Minimally Invasive Treatment of Nasal Valve Collapse

Policy # 00657
Original Effective Date: 01/23/2019
Current Effective Date: 01/23/2019

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.

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 insertion of an absorbable lateral nasal implant for the treatment of symptomatic nasal valve collapse to be **investigational.***

Based on review of available data, the Company considers ablative techniques (e.g. radiofrequency ablation) that create submucosal lesions in the nostril and/or lateral nasal wall for the treatment of symptomatic nasal valve collapse to be **investigational.***

Based on review of available data, the Company considers all other minimally invasive techniques, including those that do not involve cartilage grafting and/or complex suture techniques (e.g. lateral crural turn in flap), for the treatment of symptomatic nasal valve collapse to be **investigational.***

Background/Overview

NASAL OBSTRUCTION
Nasal obstruction is defined clinically as a patient symptom that presents as a sensation of reduced or insufficient airflow through the nose. Commonly, patients will feel that they have nasal congestion or stuffiness. In adults, clinicians focus the evaluation of important features of the history provided by the patient such as whether symptoms are unilateral or bilateral. Unilateral symptoms are more suggestive of structural causes of nasal obstruction. A history of trauma or previous nasal surgery, especially septoplasty or rhinoplasty, is also important. Diurnal or seasonal variation in symptoms is associated with allergic conditions.

Etiology
Nasal obstruction associated with the external nasal valve is commonly associated with post-rhinoplasty or traumatic sequelae and may require functional rhinoplasty procedures. A common cause of internal nasal valve collapse is septal deviation. Prior nasal surgery, nasal trauma, and congenital anomaly are additional causes.

Pathophysiology
The internal nasal valve, bordered by the collapsible soft tissue between the upper and lower lateral cartilages, anterior end of the inferior turbinate, and the nasal septum, forms the narrowest part of the nasal airway. During inspiration, the lateral wall cartilage is dynamic and draws inward toward the septum and the internal nasal valve narrows providing protection to the upper airways. The angle at the junction between the septum and upper lateral cartilage is normally 10° to 15° in white populations. Given that the internal nasal valve accounts for at least half of the nasal airway resistance; even minor further narrowing of this

area can lead to symptomatic obstruction for a patient. Damaged or weakened lateral nasal cartilage will further decrease airway capacity of the internal nasal valve area, increasing airflow resistance and symptoms of congestion.

Physical Examination
A thorough physical examination of the nose, nasal cavity, and the nasopharynx is generally sufficient to identify the most likely etiology for the nasal obstruction. Both the external and internal nasal valve areas should be examined. The external nasal valve is at the level of the internal nostril. It is formed by the caudal portion of the lower lateral cartilage, surrounding soft tissue and the membranous septum.

The Cottle maneuver is an examination in which the cheek on the symptomatic side is gently pulled laterally with 1 to 2 fingers. If the patient is less symptomatic with inspiration during the maneuver, the assumption is that the nasal valve has been widened from a collapsed state or dynamic nasal valve collapse. An individual can perform the maneuver on oneself and it is subjective. A clinician performs the modified Cottle maneuver. A cotton swab or curette is inserted into the nasal cavity to support the nasal cartilage and the patient reports whether there is an improvement in the symptoms with inspiration. In both instances, a change in the external contour of the lateral nose may be apparent to both the patient and the examiner.

Measuring Nasal Obstruction
Stewart et al (2004) proposed the Nasal Obstruction Symptom Evaluation as a validated sinonasal-specific health status instrument that is used to assess the impact of nasal obstruction on the quality of life of affected persons. It is a 5-item questionnaire on breathing problems: nasal congestion or stuffiness, nasal blockage or obstruction, trouble breathing through the nose, trouble sleeping, and inability to get enough air through the nose during exercise or exertion. The responses are made on a Likert-type scale ranging from 0 (not a problem) to 4 (severe problem). The range of raw scores is 0 to 20. The score is then scaled to a potential total score of 0 to 100 by multiplying the raw score by 5. A score of 100 means the worst possible problem with nasal obstruction.

Lipan and Most (2013) developed a Nasal Obstruction Symptom Evaluation scale–based nasal obstruction severity classification system. The system is proposed as a means to classify patients for clinical management as well as to better define study populations and describe treatment or intervention responses (see Table 1).

