Sinus Ostial Dilatation with Balloon Catheter for Rhinosinusitis

Policy # 00292
Original Effective Date: 04/13/2011
Current Effective Date: 09/13/2021
Returned to Active Status: 12/01/2015

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.

When Services May Be Eligible for Coverage

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

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider sinus ostial dilatation with balloon catheter for the treatment of chronic rhinosinusitis or recurrent acute rhinosinusitis to be **eligible for coverage.****

Patient Selection Criteria for chronic rhinosinusitis

Coverage eligibility will be met when the following criteria are present:

- Chronic rhinosinusitis without nasal polyps in an adolescent or adult patient, which has persisted for a minimum of 12 weeks despite aggressive medical therapy. This should include documentation of treatment with all of the following:
  - Saline nasal irrigation for at least 8 consecutive weeks
  - Intranasal corticosteroids for at least 8 weeks
  - Two 10-day courses of antibiotics or one prolonged course of oral antibiotic for at least 21 days; AND
- Chronic rhinosinusitis of the sinus to be dilated is confirmed with nasal endoscopy and computed tomography as evidenced by:
  - Purulent (not clear) mucus OR edema in the middle meatus, anterior ethmoid, or sphenoethmoid region; AND
  - Significant mucosal thickening of greater than 3 mm, opacification, or air-fluid levels documented by a formal CT scan report from an independent radiologist.

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Patient Selection Criteria for recurrent acute rhinosinusitis
Coverage eligibility will be met when the following criteria are present:

- Four or more documented and treated episodes in a 12 month period; AND
- Nasal endoscopy performed during the fourth episode showing purulent (not clear) mucus OR edema in the middle meatus, anterior ethmoid, or sphenoethmoid region; AND
- CT imaging performed during the fourth episode should demonstrate pathology in the sinus to be dilated that meets the same CT imaging criteria (significant mucosal thickening of greater than 3 mm, opacification, or air-fluid levels documented by a formal CT scan report from an independent radiologist.)

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

The use of sinus ostial dilatation with balloon catheter when patient selection criteria are not met is considered to be **investigational.***

Based on review of available data, the Company considers sinus ostial dilatation with balloon catheter for the treatment of nasal polyps or tumors to be **investigational.***

Based on review of available data, the Company considers sinus ostial dilatation with balloon catheter for children ages 12 and under to be **investigational.***

Based on review of available data, the Company considers dilation of sinus ostia using a device other than balloon catheter, including but not limited to reusable dilators (e.g. Simplicity®‡ Dilators), to be **investigational.***

Policy Guidelines

When indicated and appropriate, optimal medical therapy should include also:

- Allergy evaluation, education, and optimal treatment;
- Decongestants;

- Treatment of rhinitis medicamentosa (rebound nasal congestion due to extended use of topical decongestants); and
- Education on environmental irritants including tobacco smoke.

Balloon Ostial Dilation (BOD) used in combination with Functional Endoscopic Sinus Surgery (FESS)

- BOD when used as a tool during functional endoscopic sinus surgery (FESS) in the same sinus cavity is considered to be an integral part of the FESS procedure.
- When BOD is used as an adjunct to FESS (defined as FESS on one sinus and BOD on another sinus in the same patient during the same operation) medical necessity criteria for BOD apply to the sinus being considered for BOD.

Considerations for the use of BOD in children under age 18 years include the following:

- FDA labeling for several 510(k) cleared devices includes use in children 17 years of age and under and is indicated to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures.
- A 2014 AAO-HNS Clinical Consensus Statement on Pediatric Chronic Rhinosinusitis had near consensus on the safety of BOD in children but did not reach a consensus on efficacy.
- American Academy of Pediatrics Clinical Practice Guidelines only address the diagnosis and treatment of acute bacterial rhinosinusitis.

For patients undergoing evaluation for surgical management of chronic sinusitis (either dilation or standard functional endoscopic sinus surgery), the CT scan on which the surgical plan and evaluation are based is typically performed within 90 days of the planned procedure. CT scans beyond 90 days may be repeated, as both disease and anatomy may have changed. CT scans older than 90 days may rarely be used in adult patients when the symptoms and/or condition have not changed since the CT scan was obtained.

When assessing for response to therapy and potential surgical candidacy for patients with chronic rhinosinusitis, CT scanning is typically indicated approximately 1-2 weeks following completion of aggressive medical therapy. Imaging prior to this time may underrepresent patient response and overrepresent disease burden. However, in certain circumstances, such as in lack of response to

treatment or uncertainty of diagnosis, imaging may be indicated earlier in the treatment course or even prior to the initiation of treatment.

