



# Louisiana

## Outpatient Pulmonary Rehabilitation

**Policy #** 00621

**Original Effective Date:** 10/01/2018

**Current Effective Date:** 06/10/2024

*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: Lung and Lobar Lung Transplant is addressed separately in medical policy 00414.*

### 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 a single course of pulmonary rehabilitation (PR) in the outpatient ambulatory care setting for treatment of chronic pulmonary disease (e.g., moderate-to-severe chronic obstructive pulmonary disease (COPD), bronchiectasis, cystic fibrosis, interstitial lung disease) for individuals with moderate-to-severe disease who are experiencing disabling symptoms and significantly diminished quality of life despite optimal medical management to be **eligible for coverage.\*\***

Based on review of available data, the Company may consider a single course of pulmonary rehabilitation (PR) in an outpatient ambulatory care setting as a preoperative conditioning component for those considered appropriate candidates for lung volume reduction surgery (LVRS) or for lung transplantation (see medical policy 00414) to be **eligible for coverage.\*\***

Based on review of available data, the Company may consider pulmonary rehabilitation (PR) programs following lung transplantation to be **eligible for coverage.\*\***

*Note: Frequency and duration of the program may vary according to the individual's needs. It is not uncommon for the individual to receive therapy 2 or 3 times per week for 6 to 12 weeks. Improvement in functional exercise capacity seems to plateau within 12 weeks of the start of the program, despite continued training.*

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### **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 pulmonary rehabilitation (PR) programs following other types of lung surgery, included but not limited to lung volume reduction surgery (LVRS) and surgical resection of lung cancer to be **investigational**.\*

Based on review of available data, the Company considers pulmonary rehabilitation programs in the outpatient ambulatory care setting for the treatment of post-acute sequelae of SARS-CoV-2 infection to be **investigational**.\*

Based on review of available data, the Company considers multiple courses of pulmonary rehabilitation (PR), either as maintenance therapy in individuals who initially respond, or in individuals who fail to respond, or whose response to an initial rehabilitation program has diminished over time to be **investigational**.\*

Based on review of available data, the Company considers home-based pulmonary rehabilitation (PR) programs to be **investigational**.\*

Based on review of available data, the Company considers pulmonary rehabilitation (PR) programs in all other situations to be **investigational**.\*

### **Policy Guidelines**

A pulmonary rehabilitation outpatient program is a comprehensive program that generally includes team assessment, individual training, psychosocial intervention, exercise training, and follow-up. The overall length of the program and the total number of visits for each component may vary from program to program.

Team assessment includes input from a physician, respiratory care practitioner, nurse, and psychologist, among others.

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Individual training includes breathing retraining, bronchial hygiene, medications, and proper nutrition.

Psychosocial intervention addresses support system and dependency issues.

Exercise training includes strengthening and conditioning, and may include stair climbing, inspiratory muscle training, treadmill walking, cycle training (with or without ergometer), and supported and unsupported arm exercise training. Exercise conditioning is an essential component of pulmonary rehabilitation. Education in disease management techniques without exercise conditioning does not improve the health outcomes of individuals who have chronic obstructive pulmonary disease.

Follow-up to a comprehensive outpatient pulmonary rehabilitation program may include supervised home exercise conditioning.

Candidates for pulmonary rehabilitation should be medically stable and not limited by another serious or unstable medical condition. Contraindications to pulmonary rehabilitation include severe psychiatric disturbance (eg, dementia, organic brain syndrome) and significant or unstable medical conditions (eg, heart failure, acute cor pulmonale, substance abuse, significant liver dysfunction, metastatic cancer, disabling stroke).

## **Background/Overview**

### **Pulmonary Rehabilitation**

In 2013, the American Thoracic Society and the European Respiratory Society defined pulmonary rehabilitation as a “comprehensive intervention based on a thorough patient assessment followed by patient-tailored therapies that include, but are not limited to exercise training, education, and behavior change.” Pulmonary rehabilitation programs are intended to improve patient functioning and quality of life. Most research has focused on patients with chronic obstructive pulmonary disease, although there has been some interest in patients with asthma, cystic fibrosis, or bronchiectasis.

Pulmonary rehabilitation is also routinely offered to patients awaiting lung transplantation and lung volume reduction surgery. Pulmonary rehabilitation before lung surgery may stabilize or improve

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patients' exercise tolerance, teach patients techniques that will help them recover after the procedure, and allow health care providers to identify individuals who might be suboptimal surgical candidates due to noncompliance, poor health, or other reasons.

