LOUISIANA BLUE

Tibial Nerve Stimulation

Policy # 00415
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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.

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*
- *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.

Based on review of available data, the Company considers subcutaneous tibial nerve stimulation delivered by an implantable peripheral neurostimulator system (e.g., eCoin®‡) for all indications, including individuals with non-neurogenic urinary dysfunction including overactive bladder to be **investigational.***

Based on review of available data, the Company considers transcutaneous tibial nerve stimulation (e.g., Vivally System) for individuals with bladder conditions of urge urinary incontinence and urinary urgency to be **investigational.***

Policy Guidelines

Individuals may be considered to have failed behavioral therapies following an appropriate duration of 8 to 12 weeks without meeting treatment goals.

Individuals may be considered to have failed pharmacologic therapies following 4 to 8 weeks of treatment without meeting treatment goals.

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.

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.

Percutaneous tibial nerve stimulation is less invasive than traditional sacral nerve neuromodulation (see medical policy 00108 Sacral Nerve Neuromodulation/Stimulation), 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.

Percutaneous tibial nerve stimulation has also been proposed as a treatment for non-neurogenic and neurogenic bladder syndromes and fecal incontinence.

Subcutaneous Tibial Nerve Stimulation
The current indication approved by the FDA for subcutaneous tibial nerve stimulation (STNS) is urgency urinary incontinence in individuals who are intolerant or who have had an inadequate response to more conservative treatments or who have undergone a successful trial of PTNS. STNS is administered through a coin-sized leadless battery-powered implant (see Regulatory section). STNS offers a less invasive alternative to traditional sacral nerve neuromodulation and offers a convenient delivery system for automated treatments without the need for chronic outpatient PTNS treatment sessions.

Transcutaneous Tibial Nerve Stimulation
The current indication approved by the FDA for transcutaneous tibial nerve stimulation (TTNS) (Vivally System; see Regulatory section) is for the treatment of individuals with the bladder conditions of urge urinary incontinence and urinary urgency. The device consists of a stimulator that is worn on the ankle and delivers electrical signals to the tibial nerve. This is typically an at-home treatment.

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 the FDA through the 510(k) process to treat patients suffering from urinary urgency, urinary frequency, and urge incontinence. Additional PTNS devices have been cleared for marketing through the 510(k) process. They are listed in Table 1.

The devices are not FDA cleared for other indications, such as the treatment of fecal incontinence.

Wireless technology is evolving for the treatment of overactive bladder. In March 2022, the eCoin®‡ Peripheral Neurostimulator System (Valencia Technologies Corporation) became the first subcutaneous tibial nerve stimulation implant approved by the FDA through the premarket authorization (PMA) process for individuals with urgency urinary incontinence (P200036; FDA Product Code: QPT).

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

Device Name	Manufacturer	Cleared	510(k)	Indications
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
ZIDA Wearable Neuromodulation System	Exodus Innovations	Mar 2021	K192731	Treatment of patients with an overactive bladder and associated symptoms of urinary urgency, urinary frequency, and urge incontinence
Vivally System Wearable, Non-Invasive Neuromodulation System and Mobile Application	Avation Medical, Inc.	Apr 2023	K220454	Treatment of patients with bladder conditions of urinary incontinence and urinary urgency.

FDA: U.S. Food and Drug Administration.

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 regulations, other plan medical policies, and accredited national guidelines.

Description

Percutaneous tibial nerve stimulation (PTNS; also known as posterior tibial nerve stimulation) is an electrical neuromodulation technique used primarily for treating voiding dysfunction. Subcutaneous tibial nerve stimulation via an implantable peripheral neurostimulator is an alternate technique for treating urgency urinary incontinence associated with overactive bladder syndrome.

Summary of Evidence
For individuals who have non-neurogenic urinary dysfunction including overactive bladder and have failed behavioral and pharmacologic therapy who receive an initial course of percutaneous tibial nerve stimulation (PTNS), the evidence 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-blind, sham-controlled SUmiT trial, which reported a statistically significant benefit of PTNS versus sham at 12 weeks. In an additional, small sham-controlled trial, a 50% reduction in urge incontinent episodes was attained in 71% of the 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 an improvement in the net health outcome.

For individuals who have overactive bladder syndrome that have failed behavioral and pharmacologic therapy who respond to an initial course of PTNS and 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 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. Percutaneous tibial nerve stimulation 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. Typical regimens schedule maintenance treatments every 4-6 weeks. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have non-neurogenic urinary dysfunction including overactive bladder and who have failed behavioral and pharmacologic therapy or who have responded to an initial course of PTNS and then receive subcutaneous tibial nerve stimulation (STNS), the evidence includes single-arm studies. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The pivotal open-label, single-arm study leading to FDA-approval of the subcutaneously implanted, wireless eCoin tibial nerve stimulation system demonstrated a 68% response rate at 48 weeks of follow-up which surpassed a performance goal of 40%. However, the certainty of the evidence is limited by the lack of comparator group and a lower response rate observed during the COVID-19 pandemic. Additionally, the FDA noted that the

performance goal was identified after patients had already been implanted. An ongoing post-approval study may elucidate the certainty of benefit, including safety of reimplantation given battery lifespan concerns. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 1 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 that the technology results in an improvement in the net health outcome.

