, smoking cessation) along with pelvic floor exercises and bladder training are part of the initial treatment of overactive bladder symptoms and both types of incontinence. Pharmacotherapy is another option, and different medications target different symptoms. Some individuals experience mixed incontinence.

If behavioral therapies and pharmacotherapy are unsuccessful, percutaneous tibial nerve stimulation (PTNS), sacral nerve stimulation, or botulinum toxin may be recommended.

Percutaneous Tibial Nerve Stimulation

The current indication cleared by the U.S. Food and Drug Administration (FDA) for PTNS is overactive bladder and associated symptoms of urinary frequency, urinary urgency, and urge incontinence.

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Altering the function of the posterior tibial nerve with PTNS is believed to improve voiding function and control. The mechanism of action is believed to be retrograde stimulation of the lumbosacral nerves (L4-S3) via the posterior tibial nerve located near the ankle. The lumbosacral nerves control the bladder detrusor and perineal floor.

Administration of PTNS consists of inserting a needle above the medial malleolus into the posterior tibial nerve followed by the application of low-voltage (10 mA, 1-10 Hz frequency) electrical stimulation that produces sensory and motor responses as evidenced by a tickling sensation and plantarflexion or fanning of all toes. Noninvasive PTNS has also been delivered with transcutaneous or surface electrodes. The recommended course of treatment is an initial series of 12 weekly office-based treatments followed by an individualized maintenance treatment schedule.

PTNS is less invasive than traditional sacral nerve neuromodulation (see medical policy 00108), which has been successfully used to treat urinary dysfunction but requires implantation of a permanent device. In sacral root neuromodulation, an implantable pulse generator that delivers controlled electrical impulses is attached to wire leads that connect to the sacral nerves, most commonly the S3 nerve root that modulates the neural pathways controlling bladder function.

PTNS has also been proposed as a treatment for non-neurogenic and neurogenic bladder syndromes and fecal incontinence.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2005, the Urgent[®] PC Neuromodulation System was the initial PTNS device cleared for marketing by FDA through the 510(k) process to treat patients suffering from urinary urgency, urinary frequency, and urge incontinence. Additional percutaneous tibial nerve stimulators have been cleared for marketing through the 510(k) process. They are listed in Table 1.

The Urgent PC Neuromodulation System and NURO[™] Neuromodulation System are not FDA-cleared for other indications, such as the treatment of fecal incontinence.

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Wireless technology is evolving for the treatment of overactive bladder; it is approved in Europe. BlueWind (BlueWind Medical) is a wireless, battery-less, miniature implantable neurostimulator activated by an external device worn at the ankle.

Table 1. FDA-Cleared Percutaneous Tibial Nerve Stimulators (FDA Product Code: NAM)

Device Name	Manufacturer	Cleared	510(k)	Indications
Urgent PC Neuromodulation System	Uroplasty, now Cogentix Medical	Oct 2005	K052025	Treatment of urinary urgency, urinary frequency, and urge incontinence
Urgent PC Neuromodulation System	Uroplasty, now Cogentix Medical	Jul 2006	K061333	FDA determined the 70% isopropyl alcohol prep pad contained in the kit is subject to regulation as a drug
Urgent PC Neuromodulation System	Uroplasty, now Cogentix Medical	Aug 2007	K071822	Labeling update, intended use is unchanged
Urgent PC Neuromodulation System	Uroplasty, now Cogentix Medical	Oct 2010	K101847	Intended use statement adds the diagnosis of overactive bladder
NURO Neuromodulation System	Advanced Uro-Solutions, now Medtronic	Nov 2013	K132561	Treatment of patients with overactive bladder and associated symptoms of urinary urgency, urinary frequency, and urge incontinence

FDA: Food and Drug Administration.

Rationale/Source

Percutaneous tibial nerve stimulation (PTNS; also known as posterior tibial nerve stimulation) is an electrical neuromodulation technique used primarily for treating voiding dysfunction.

The following conclusions are based on a review of the evidence, including but not limited to, published evidence and clinical expert opinion, solicited via BCBSA's Clinical Input Process.

For individuals who have non-neurogenic urinary dysfunction including overactive bladder and have failed behavioral and pharmacologic therapy who receive an initial course of PTNS, the evidence