### **Rationale/Source**

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

### **Description**

Pulmonary rehabilitation is a multidisciplinary approach to reducing symptoms and improving quality of life in individuals with compromised lung function. Pulmonary rehabilitation programs generally include a patient assessment followed by therapeutic interventions including exercise training, education, and behavior change.

### **Summary of Evidence**

#### **Chronic Pulmonary Disease Rehabilitation**

For individuals with moderate-to-severe chronic obstructive pulmonary disease (COPD) who receive a single course of outpatient pulmonary rehabilitation, the evidence includes numerous systematic reviews of randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, and quality of life. The published studies found improved outcomes (ie, functional ability, quality of life) in patients with moderate-to-severe COPD who underwent a comprehensive pulmonary rehabilitation program in the outpatient setting. Among the many randomized trials, the structure of the pulmonary rehabilitation programs varied, so it is not possible to provide guidance on the optimal components or duration of a pulmonary rehabilitation program. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with idiopathic pulmonary fibrosis who receive a single course of outpatient pulmonary rehabilitation, the evidence includes 3 systematic reviews of RCTs. Relevant outcomes

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are symptoms, functional outcomes, and quality of life. Significant differences favoring pulmonary rehabilitation over usual care were seen in 6-minute walk distance (6MWD) in the short term. Starting at 3 months post-intervention, outcomes did not differ between groups. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with bronchiectasis who receive a single course of outpatient pulmonary rehabilitation, the evidence includes a systematic review of RCTs and an RCT published after the systematic review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic review included 4 RCTs on pulmonary rehabilitation for patients with bronchiectasis found that some, but not all, outcomes, improved more with pulmonary rehabilitation than with nonexercise control conditions immediately after the intervention. An RCT published after the systematic review found that 6MWD and quality of life scores increased with pulmonary rehabilitation compared to a non-exercise control group in the short-term. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Although most published evidence on outpatient pulmonary rehabilitation for chronic pulmonary diseases assesses COPD, observational studies have reported on outcomes from pulmonary rehabilitation for other chronic pulmonary diseases. Clinical guidelines from pulmonary organizations have supported the use of outpatient pulmonary rehabilitation for individuals who are experiencing disabling symptoms and have significantly diminished quality of life despite optimal medical management. Therefore, outpatient pulmonary rehabilitation may be considered medically necessary for this population.

### **Preparation for Lung Surgery**

For individuals with scheduled lung surgery for volume reduction, transplantation, or resection who receive a single course of preoperative outpatient pulmonary rehabilitation, the evidence includes RCTs and observational studies. Relevant outcomes are symptoms, functional outcomes, and quality of life. There is a lack of large RCTs comparing pulmonary rehabilitation with no pulmonary rehabilitation for preoperative candidates undergoing lung volume reduction surgery, lung transplantation, or lung cancer resection. Moreover, the available studies have evaluated exercise programs, but not necessarily comprehensive pulmonary rehabilitation programs. Also, the few small RCTs and observational studies have only reported short-term outcomes and there was inconsistent evidence of benefit on these outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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Findings from the National Emphysema Treatment Trial have suggested that pulmonary rehabilitation is an appropriate component of care for patients with COPD before undergoing lung volume reduction surgery. Also, pulmonary rehabilitation is considered the standard of care in individuals undergoing lung transplantation to maximize preoperative pulmonary status. Thus, pulmonary rehabilitation may be considered medically necessary for individuals considered appropriate candidates for lung volume reduction surgery or lung transplantation.

### **Pulmonary Rehabilitation After Lung Surgery**

For individuals who have had lung volume reduction surgery who receive a single course of outpatient pulmonary rehabilitation, the evidence includes a case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. No published RCTs were identified. The case series evaluated a comprehensive pulmonary rehabilitation program after lung volume reduction surgery in 49 patients who had not received preoperative pulmonary rehabilitation. Health-related quality of life was higher at 3 to 6 months and 12 to 18 months post-surgery. The series did not provide data on patients who underwent lung volume reduction surgery and did not have postoperative pulmonary rehabilitation, or patients who had preoperative pulmonary rehabilitation. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have had lung transplantation who receive a single course of outpatient pulmonary rehabilitation, the evidence includes RCTs, a systematic review, and a case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. Neither of the 2 RCTs identified in a 2010 systematic review reported on functional outcomes, but uncontrolled studies have reported improvements in functional outcomes. An RCT, published after the systematic review, found that patients who had a postsurgical exercise intervention walked more 1-year post discharge than before and had a significantly greater 6MWD. Findings on other outcomes were mixed. The most recent RCT (2017) did not identify a difference in outcomes with longer duration of pulmonary rehabilitation. Case series data also support improvements in 6MWD after postoperative pulmonary rehabilitation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have had lung cancer resection who receive a single course of outpatient pulmonary rehabilitation, the evidence includes 2 RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. One small RCT evaluated a comprehensive pulmonary