Background/Overview

The balloon ostial dilatation procedure involves placing a balloon in the sinus ostium and inflating the balloon to stretch the opening. It can be performed as a stand-alone procedure or as an adjunctive procedure to FESS.

Chronic rhinosinusitis (CRS) is characterized by purulent nasal discharge, usually without fever, that persists for weeks to months. Symptoms of congestion often accompany the nasal discharge. There also may be mild pain and/or headache. Thickening of mucosa may restrict or close natural openings between sinus cavities and the nasal fossae, although symptoms are variable because considerable variation exists in the location and shape of these sinus ostia.

Estimates are that approximately 30 million individuals in the United States suffer from chronic sinusitis. Most cases are treated with medical therapy, but surgical drainage is an option for patients who fail to respond to medical therapy. Functional endoscopic sinus surgery has become an important aspect for surgical management of chronic sinusitis. For this procedure, a fiberoptic nasal endoscope is used to visualize the sinus ostia, and any obstruction found is corrected. This procedure restores patency and allows air and mucous transport through the natural ostium. Approximately 350,000 FESS procedures are done each year in the United States for chronic sinusitis.

A newer procedure, balloon ostial dilatation can be used as an alternative to FESS or as an adjunct to FESS for those with chronic sinusitis. The goal of this technique, when used as an alternative to FESS, is to achieve improved sinus drainage using a less invasive approach. When used as an adjunct to FESS, it is intended to facilitate and/or increase access to the sinuses. The procedure involves placing a guidewire in the sinus ostium, advancing a balloon over the guidewire, and then stretching the opening by inflating the balloon. The guidewire location is confirmed with fluoroscopy or with direct transillumination of the targeted sinus cavity. General anesthesia may be needed for this procedure to minimize patient movement.

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The maxillary sinus creates a unique challenge. The maxillary ostia, located within the ethmoid infundibulum, often cannot be accessed transnasally without excising a portion of the uncinate process. An alternate approach to the maxillary ostia is through the sinus, via the canine fossa. A guidewire can be advanced from within the maxillary sinus to the nasal fossa. The dilating balloon can enlarge the ostia while deflecting the uncinate process.

Recently marketed reusable stainless steel dilators (e.g. Simplicity®‡ Dilators) may be comparable to balloon ostial dilators, however published evidence is insufficient at this time to support long-term efficacy and safety with their use, and confirm appropriate patient selection. In addition, there is not enough data comparing these reusable dilators to balloon dilation catheters cleared by FDA.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2008, the Relieva™‡ Sinus Balloon Catheter (Acclarent, Menlo Park, CA) was cleared for marketing by the U.S. FDA through the 510(k) process. FDA determined that this device was substantially equivalent to existing devices for use in dilating the sinus ostia and paranasal spaces in adults and maxillary sinus spaces in children. Subsequent devices developed by Acclarent have also been cleared by FDA through the 510(k) process. They include the Relieva Spin Sinus Dilation System®‡ (cleared in 2011) and the Relieva Seeker Balloon Sinuplasty System®‡ (cleared in 2012).

In 2008, the FinESS™‡ Sinus Treatment (Entellus Medical, Maple Grove, MN) was cleared for marketing by FDA through the 510(k) process. The indication noted is to access and treat the maxillary ostia/ethmoid infundibulum in adults using a transantral approach (FDA product code: EOB). The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures. Two other balloon sinus ostial dilation devices, the ENTrigue®‡ Sinus Dilation System (ENTrigue Surgical, acquired by more recently by Smith & Nephew), and the XprESS™‡ Multi-Sinus Dilation Tool, also received 510(k) clearance in 2012.

In 2013, a sinus dilation system (Medtronic Xomed, Jacksonville, FL), later named the NuVent™‡ EM Balloon Sinus Dilation System, was cleared for marketing by FDA through the 510(k) process for use in conjunction with a Medtronic computer-assisted surgery system when surgical navigation

or image-guided surgery may be necessary to locate and move tissue, bone, or cartilaginous tissue surrounding the drainage pathways of the frontal, maxillary, or sphenoid sinuses.

