

Remote Electrical Neuromodulation for Migraines

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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.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

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.*

Preventive treatment: Initiation of Use

Based on review of available data, the Company may consider remote electrical neuromodulation (REN [e.g. Nerivio]) for the prevention of migraine to be **eligible for coverage**** when **ALL** of the following criteria are met:

- Individuals are 8 years of age or older; **AND**
- Headaches meet the International Classification of Headache Disorders (ICHD-3) diagnostic criteria for episodic or chronic migraine with or without aura
*(Note: The International Classification of Headache Disorders ICDH-3 criteria for migraine with and without aura can be accessed at <https://ichd-3.org/1-migraine/>); **AND***
- The REN device will be used for the prevention of migraine in individuals with 6 to 24 headache days (defined as a calendar day with headache regardless of severity or duration) per 28-day period in each of the 3 months preceding use of the REN device; **AND**
- **ANY** of the following additional criteria must also be met:
 - Insufficient response, contraindication, or intolerance to 2 or more guideline-recommended preventive headache medications (e.g., anticonvulsants, antihypertensives, antidepressants, CGRP inhibitors); **OR**
 - Individuals are 8 to 17 years of age; **OR**
 - Individuals are pregnant, breastfeeding, or planning to conceive; **OR**
 - At risk for or have a history of medication overuse headache; **OR**
 - At risk for drug-drug interactions with medications for comorbid conditions.

Preventive treatment: Continuation of Use

Based on review of available data, the Company may consider continued use of the remote electrical neuromodulation (REN) device and/or accessories for the prevention of migraine to be **eligible for coverage**** when the following criteria are met:

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- Documented compliance with ongoing use; **AND**
- Documentation of clinical benefit based on **ANY** of the following:
 - Improvements in pain relief or freedom; **OR**
 - Reduction in headache frequency, duration, or severity; **OR**
 - Reduction in functional disability; **OR**
 - Reduction in absenteeism; **OR**
 - Reduction in concomitant headache medications.

Note: Assessment of clinical benefit is reasonable after a minimum of 8-12 weeks for preventive treatment.

When Services Are Considered Not Medically Necessary

The use of remote electrical neuromodulation (REN [e.g. Nerivio]) for the prevention of migraine when criteria are not met is considered to be **not medically necessary**.**

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 remote electrical neuromodulation for acute migraine to be **investigational**.*

Background/Overview

Migraine

Migraine is a neurologic disease characterized by recurrent moderate to severe headaches with associated symptoms that can include aura, photophobia, nausea, and/or vomiting. Overall migraine prevalence in the United States is about 15% but varies according to population group. Prevalence is higher in women (21%), among American Indian/Alaska Natives (22%), and among 18- to 44-year-olds (19%). Social determinants including low education level (18%), use of Medicaid (27%), high poverty level (23%), and being unemployed (22%) are also associated with higher rates of migraine.

Migraine is categorized as episodic or chronic depending on the frequency of attacks. Generally, episodic migraine is characterized by 14 or fewer headache days per month and chronic migraine is characterized by 15 or more headache days per month. Specific International Classification of Headache Disorders diagnostic criteria are as follows:

- Episodic migraine:
 1. Untreated or unsuccessfully treated headache lasting 4 to 72 hours
 2. Headache has at least 2 of the following characteristics:
 - a. Unilateral location
 - b. Pulsating quality
 - c. Moderate or severe pain intensity

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- d. Aggravation by or causing avoidance of routine physical activity
- 3. At least 1 of the following during headache:
 - a. Nausea and/or vomiting
 - b. Photophobia or phonophobia.
- Chronic migraine:
 - 1. Migraine-like or tension-type headache on 15 or more days per month for more than 3 months
 - 2. At least 5 headache attacks without aura meet episodic migraine criteria 1 to 3, and/or at least 5 headache attacks with aura meet episodic migraine criteria 2 to 3
 - 3. On more than 8 days per month for more than 3 months, fulfilling any of the following criteria:
 - 1. For migraine without aura, episodic migraine criteria 2 and 3
 - 2. For migraine with aura, episodic migraine criteria 1 and 2
 - 3. Believed by the patient to be migraine at onset and relieved by a triptan or ergot derivative.