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rehabilitation program in patients who underwent thoracotomy for lung cancer. The trial was terminated early, had a high dropout rate, and reported mixed findings. An exercise-only intervention in patients who had lung cancer surgery had mixed findings and did not evaluate functional outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### **Post-Acute Sequelae of SARS-CoV-2 Infection**

For individuals who have post-acute sequelae of SARS-CoV-2 infection, the evidence includes systematic reviews of RCTs and cohort studies. Relevant outcomes are symptoms, functional outcomes, and quality of life. One systematic review pooled data from 10 RCTs and found significant improvement in quality of life, dyspnea scores, and functional capacity with telerehabilitation compared with sham intervention, no intervention, or usual care including face-to-face intervention. Lung function and adverse events were not different between groups. Other systematic reviews also found benefit with ambulatory pulmonary rehabilitation in these patients, but the data were not pooled and the evidence is limited by a small number of studies most of which are observational in nature. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### **Repeat or Maintenance Pulmonary Rehabilitation**

For individuals who have had an initial course of pulmonary rehabilitation who receive repeat or maintenance outpatient pulmonary rehabilitation, the evidence includes a limited number of RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. One small RCT evaluating repeat pulmonary rehabilitation programs had methodologic limitations and did not report inpatient and outpatient outcomes separately; it also lasted only 3 weeks. In the evaluation of maintenance pulmonary rehabilitation programs, evidence was mixed. Due to the paucity of RCTs, methodologic limitations of available trials, and lack of clinically significant findings, the evidence to determine the effect of maintenance pulmonary rehabilitation programs on health outcomes in patients with COPD is insufficient. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### **Home-Based Pulmonary Rehabilitation**

For individuals who have an indication for outpatient pulmonary rehabilitation who receive a single course of home-based pulmonary rehabilitation, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and quality of life. Most studies of home-

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based pulmonary rehabilitation have compared outcomes with standard care. Very few have compared home-based pulmonary rehabilitation with the hospital- or clinic-based pulmonary rehabilitation, and the available studies are mostly of low quality. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## **Supplemental Information**

### **Practice Guidelines and Position Statements**

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

### **American Thoracic Society and European Respiratory Society**

A 2015 joint statement on pulmonary rehabilitation was issued by the ATS and the European Respiratory Society. The statement included the following relevant conclusions:

- “Pulmonary rehabilitation (PR) has demonstrated physiological, symptom-reducing, psychosocial, and health economic benefits in multiple outcome areas for patients with chronic respiratory diseases.”
- “The evidence indicates that patients who benefit from PR include not only persons with moderate to severe airflow limitation but also those with mild to moderate airflow limitation with symptom-limited exercise tolerance, those after hospitalization for COPD exacerbation, and those with symptomatic non-COPD respiratory conditions.”
- “Patients graduating from a PR program stand to benefit from a home, community-based, or program-based maintenance exercise program to support the continuation of positive exercise behavior.”

In 2017, the Society issued a joint statement on the management of COPD exacerbation. For patients hospitalized with a COPD exacerbation, they suggest “the initiation of pulmonary rehabilitation within 3 weeks after hospital discharge” (strength: conditional; quality of evidence: very low). In addition, “[they] suggest not initiating pulmonary rehabilitation during hospitalisation” (strength: conditional; quality of evidence: very low).

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In 2021, the ATS published a report from a workshop that was convened to achieve consensus on the essential components of pulmonary rehabilitation and to identify requirements for successful implementation of emerging program models. A Delphi process involving experts from across the world identified 13 "essential" components of pulmonary rehabilitation that must be delivered in any program model, encompassing patient assessment, program content, method of delivery, and quality assurance; an additional 27 "desirable" components were also identified. See the full text of this publication for further details.

### Global Initiative for Chronic Obstructive Lung Disease

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) updates their guidelines annually on the diagnosis, management, and prevention of COPD. In their 2024 guidance, GOLD notes that:

"Pulmonary rehabilitation should be considered as part of integrated patient management... Optimum benefits are achieved from programs lasting 6 to 8 weeks. Available evidence indicates that there are no additional benefits from extending pulmonary rehabilitation to 12 weeks. Supervised exercise training at least twice weekly is recommended, and this can include any regimen from endurance training, interval training, resistance/strength training; upper and lower limbs ideally should be included as well as walking exercise; flexibility, inspiratory muscle training and neuromuscular electrical stimulation can also be incorporated. In all cases the rehabilitation intervention (content, scope, frequency, and intensity) should be individualized to maximize personal functional gains."