Table 1. NOSE Severity Classification

Severity Class	NOSE Score Range
Mild	5-25
Moderate	30-50
Severe	55-75
Extreme	80-100

NOSE: Nasal Obstruction Symptom Evaluation.

Treatment
Treatment of symptomatic nasal valve collapse includes the use of nonsurgical interventions such as the adhesive strips applied externally across the nose (applying the principle of the Cottle maneuver) or use of

nasal dilators, cones, or other devices that support the lateral nasal wall internally (applying the principle of the modified Cottle maneuver).

Severe cases of obstruction result from nasal valve deformities are treated with surgical grafting to widen and/or strengthen the valve. Common materials include cartilaginous autografts and allografts, as well as permanent synthetic grafts. Cartilage grafts are most commonly harvested from the patient's nasal septum or ear.

Nasal Implants
The placement of an absorbable implant to support the lateral nasal cartilages has been proposed as an alternative to more invasive grafting procedures in patients with severe nasal obstruction. It is believed that the implant dissolves over time, resulting in remodeling of the lateral nasal wall and the generation of scar tissue that adds rigidity and prevents collapse.

Ablative Techniques
The use of ablative technologies, such as radiofrequency ablation, has been proposed as a treatment alternative to grafting procedures in patients with severe nasal obstruction. Typically, several submucosal lesions are created in the nasal ala and/or nasal side wall. It is believed that as these lesions heal over time, there is resultant remodeling of the lateral nasal wall and the generation of scar tissue that adds rigidity and prevents collapse.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
In May 2016, LATERA®‡ (Spirox) was cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process (Food and Drug Administration product code: NHB). LATERA is the only commercially available absorbable nasal implant for treatment of nasal valve collapse. It is a class II device and regulatory details are summarized in Table 2.

Table 2. Absorbable Nasal Implant Cleared by the Food and Drug Administration

Product	Manufacturer	Date Cleared	510(k) No.	Indication
LATERA absorbable nasal implant	Spirox (part of Stryker)	2016	K161191	Supporting nasal upper and lower lateral cartilage

Centers for Medicare and Medicaid Services (CMS)
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.

Rationale/Source

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to

ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

ABSORBABLE LATERAL NASAL VALVE IMPLANT

Clinical Context and Therapy Purpose

The purpose of insertion of an absorbable nasal valve implant in patients who have symptomatic nasal valve obstruction due to nasal valve collapse is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of an absorbable nasal valve implant in patients who have symptomatic nasal valve obstruction due to nasal valve collapse improve the net health outcome?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is adults who have severe symptomatic nasal obstruction symptoms due to internal nasal valve (also known as zone 1) collapse (NVC). NVC is one of the recognized structural causes of obstructed breathing and congestion, and the diagnosis is primarily clinical. NVC may be unilateral or bilateral and is typically constant with each inspiration. The condition may occur in association with prior trauma or rhinonasal surgery. The evaluation consists of clinical history to elicit alternative causes or co-occurring conditions such as obstructive sleep apnea or medication use. In addition to examination of the head and neck, the Cottle maneuver or modified Cottle maneuver (previously described) is used to rule in NVC. Anterior rhinoscopy and nasal endoscopy are used and rule out structural abnormalities such as septal deviation or mucosal conditions such as enlarged turbinates. Radiographic studies are not generally indicated.

Interventions

The therapy being considered is unilateral or bilateral insertion of an absorbable nasal implant into the lateral nasal wall. The product is predominantly cylindrical in shape with a diameter of 1 mm and an overall

length of 24 mm with a forked distal end for anchoring into the maxillary periosteum. It is composed of poly(L-lactide-*co*-D-L-lactide) 70:30 copolymer, which is absorbed in the body over approximately 18 months. It is packaged with a 16-gauge insertion device. The available product information describes the integrity of the implant to be maintained for 12 months after implantation while a fibrous capsule forms around the device. A remodeling phase where collagen replaces the implant within the capsule persists through 24 months and is the purported mechanism of support for the lateral nasal wall support.

Comparators
The following therapies and practices are currently being used to treat NVC: nonsurgical treatments include the use of externally applied adhesive strips or intranasal insertion of nasal cones. The basic mechanism of action of these treatments is to widen the nasal valve and permit increased airflow. Surgical grafting using either autologous cartilage (typically from the nasal septum, ear, or homologous irradiated rib cartilage) or a permanent synthetic implant may be performed to provide structural support to the lateral wall support defect.