Migraine attacks, whether due to episodic or chronic migraine, require acute management. The goal of acute treatment is to provide pain and symptom relief as quickly as possible while minimizing adverse effects, with the intent of timely return to normal function. Pharmacologic interventions for treatment of acute migraine vary according to migraine severity. First-line therapy for an acute episode of mild or moderate migraine includes oral non-steroidal anti-inflammatory drugs (NSAIDs) or acetaminophen. Moderate to severe migraine can be treated through the use of triptans or an NSAID-triptan combination. Antiemetics can be added for migraine accompanied by nausea or vomiting, though certain antiemetic medications used as monotherapy can also provide migraine relief. Other pharmacologic interventions used to treat acute migraine include calcitonin-gene related peptide antagonists, which can be used in patients with an insufficient response or contraindications to triptans, lasmiditan, and dihydroergotamine. Migraine can be managed at home, although acute migraine is a frequently cited reason for primary care and emergency department visits. Regular use of pharmacologic interventions can result in medication overuse, which in turn could lead to rebound headache and increased risk of progression from episodic to chronic migraine.

Many individuals who suffer from migraine may also benefit from preventive migraine therapy, including those with frequent or long-lasting migraines, migraine attacks that diminish quality of life or cause significant disability despite acute treatment, contraindications to or failure of acute therapies, and risk of medication overuse headache. The main goals of preventive therapy are to reduce future attack frequency, severity, and duration, improve responsiveness to acute treatments, improve function and reduce disability, and prevent progression of episodic migraine to chronic migraine. For most adults with episodic migraines who may benefit from preventive therapy, initial therapy with an antiepileptic drug (divalproex sodium, sodium valproate, topiramate) or beta-blockers (metoprolol, propranolol, timolol) is recommended. Frovatriptan may be beneficial as initial therapy for prevention of menstrually associated migraine. Antidepressants (amitriptyline, venlafaxine), alternative beta-blockers (atenolol, nadolol), and additional triptans (naratriptan, zolmitriptan for menstrually associated migraine prevention) may be considered if initial therapy is unsuccessful. For preventive treatment of pediatric migraine, many children and adolescents who

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received placebo in clinical trials improved and most preventive medications were not superior to placebo. Possibly effective preventive treatment options for children and adolescents may include amitriptyline, topiramate, or propranolol.

Remote Electrical Neuromodulation

Remote electrical neuromodulation (REN) may offer an alternative to pharmacologic interventions for patients with acute migraine or it may decrease the use of abortive or preventive medications and the risk of medication overuse to treat or prevent acute migraines. The only currently available REN device (NerivioTM) cleared for use by the Food and Drug Administration (FDA) is worn on the upper arm and stimulates the peripheral nerves to induce conditioned pain modulation (CPM). The conditioned pain in the arm induced by the Nerivio REN device is believed to reduce the perceived migraine pain intensity. Control of the REN device is accomplished through Bluetooth communication between the device and the patient's smartphone or tablet. For acute treatment, at onset of migraine or aura and no later than within 1 hour of onset, the user initiates use of the device through their mobile application. When used for preventive treatment, the device should be used every other day, controlled by the individual through their smartphone or tablet application. Patient-controlled stimulation intensity ranges from 0% to 100%, corresponding to 0 to 40 milliamperes (mA) of electrical current. Patients are instructed to set the device to the strongest stimulation intensity that is just below their perceived pain level. The device provides stimulation for up to 45 minutes before turning off automatically. The Nerivio manufacturer indicates that the device can be used instead of or in addition to medication.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In May 2019, Nerivio MigraTM (Theranica Bio-Electronics Ltd.) was granted a de novo classification by the FDA (class II, special controls, product code: QGT). This new classification applied to this device and substantially equivalent devices of this generic type. Nerivio Migra was initially cleared for treatment of acute migraine in adults who do not have chronic migraine.

In October 2020, Nerivio was cleared for marketing by the FDA through the 510(k) process (K201824). FDA determined that this device was substantially equivalent to Nerivio Migra for use in adults. The device name changed to just "Nerivio" and the exclusion of chronic migraine patients was removed. The Nerivio device can provide more treatments than the predicate Nerivio Migra (12 treatments vs. 8 treatments) and has a longer shelf life (24 months vs. 9 months). In January 2021, the Nerivio device was cleared for use in patients aged 12 to 17 years. In February 2023, Nerivio's indication was expanded to include preventive treatment of migraine with or without aura in individuals 12 years and age or older and was cleared for marketing through the 510(k) process (K223169). In May 2025, the Nerivio and rechargeable Nerivio Infinity devices were cleared for marketing (K241756) with an expanded indication for acute and/or preventive treatment of migraine with or without aura in patients 8 years and older.