The benefits to patients with COPD from pulmonary rehabilitation cited in the guidelines are listed in Table 1.

**Table 1. Benefits of Pulmonary Rehabilitation in Patients with COPD (GOLD guidelines)**

Pulmonary Rehabilitation Benefit	LOE
Pulmonary rehabilitation improves dyspnea, health status, and exercise tolerance in stable patients.	A
Pulmonary rehabilitation reduces hospitalization among patients who have had a recent exacerbation ( $\leq 4$ weeks from prior hospitalization).	B

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Pulmonary rehabilitation leads to a reduction in symptoms of anxiety and depression.	A
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COPD: chronic obstructive pulmonary disease; GOLD: Global Initiative for Chronic Obstructive Lung Disease; LOE: level of evidence.

Related to the setting of pulmonary rehabilitation, the GOLD guidelines state that "community-based and home-based programs have been shown to be as effective as hospital-based programs in randomized controlled trials, as long as the frequency and intensity are equivalent." This statement cites studies described alone or included in systematic reviews in the Rationale Section (Maltais et al 2008 and Holland et al 2017).

### National Institute for Health and Care Excellence

In 2021, NICE issued a rapid guideline on managing the long-term effects of COVID-19. The guideline recommends using a "multidisciplinary approach to guide rehabilitation, including physical, psychological and psychiatric aspects of management...including fatigue management, breathing retraining, and psychological or psychiatric support."

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

In 2007, the Centers for Medicare & Medicaid Services affirmed its position that a national coverage determination for pulmonary rehabilitation is not appropriate.

### Ongoing and Unpublished Clinical Trials

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

**Table 2. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			

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NCT05990946	A Prospective, Randomized, Controlled Study to Evaluate the Impact of Remote Symptom Management Via Smartphone App Based on Electronic Patient-Reported Outcomes on Rehabilitation Exercise Adherence After Minimally Invasive Surgery in Lung Cancer Patients	224	Mar 2024
NCT06085261	Chronic Obstructive Pulmonary Disease: A Multi-center Supervised Tele-rehabilitation Study	360	Dec 2024
NCT06077994	The Enhanced Pulmonary Rehabilitation Program With Digital Remote Patient Monitoring: A Feasibility Randomized Clinical Trial	74	Oct 2024
NCT05136300	Pulmonary Rehabilitation After Minimal Invasive Surgery in Lung Cancer	100	Jul 2023
NCT02842463	Use of the 6-minute Stepper Test to Individualise Pulmonary Rehabilitation in Patients With Mild to Moderate Chronic Obstructive Pulmonary Disease	80	Dec 2023
<i>Unpublished</i>			
NCT03326089	Short and Long-term Effects of Oxygen Supplemented Pulmonary Rehabilitation in Idiopathic Pulmonary Fibrosis	20 (actual)	Aug 2023
NCT03299504	Factors Predicting Success in Lung Transplant Recipients Who Have Participated in the COLTT Program (Daily Intensive Post-hospitalization Rehabilitation): A Retrospective Review	105 (actual)	Apr 2018 (last updated 08/24/18)

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NCT03244137	Effects of Pulmonary Rehabilitation on Cognitive Function in Patients With Severe to Very Severe Chronic Obstructive Pulmonary Disease	56 (actual)	Dec 2019 (last updated 01/07/20)
NCT02426437	How Does Early Rehabilitation Affect Patient-centred Health Outcomes and Cardiovascular Risk in COPD Patients	87 (actual)	Dec 2019 (last updated 04/08/21)

NCT: national clinical trial.

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## **Policy History**

Original Effective Date: 10/01/2018

Current Effective Date: 06/10/2024

07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. New policy.
07/03/2019	Medical Policy Committee review
07/18/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/02/2020	Medical Policy Committee review
07/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/16/2020	Coding update
07/01/2021	Medical Policy Committee review
07/14/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/20/2021	Coding update
07/07/2022	Medical Policy Committee review
07/13/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/06/2023	Medical Policy Committee review
07/12/2023	Medical Policy Implementation Committee approval. Examples and <i>Note</i> added. Coverage eligibility unchanged.
05/02/2024	Medical Policy Committee review

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05/08/2024 Medical Policy Implementation Committee approval. Added an investigational statement for pulmonary rehabilitation programs in the outpatient ambulatory care setting for the treatment of post-acute sequelae of SARS-CoV-2 infection.

Next Scheduled Review Date: 05/2025

### **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 2023 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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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	94625, 94626
HCPCS	G0237, G0238, G0239, G0302, G0303, G0304, G0305, S9473
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

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- 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.

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