Outcomes
The general outcomes of interest are change in symptoms and disease status, treatment-related morbidity, functional status, and change in quality of life. The Nasal Obstruction Symptom Evaluation (NOSE) score is an accepted symptom questionnaire for research purposes. The score can also be stratified to indicate the degree of severity of the nasal obstruction symptoms. The insertion of the absorbable implant is performed under local anesthesia and the adverse event profile includes mild pain, irritation, bruising and inflammation, awareness of the presence of the implant, infection, and the need for device retrieval prior to complete absorption.

Timing
The duration of follow-up to assess early procedural outcomes is 1 month and at least 24 months would be required to evaluate the durability of symptom improvement as well as to confirm the association with the purported device mechanism of action.

Setting
Insertion of an absorbable nasal implant is performed in the outpatient setting by an otolaryngologist or plastic surgeon.

Study Selection Criteria
No randomized comparative studies were identified to evaluate the absorbable nasal implant. The best available evidence consists of 2 nonrandomized prospective industry-sponsored studies of the commercially available absorbable nasal implant.

Nonrandomized Studies
The characteristics and results of nonrandomized studies are summarized in Tables 3, 4, and 5.

Table 3. Summary of Key Nonrandomized Study Characteristics

Study	Study Type	Country	Dates	Participants[a]	Treatment, n	Follow-Up
Stolovitzky et al (2018)	Prospective single cohort	U.S. (14 clinical sites)	Sep 2016-Mar 2017	101	• Insertion of implant[b] alone: 43 • Insertion of implant[b] plus adjunctive procedure: 58	1, 3, 6 mo
San Nicoló et al (2017)	Prospective single cohort	Germany (3 clinical sites)	NR	30	Insertion of 56 lateral wall implant[b]: • Bilateral: 26 • Unilateral: 4	1 wk and 1, 3, 6, 12 mo

NOSE: Nasal Obstruction Symptom Evaluation; NR: not reported.
[a] Baseline inclusion criteria: NOSE score ≥55. Baseline exclusion criteria: septoplasty or turbinate reduction within 6 mo, rhinoplasty within 12 mo, recurrent nasal infection, intranasal steroids, permanent nasal implants or dilators, precancerous or cancerous lesions, radiation or chemotherapy within 24 mo.
[b] Absorbable polylactide implant marketed in the United States as Latera.

Table 4. Summary of Key Nonrandomized Study NOSE Score Results

Study	Baseline	1 Month	3 Months	6 Months	12 Months
Stolovitzky et al (2018)					
N or n	101	99	97	87	
Mean score (SD)	79.5 (13.5)	34.6 (25.0)	32.0 (28.4)	30.6 (25.8)	
p[a]		<0.05	<0.01	<0.01	
Mean change from baseline (SD)		NR	NR	NR	
Response rate[b] for implant alone group[c]		90.5%	87.8%	89.2%	
San Nicoló et al (2017)					
N or n	30		29	30	29
Mean score (SD)	76.7 (14.8)	NR	28.4	33.3	35.2
Mean change from baseline (SD)			-48.4 (26.9)	-43.3 (29.7)	-40.9 (29.2)
p[d]			<0.001	<0.001	<0.001
N or n		NR	29	30	29
Response rate, n (%)[b]			25 (86.2)	24 (80)	22 (75.9)

CI: confidence interval; NOSE: Nasal Obstruction Symptom Evaluation; NR: not reported; SD: standard deviation.
[a] Paired *t* tests were used to compare the mean baseline value with each of the follow-up time points to determine whether there was evidence of significant reductions in NOSE scores. CIs not reported.
[b] Response rate was defined as an improvement of at least 1 NOSE score category or a 20% reduction in NOSE score.
[c] Implant alone group was taken to be n=43 but any loss to follow-up for this subgroup was not reported for this outcome.
[d] Paired *t* tests comparing the mean preoperative NOSE score to the mean score at each follow-up time point. CIs not reported.