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includes randomized sham-controlled trials, randomized controlled trials (RCTs) with an active comparator, and systematic reviews. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The Sham Effectiveness in Treatment of Overactive Bladder Symptoms (SUMiT) and the Overactive Bladder Innovative Therapy (OrBIT) trials are 2 key industry-sponsored RCTs. Systematic reviews that included these and other published trials have found short-term reductions in voiding dysfunction with PTNS. The largest, highest quality study was the double-blinded, sham-controlled SUMiT trial, which reported a statistically significant benefit of PTNS vs sham at 12 weeks. In an additional, small sham-controlled trial, a 50% reduction in urge incontinent episodes was attained in 71% of PTNS group compared with 0% in the sham group. The nonblinded OrBIT trial found that PTNS was noninferior to medication therapy at 12 weeks. Adverse events were limited to local irritation effects. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have overactive bladder syndrome that has failed behavioral and pharmacologic therapy who respond to an initial course of PTNS who receive maintenance PTNS, the evidence includes observational studies and systematic reviews. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The SUMiT and the OrBIT trials each included extension studies that followed individuals who responded to the initial course of PTNS and continued to receive periodic maintenance therapy. There is variability in the interval between and frequency of maintenance treatments, and an optimal maintenance regimen remains unclear. There are up to 36 months of observational data available, reporting that there is a durable effect for some of these patients. While comparative data are not available after the initial 12-week treatment period, the observational data support a clinically meaningful benefit for use in individuals who have already failed behavioral and pharmacologic therapy and who respond to the initial course of PTNS. PTNS may allow such individuals to avoid more invasive interventions. Adverse events appear to be limited to local irritation for both short- and long-term PTNS use. The published evidence supports a meaningful improvement in the net health outcome. Evidence reported through clinical input further supports that this use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice. Typical regimens schedule maintenance treatments every 4-6 weeks. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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For individuals who have neurogenic bladder dysfunction who receive PTNS, the evidence includes several RCTs and a systematic review of RCTs and observational data. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Only a few RCTs evaluating tibial nerve stimulation for treating neurogenic bladder have been published to date, and all but one performed transcutaneous stimulation rather than PTNS. Studies varied widely in factors such as study populations and comparator interventions. Study findings have not reported that tibial nerve stimulation significantly reduced incontinence symptoms and improved other outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have fecal incontinence who receive PTNS, the evidence includes several RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The available RCTs have not found a clear benefit of PTNS. Neither of the sham-controlled trials found that active stimulation was superior to sham for achieving the primary outcome, at least a 50% reduction in mean weekly fecal incontinence episodes. The larger sham-controlled randomized trial did find a significantly greater decrease in the absolute number of weekly incontinence episodes in the active treatment group, but the overall trial findings did not suggest the superiority of PTNS over sham treatment. A meta-analysis of a single RCT and several observational studies reported that patients receiving sacral nerve stimulation experienced significant benefits compared with patients receiving PTNS. A post hoc analysis of the larger trial suggested a subset of patients with fecal incontinence (those without concomitant obstructive defecation) may benefit from PTNS. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

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2018 Input

In response to requests, clinical input on use of maintenance percutaneous tibial nerve stimulation (PTNS) for individuals with non-neurogenic urinary dysfunction including overactive bladder who have failed behavioral and pharmacologic therapy and respond to an initial course of PTNS was received from 3 physician respondents identified by specialty societies while this policy was under review in 2018.

Based on the evidence and independent clinical input, the clinical input supports that the following indication provides a clinically meaningful improvement in the net health outcome and is consistent with generally accepted medical practice:

- Use of monthly maintenance PTNS for individuals with non-neurogenic urinary dysfunction including overactive bladder who have failed behavioral and pharmacologic therapy and respond to an initial course of PTNS.

Practice Guidelines and Position Statements

American Urological Association et al

The American Urological Association and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (2019) published updated guidelines on the diagnosis and treatment of non-neurogenic overactive bladder in adults. The guidelines included a statement that clinicians may offer percutaneous tibial nerve stimulation (PTNS) as a third-line treatment option in carefully selected patients. The statement carried a grade C rating, indicating that the balance of benefits and risks/burdens are uncertain.

American College of Obstetricians and Gynecologists

The American College of Obstetricians and Gynecologists (2015) practice bulletin on the treatment of urinary incontinence in women did not address PTNS or other types of nerve stimulation.

American Gastroenterological Association

The American Gastroenterological Association (2017) issued an expert review and clinical practice update on surgical interventions and device-aided therapy for the treatment of fecal incontinence. The update stated that "until further evidence is available, percutaneous tibial nerve stimulation should not be used for managing FI [fecal incontinence] in clinical practice."

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Canadian Urological Association

The Canadian Urological Association (2019) published guidelines for the diagnosis, management, and surveillance of neurogenic bladder dysfunction. The guidelines stated that "PTNS appears to be well-tolerated and effective in small studies, with minimal reported adverse events, mainly mild to moderate pain at the puncture site." This statement carried a grade C rating, with remarks that the evidence was limited by few studies, heterogeneous populations, small sample sizes, and nonrandomized study designs. Although some efficacy has been demonstrated in patients with multiple sclerosis, the guidelines caution that it is unknown which subgroups of neurogenic bladder dysfunction will respond best to this therapy.

European Association of Urology

The European Association of Urology (2018) conducted a review of third-line therapies for patients with overactive bladder who do not respond to bladder training or pharmacotherapy. The Association found that botulinum toxin, PTNS, and sacral nerve stimulation may be effective treatments for OAB. There was no high-quality evidence showing the superiority of one therapy over another. Age, comorbidities, patient preference, and surgical expertise were factors to be considered when treatment decisions are made. Table 2 compares the treatment options.