The Nerivio is indicated for acute and/or preventive treatment of migraine with or without aura in patients 8 years of age or older. It is a prescription use, self-administered device for use in the home

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environment at the onset of migraine headache or aura for acute treatment, or every other day for preventive treatment.

The NerivioInfinity is indicated for acute and/or preventive treatment of migraine with or without aura in patients 8 years of age or older. It is a prescription use, self-administered device for use in the home environment at the onset of migraine headache or aura for acute treatment, or every other day for preventive treatment.

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

Migraine attacks due to episodic or chronic migraine require acute management. Some individuals may also require preventive migraine therapy. Current first-line therapy for treatment and prevention of acute migraine involves use of various pharmacologic interventions. Regular use of pharmacologic interventions can result in medication overuse and increased risk of progression from episodic to chronic migraine. Nonpharmacologic remote electrical neuromodulation (REN) may offer an alternative to pharmacologic interventions for patients with migraine.

Summary of Evidence

For individuals with acute migraine due to episodic or chronic migraine who receive remote electrical neuromodulation (REN), the evidence includes 2 randomized controlled trials (RCTs) and nonrandomized, uncontrolled studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Use of an active REN device resulted in more patients with improved pain and symptoms at 2-hour follow-up compared with a sham device based on 2 small (N=212) RCTs with numerous relevance limitations. Based on the existing evidence, it is unclear how Nerivio would fit into the current acute migraine management pathway. No significant between-group difference in functional disability or quality of life was noted in a post-hoc analysis of the pivotal RCT. Additionally, controlled studies in adolescent and pediatric populations are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For adult individuals who may benefit from preventive migraine therapy, including those with frequent or long-lasting episodic or chronic migraines, migraine attacks that diminish quality of life or cause significant disability despite acute treatment, contraindications to or failure of acute therapies, and risk of medication overuse headache, who receive REN, the evidence includes 1 RCT and 1 prospective, observational study. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Use of an active REN device resulted in more adults with decreased migraine days per month, regardless of episodic or chronic subtype, when used every

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other day for 8 weeks compared with a sham device based on 1 RCT (N=248). Prospective, observational data in 3 real world evidence studies using the device for acute treatment of migraine demonstrated a significant reduction in migraine headache days from baseline to months 2 and 3 with device use in adolescent patients along with minimal safety risks. Based on the existing evidence, it is unclear how Nerivio would fit into the current migraine prevention pathway, although it could provide benefit for those who do not receive adequate benefit from pharmacologic first- or second-line therapies, or who may have a contraindication to pharmacologic therapies. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For adolescent individuals who may benefit from preventive migraine therapy who receive REN, the evidence includes data from the summary submitted in the FDA approval packet and 1 RWE analysis. The data in the FDA summary were collected from adolescents who used the device for acute migraine treatment, but use was equivalent to the suggested preventive use (10 times per month or higher). There was substantial reduction from baseline during months 2 and 3 of device use. This data is limited by a lack of comparator and no description of medications or alternative interventions patients were additionally using. A prospective, real-world evidence analysis investigated the use of Nerivio in adolescents over a 3 month period. There was a statistically significant monthly reduction in mean monthly migraine treatment days. Well-defined, controlled studies are required to confirm benefit in this population. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For children who may benefit from preventive migraine therapy who receive REN, the evidence includes the FDA summary for the expanded approval of preventive use of Nerivio in pediatric patients (ages 8-11) based on a retrospective real-world analysis. Preventive use of the device was assumed by analyzing patients whose frequency of use in month one was suggestive of preventive treatments. No specific data on proportion of patients in whom preventive use was assumed or efficacy outcomes in the assumed preventive use population were reported. Well-defined, controlled studies are required to confirm benefit in this population. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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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2025 Input

Clinical input was sought to help determine whether the use of remote electrical neuromodulation (i.e., Nerivio) for the listed populations would provide a clinically meaningful improvement in net health outcome and represents generally accepted medical practice:

- Individuals who are 12 years and older with episodic or chronic migraine, with or without aura, who are treated for acute migraine or migraine prophylaxis
- Individuals who are 8-11 years old with episodic or chronic migraine, with or without aura, who are treated for acute migraine or migraine prophylaxis

In response to structured requests, clinical input was received from 4 respondents, including 1 physician-level respondent identified by the American Academy of Neurology (AAN), and 3 physician-level responses identified by various academic medical centers. In addition, an informal response was provided by the American Academy of Pediatrics Section on Neurology (AAP).