Table 5. Summary of Key Nonrandomized Study Safety and Adverse Event Results

Study	1 Month	3 Months	6 Months	12 Months
Stolovitzky et al (2018)				
Adverse events		99[b]		
Device related[a]		19 events in 17 patients[c]		
San Nicoló et al (2017)				
N or n	30	29	30	29
Device tolerability, % (n)				
None/mild pain	30 (100)	29(100)	29 (96.7)	29(100)
Not assessed			1 (3.3)	
Cosmetic changes[d]	26 (86.7)	27 (93.1)	27 (90.0)	26 (89.7)

Device-related adverse events[e]	5	0	0	0

[a] Defined as implant- or procedure-related.
[b] Taken to be n=99 but no specific reporting for this category.
[c] Total number only reported for inflammation, foreign body sensation, skin irritation, hematoma, infection, and implant retrievals.
[d] Photographic review.
[e] Three device retrievals, 1 hematoma, and 1 inflammation.

Stolovitzky (2018) reported on 6-month outcomes for 101 patients with severe-to-extreme class of NOSE scores were enrolled at 14 U.S. clinics between September 2016 and March 2017. In the total cohort, 40.6% had a history of allergic rhinitis and 32.7% had a history of sinus disease. The types and rates of prior rhinologic surgeries were septoplasty (26.7%), turbinate reduction (29.7%), endoscopic sinus surgery (22.8%), and rhinoplasty (10.9%). The rate of prior septoplasty was 53.5% in the group that received the absorbable implant alone and 87.9% in the group that received implant plus adjunctive surgery. Overall, fifty-eight (57%) patients had adjunctive procedures (not expressly reported) in addition to the implant placement. In addition to the NOSE score, patients were assessed pre- and postoperatively with the Lateral Wall Insufficiency score, which is based on a review of a lateral wall motion video. Patients reported visual analog scale scores for nasal congestion at each follow-up visit.

The purpose of the gaps tables (see Tables 6 and 7) is to display notable gaps identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of the evidence supporting the position statement.

Table 6. Relevance Gaps

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Stolovitzky et al (2018)	1. Patient population varied in important clinical characteristics and types and rates of prior rhinologic surgery 2. Clinical context for patient selection for absorbable implant vs implant plus adjunctive surgery not described 5. Implant plus adjunctive surgery group a subpopulation of potential intended use			6. Clinically significant difference not supported. A positive responder could still have severe symptoms.	1. Duration of outcomes reporting less than duration of absorption of device and purported completion of remodeling phase
San Nicoló et al (2017)	2. Clinical context for patient selection for absorbable implant vs alternative surgery not described 3. Study population is heterogenous: 68% had prior rhinonasal surgery			6. Clinically significant difference not supported. A positive responder could still have severe symptoms.	1. Duration of outcomes reporting less than duration of absorption of device and purported completion of remodeling phase

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use. 5. Study population is subpopulation of intended use
[b] Intervention key: 1.Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator
[c] Comparator key: 1.Not clearly defined; 2.Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1.Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Not CONSORT reporting of harms; 4.Not established and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported
[e] Follow-Up key: 1. Not sufficient duration for benefits; 2. Not sufficient duration for harms.

Table 7. Study Design and Conduct Gaps

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Stolovitzky et al (2018)[7]		1. No sham control and not blinded to treatment assignment		1. Data incomplete for populations assessed for various outcomes 2. Missing data for patients who had device retrievals		
San Nicoló et al (2017)[8]		1. No sham control and not blinded to treatment assignment		2. Missing data for patients who had device retrievals		

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

ABLATIVE TECHNIQUES TO TREAT NASAL VALVE COLLAPSE

Clinical Context and Therapy Purpose

The purpose of creating submucosal ablative lesions as a means to strengthen the nasal ala and/or lateral nasal wall in patients who have symptomatic nasal valve obstruction due to nasal valve collapse is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the creation of ablative lesions in the nasal ala/nasal sidewall of patients who have symptomatic nasal valve obstruction due to nasal valve collapse improve the net health outcome?

Available Research and Data

At this time, several different devices are used to create submucosal lesions in the nasal ala and/or nasal sidewall. Examples include the Aquamantys by Medtronic and Vivaer by Aerin Medical. The Aquamantys system has been around for many years and creates bipolar cautery lesions. Vivaer was created specifically for the treatment of nasal valve collapse and received Premarket approval from the FDA via the 501(k) pathway in December 2017. These devices work by inserting a probe into the subcutaneous tissues of the nasal ala and/or lateral nasal wall and ablating the surrounding tissue. As the tissue heals, there is theoretically scarring and remodeling that may lead to stiffening of the lateral wall and resistance to collapse. To date, no studies have been published on this technology. FDA approval of Vivaer was obtained through submission of results on 50 patients by Aerin Medical, and data has been presented in abstract form at one national otolaryngology meeting. The company (Aerin Medical) also states on their website that over 1,000 patients have been treated with their device. However, there is no published data on the use of submucosal ablative technologies in the treatment of nasal valve collapse.