Table 2. Comparisons of SNM, PTNS, and Botulinum Toxin as Treatments for Overactive bladder

	SNM	PTNS	Botulinum Toxin Type A
FDA/EC approval	Yes	Yes	Yes
Long-term results	Yes	No	Limited
Advantages	<ul style="list-style-type: none"> Minimally invasive Effective for urinary and bowel disorders 	<ul style="list-style-type: none"> Noninvasive Uncomplicated procedure 	<ul style="list-style-type: none"> Minimally invasive Direct effect

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Disadvantages	<ul style="list-style-type: none"> • Permanent implant • Battery replacement every 5-8 y 	<ul style="list-style-type: none"> • May need to repeat procedure every 8-12 wk • Inferior efficacy 	<ul style="list-style-type: none"> • Repeat after 6-12 mo • Need for CISC
Reversibility	Removal of implant	Instantly reversible	After 6 mo
Adverse events	<ul style="list-style-type: none"> • Wound infection • Device-related pain • Device malfunction 	<ul style="list-style-type: none"> • None 	<ul style="list-style-type: none"> • Urinary retention • Urinary tract infection • Hematuria

Adapted from Marcelissen et al (2018).

CISC: clean intermittent self-catheterization; EC: European Commission; FDA: Food and Drug Administration; PTNS: percutaneous tibial nerve stimulation; SNM: sacral neuromodulation.

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 unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT02299544	Safety and Performance of the BlueWind System for the Treatment of Patients With Overactive Bladder (OAB)	36	Aug 2018

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NCT02888899	Percutaneous Tibial Nerve Stimulation in Combination With Biofeedback in Patients With Fecal Incontinence - A Randomized Controlled Trial	Unknown	Mar 2019
NCT03559946 ^a	Condensed Percutaneous Tibial Nerve Stimulation (PTNS) Protocol	66	Apr 2019
NCT03547518	Sham Controlled Trial of Rapid Induction Percutaneous Tibial Nerve Stimulation	64	May 2020
NCT02190851	Evaluation of Treatment by Transcutaneous Electrical Nerve Stimulation (TENS) of the Posterior Tibial Nerve for Lower Urinary Tract Disorders in Parkinson's Syndrome	220	Dec 2020
<i>Unpublished</i>			
NCT02657057	Effects of Transcutaneous and Percutaneous PTNS on Idiopathic OAB	68	Mar 2017 (completed)
NCT01940367	Percutaneous Tibial Nerve Stimulation vs. Transcutaneous Electrical Nerve Stimulation for Overactive Bladder: A Randomized Trial	114	Dec 2017 (unknown)
NCT01162525	Percutaneous Tibial Nerve Stimulation (pTNS) for Patients with Fecal Urge Incontinence	100	Dec 2017 (completed)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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Louisiana

Percutaneous Tibial Nerve Stimulation

Policy # 00415

Original Effective Date: 04/16/2014

Current Effective Date: 07/13/2020

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Policy History

Original Effective Date: 04/16/2014

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- 04/06/2014 Medical Policy Committee review
- 04/16/2014 Medical Policy Implementation Committee approval. New policy.
- 07/10/2014 Medical Policy Committee review
- 07/16/2014 Medical Policy Implementation Committee approval. Coverage changed from investigational to eligible for coverage with criteria for selected patients with non-neurogenic overactive bladder. Posterior tibial nerve stimulation is investigational when Patient Selection Criteria are not met and in all other situations.
- 06/04/2015 Medical Policy Committee review
- 06/17/2015 Medical Policy Implementation Committee approval. No change to coverage.
- 08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
- 06/02/2016 Medical Policy Committee review
- 06/20/2016 Medical Policy Implementation Committee approval. No change to coverage.
- 01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

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- 09/07/2017 Medical Policy Committee review
- 09/20/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 06/07/2018 Medical Policy Committee review
- 06/20/2018 Medical Policy Implementation Committee approval. Title changed from “Posterior Tibial Nerve Stimulation for Voiding Dysfunction” to “Percutaneous Tibial Nerve Stimulation”. Revised eligible for coverage statements for use of PTNS in OAB syndrome that has failed behavioral and pharmacologic therapy. In these patients, PTNS is considered eligible for coverage as an initial course of therapy and maintenance therapy for individuals who respond to initial course. Investigational statement edited to be investigational for all indications with bullet points for urinary and fecal incontinence. Added a Policy Guidelines section.
- 06/06/2019 Medical Policy Committee review
- 06/19/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 12/10/2019 Coding update
- 06/04/2020 Medical Policy Committee review
- 06/10/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 06/2021

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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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	64566, 64999
HCPCS	No codes
ICD-10 Diagnosis	N32.81, N39.3, N39.498, R32, R33.0, R33.8, R33.9, R35.0, R39.14, R39.15 Code added eff 1/1/2020: Z96.82

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

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

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1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

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

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

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

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

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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