Clinical input supports this use provides a clinically meaningful benefit, with the majority of respondents supportive that its use is consistent with generally accepted medical practice. Respondents noted that all patients with migraine may benefit from a nonpharmacologic option for either stand-alone or adjunctive use, particularly among those who have failed other options, who have contraindications or an intolerance to alternatives, who are at risk for or have a history of medication overuse headache, or who are at risk of drug-drug interactions. While some clinicians trial acute treatment with REN first, failure in the abortive setting does not preclude success with preventive use. Additionally, clinicians support first-line use of REN for acute or preventive treatment, particularly in adolescent and pediatric populations where there are limited alternatives with evidence of efficacy or suitable side effect profiles. Respondents emphasize that the discreet nature of the REN device is ideal for use by children and adolescents in the school setting.

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 Academy of Neurology/American Headache Society

A 2012 joint guideline by the American Academy of Neurology (AAN) and the American Headache Society (AHS) on pharmacologic treatment for episodic migraine prevention in adults was published prior to the approval of Nerivio in the US and did not address the use of remote electrical neuromodulation (REN) or other nonpharmacologic treatments. Similarly, 2019 joint guidelines issued by AAN and AHS on the treatment of acute migraine and prevention of migraine in children and adolescents did not address the use of REN or other nonpharmacologic treatments.

American Headache Society

In 2021, AHS issued guidance on the integration of new migraine treatments, including REN, into clinical practice. The AHS addressed the use of neuromodulatory devices as a group that included

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electrical trigeminal nerve stimulation, noninvasive vagus nerve stimulation, single-pulse transcranial magnetic stimulation, and REN; no guidance specific to REN use was issued.

The AHS determined that initiation of a neuromodulatory device is appropriate when all of the following criteria are met:

- Prescribed/recommended by a licensed clinician
- Patient is at least 18 years of age (*the guidance noted that 3 devices, including REN, are approved for use in patients age 12 to 17 years*)
- Diagnosis of International Classification of Headache Disorders (ICHD)-3 migraine with aura, migraine without aura, or chronic migraine
- Either of the following:
 - Contraindications to or inability to tolerate triptans
 - Inadequate response to 2 or more oral triptans, as determined by EITHER of the following:
 - Validated acute treatment patient-reported outcome questionnaire (Migraine Treatment Optimization Questionnaire, Patient Perception of Migraine Questionnaire-Revised, Functional Impairment Scale, Patient Global Impression of Change)
 - Clinician attestation.

Department of Veterans Affairs/ Department of Defense

The U.S Department of Veterans Affairs/Department of Defense (VA/DoD) 2023 guidelines for the management of headache state that "there is insufficient evidence to recommend for or against any form of neuromodulation for the treatment and/or prevention of migraine"; examples of neuromodulation treatments mentioned include remote electrical neurostimulation.

International Headache Society

In 2025, the International Headache Society (IHS) released practice guidelines on the use of non-invasive neuromodulation devices for the acute and preventive treatment of migraine. Regarding evidence-based recommendations statements on the use of REN (Nerivio), the IHS states that

- "The panel conditionally recommends the use of Nerivio for the treatment of acute migraine attacks in adult subjects with EM [episodic migraine]. Strength of the recommendation: weak in favor; Quality of the evidence: very low.
- "The panel conditionally recommends the use of Nerivio for preventive treatment of EM/CM in adult subjects with migraine. Strength of the recommendation: weak in favor; Quality of the evidence: very low.

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.

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Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Unpublished</i>			
NCT05940870 ^a	A Prospective, Open-label, Post-marketing Observational Study Assessing the Safety and Efficacy of Nerivio for Migraine Prevention in Real-world Environment	250	Aug 2024 (completed)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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Policy History

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07/07/2022	Medical Policy Committee review
07/13/2022	Medical Policy Implementation Committee approval. New policy.
07/06/2023	Medical Policy Committee review
07/12/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/12/2023	Coding update
07/02/2024	Medical Policy Committee review
07/10/2024	Medical Policy Implementation Committee approval. Added prevention of migraines to the investigational statement based on recent expansion of FDA-approved indications.
09/04/2025	Medical Policy Committee review
09/10/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/03/2026	Medical Policy Committee review
09/09/2026	Medical Policy Implementation Committee review
09/17/2026	Medical Quality Management Committee approval. Remote neuromodulation for migraines for preventive initial and continued treatment added as eligible for coverage with criteria. Added a not medically necessary statement for when criteria are not met.

Next Scheduled Review Date: 09/2027

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2025 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 Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA

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disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue 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 Louisiana Blue 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	No codes
HCPCS	A4540
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;

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- 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.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan’s authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan’s pharmacy benefit.