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. None of the sham-controlled trials found that active stimulation was superior to sham for achieving a 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. An additional sham-controlled randomized trial did not identify a benefit of PTNS over sham stimulation. 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 that the technology results in an improvement in the net health outcome.

For individuals who have urge urinary incontinence and urinary urgency who receive transcutaneous tibial nerve stimulation, the evidence includes an RCT and a nonrandomized study. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The results of the available studies did not show a clear benefit of transcutaneous tibial nerve stimulation. The RCT showed statistically significant improvements in the primary outcome measure. However, the primary outcome was a composite score of patient reported outcomes. A secondary analysis on individual symptoms showed no significant difference between the active therapy arm and the sham arm for voids or urgency leaks. The nonrandomized open-label, single-arm study showed statistically significant improvements in daily voids, incontinence episodes, and urgency episodes. However, minimal clinically important differences were not reported for these outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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.

2018 Input
Clinical input was sought to help determine whether the 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 would provide a clinically meaningful improvement in the net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 3 physician respondents identified by specialty societies.

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, clinical input supports this use provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice.

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.

American Urological Association et al
In 2019, the American Urological Association (AUA) and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) published updated guidelines on the diagnosis and treatment of non-neurogenic overactive bladder in adults. The guidelines included a statement that clinicians may offer 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. In 2024, the AUA/SUFU published a guideline on the diagnosis and treatment of idiopathic overactive bladder. In the unabridged version of the guideline, PTNS is mentioned as a minimally invasive therapy option. The guideline states that "Clinicians may offer minimally invasive procedures to patients who are unable or unwilling to undergo behavioral, non-invasive, or pharmacologic therapies (Clinical Principle)" and " Clinicians may offer patients with OAB, in the context of shared decision making, minimally invasive therapies without requiring trials of behavioral, non-invasive, or pharmacologic management (Expert Opinion)". Transcutaneous tibial nerve stimulation is included in the list of non-invasive therapies in these guidelines.

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

American Gastroenterological Association
In 2017, the American Gastroenterological Association 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."

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 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05977634	The Efficacy of Transcutaneous Tibial Nerve Stimulation on Symptoms of Overactive Bladder and Quality of Life in Women With Idiopathic Overactive Bladder	26	Aug 2026
NCT05685433[a]	A Real World Study of eCoin for Urgency Urinary Incontinence: Post Approval Evaluation (RECIPE)	200	Dec 2030
NCT05882318[a]	Evaluating Effectiveness of Sensory and Subsensory Stimulation Amplitudes With eCoin®‡ Tibial Nerve Stimulation in Urgency Urinary InContinence Episodes and Quality of Life (ESSENCE)	50	Jul 2024
NCT05422625	PTNS for Female Patients Suffering From Multiple Sclerosis (PTNS-MS)	34	Oct 2023

Unpublished			
NCT02190851	Evaluation of Treatment by Transcutaneous Electrical Nerve Stimulation (TENS) of the Posterior Tibial Nerve for Lower Urinary Tract Disorders in Parkinson's Syndrome (UROPARKTENS)	220	Oct 2020 (completed)
Terminated			
NCT05381116a	A Prospective, Sham-Controlled, Safety and Efficacy Study of a Smart, Self-Adjusting, Surgery-Free, Wearable Bladder Modulation and Digital Health System With Objective Confirmation of Nerve Activation for Use in Home by Subjects With Overactive Bladder Syndrome	125 (actual)	Jul 2023 (terminated)

NCT: national clinical trial.

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Policy History

Original Effective Date: 04/16/2014
Current Effective Date: 09/01/2025

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
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.
06/03/2021	Medical Policy Committee review
06/09/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/01/2021	Coding update
06/02/2022	Medical Policy Committee review
06/08/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/01/2023	Medical Policy Committee review
06/14/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/13/2023	Coding update
03/28/2024	Coding update
06/06/2024	Medical Policy Committee review
06/12/2024	Medical Policy Implementation Committee approval. Title changed from "Percutaneous Tibial Nerve Stimulation" to "Percutaneous and Subcutaneous Tibial Nerve Stimulation." Added an investigational statement for subcutaneous tibial nerve stimulation delivered by an implantable peripheral neurostimulator system for all indications.
09/17/2024	Coding update
06/05/2025	Medical Policy Committee review
06/11/2025	Medical Policy Implementation Committee approval. Title changed from "Percutaneous and Subcutaneous Tibial Nerve Stimulation" to "Tibial Nerve Stimulation". Added an investigational statement for tibial nerve stimulation (e.g., Vivally System) for individuals with bladder conditions of urge urinary incontinence and urinary urgency.

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 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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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	0587T, 0588T, 0589T, 0590T, 0816T, 0817T, 0818T, 0819T, 64566, 64999
HCPCS	A4545, E0736, E0737
ICD-10 Diagnosis	All related Diagnoses

*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:

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.

**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.

‡ 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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.