SUMMARY OF EVIDENCE

For individuals with symptomatic nasal obstruction due to internal nasal valve collapse who receive an absorbable lateral nasal valve implant, the evidence includes 2 nonrandomized prospective, single-cohort industry-sponsored studies. Relevant outcomes are symptoms, change in disease status, treatment-related morbidity, functional outcomes, and quality of life. Both studies are limited by the heterogeneity of the populations evaluated. Specifically, the types and rates of prior nasal procedures were not well described, nor was the clinical rationale for alternative or adjunctive procedural interventions. Overall, improvements in the Nasal Obstruction Symptom Evaluation score have been demonstrated in the study reports. However, a clinically significant difference may not be consistently apparent in small study populations. Some patients meeting the positive responder criteria still reported severe symptoms, and many patients reported some loss of improvement at 1 year. Data elements are missing or difficult to determine for important outcomes. As reported, adverse events appeared to be mild in severity and self-limiting, but still appeared common. Device retrievals are incompletely characterized. They occurred in 10% of patients in the primary cohort study, and it is not known, eg, whether a device retrieval occurred in a patient who had only a unilateral nasal implant. The need for device retrievals appears to occur early in the course of follow-up (1 month); suggesting technical experience limitations on the part of the operator or inappropriate patient selection. The duration of outcomes reporting is less than the duration of absorption of the device (18 months) and the purported completion of tissue remodeling phase (24 months). Randomized controlled trials with a sham control are feasible and should be performed. Lastly, the use of minimally invasive ablative technologies to treat nasal valve collapse is a new technique that does not yet have any published data to support its use. The evidence is insufficient to determine the effects of the technology on health outcomes.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, “Absorbable Nasal Implant for Treatment of Nasal Valve Collapse”, 7.01.163, 10:2018.
2. Howard BK, Rohrich RJ. Understanding the nasal airway: principles and practice. *Plast Reconstr Surg.* Mar 2002;109(3):1128-1146; quiz 1145-1146. PMID 11884847
3. Stewart MG, Witsell DL, Smith TL, et al. Development and validation of the Nasal Obstruction Symptom Evaluation (NOSE) scale. *Otolaryngol Head Neck Surg.* Feb 2004;130(2):157-163. PMID 14990910

4. Lipan MJ, Most SP. Development of a severity classification system for subjective nasal obstruction. *JAMA Facial Plast Surg.* Sep-Oct 2013;15(5):358-361. PMID 23846399
5. Rhee JS, Weaver EM, Park SS, et al. Clinical consensus statement: Diagnosis and management of nasal valve compromise. *Otolaryngol Head Neck Surg.* Jul 2010;143(1):48-59. PMID 20620619
6. Fraser L, Kelly G. An evidence-based approach to the management of the adult with nasal obstruction. *Clin Otolaryngol.* Apr 2009;34(2):151-155. PMID 19413614
7. Spirox. Latera. 2017; http://www.spiroxmed.com/latera. Accessed September 10, 2018.
8. Stolovitzky P, Sidle DM, Ow RA, et al. A prospective study for treatment of nasal valve collapse due to lateral wall insufficiency: Outcomes using a bioabsorbable implant. *Laryngoscope.* May 14 2018. PMID 29756407
9. San Nicoló M, Stelter K, Sadick H, et al. Absorbable implant to treat nasal valve collapse. *Facial Plast Surg.* Apr 2017;33(2):233-240. PMID 28388804

Policy History

Original Effective Date: 01/23/2019
Current Effective Date: 01/23/2019
01/10/2019 Medical Policy Committee review
01/23/2019 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 01/2020

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 2018 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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

CPT is a registered trademark of the American Medical Association.

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

Code Type	Code
CPT	30465, 30999
HCPCS	C1889, C9749
ICD-10 Diagnosis	J34.2, J34.89, J34.9

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

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

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.