Also in 2013, a sinus dilation system (Smith & Nephew), later named the Ventera™‡ Sinus Dilation System, was cleared for marketing through the 510(k) process to access and treat the frontal recesses, sphenoid sinus ostia, and maxillary ostia/ethmoid infundibula in adults using a transnasal approach. Ventera™‡Sinus Dilation System does not require a guide wire or an illumination system as it is intended for use as a tool in combination with endoscopic sinus surgery.

Table 1 summarizes the currently FDA cleared balloon sinus dilation devices.

FDA product code: LRC.

Table 1. Balloon Ostial Dilation Devices Cleared by the US Food and Drug Administration

Device	Manufacturer	510(k) No.	Date Cleared	Indication
MESIRE - Balloon Sinus Dilatation System	Meril Life Sciences	K172737	12/12/2017	Sinus Ostia Dilation
Relieva UltirraNav Sinus Balloon Catheter	Acclarent Inc.	K161698	10/24/2016	Sinus Ostia Dilation
Vent-Os Sinus Dilation Family	Sinusys Corp.	K160770	6/29/2016	Sinus Ostia Dilation
Relieva Scout Multi-Sinus Dilation System	Acclarent Inc.	K153341	2/12/2016	Sinus Ostia Dilation
XprESS Multi-Sinus Dilation System	Entellus Medical Inc.	K152434	11/20/2015	Sinus Ostia Dilation
DSS Sinusplasty Balloon Catheter	Intuit Medical Products LLC	K143738	8/27/2015	Sinus Ostia Dilation
Relieva SpinPlus Balloon Sinuplasty System	Acclarent Inc.	K143541	4/22/2015	Sinus Ostia Dilation

XprESS Multi-Sinus Dilation Tool	Entellus Medical Inc.	K142252	10/17/2014	Sinus Ostia Dilation
Relieva Scout Multi-Sinus Dilation System	Acclarent Inc.	K140160	2/20/2014	Sinus Ostia Dilation

Simplicity®‡ Solid Dilators and Simplicity®‡ Suction Dilators were registered with the FDA in 2020. According to manufacturer's website, "Simplicity Dilators are made from medical grade stainless steel parts, which are easily cleaned and sterilized for multiple uses." "Simplicity Dilators do not require cutting of nasal bone or tissue nor any manipulation or inflation of extended devices. During sinus dilation, a Simplicity dilator is positioned and used to gently open the sinus passageways, facilitating drainage of the mucus buildup."

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Practice Guidelines and Position Statements

American Academy of Otolaryngology – Head and Neck Surgery et al

In 2018, the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) published a clinical consensus statement on balloon dilation of the sinuses. Participating subgroups included the Triologic Society, the American Rhinologic Society, the American Academy of Otolaryngic Allergy, and the American Academy of Allergy, Asthma & Immunology. The expert panel used Delphi method surveys to assess consensus on proposed statements. Statements achieving a mean score of 7.00 or higher and having no more than 1 outlier (2 or more LIkert points from the mean in either direction) met criteria for consensus. Strong consensus was defined as a mean Likert score of 8.00 or higher with no outliers. The following statements met consensus; statements reaching strong consensus are highlighted.

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Patient Criteria:

- Balloon dilation is not appropriate for patients who are without both sinonasal symptoms and positive findings on CT. (Strong consensus)
- Balloon dilation is not appropriate for the management of headache in patients who do not otherwise meet the criteria for chronic sinusitis or recurrent acute sinusitis. (Strong consensus)
- Balloon dilation is not appropriate for the management of sleep apnea in patients who do not otherwise meet the criteria for chronic sinusitis or recurrent acute sinusitis. (Strong consensus)
- CT scanning of the sinuses is a requirement before balloon dilation can be performed. (Strong consensus)
- Balloon dilation is not appropriate for patients with sinonasal symptoms and a CT that does not show evidence of sinonasal disease.
- Balloon dilation can be appropriate as an adjunct procedure to FESS in patients with chronic sinusitis without nasal polyps.
- There can be a role for balloon dilation in patients with persistent sinus disease who have had previous sinus surgery.
- There is a role for balloon sinus dilation in managing patients with recurrent acute sinusitis as defined in the AAO-HNSF guideline based on symptoms and CT evidence of ostial occlusion and mucosal thickening.

Perioperative Considerations:

- Surgeons who consider reusing devices intended for dilation of the sinuses should understand the regulations set forth by the FDA for reprocessing such devices and ensure that they are followed. (Strong consensus)
- Balloon dilation can be performed under any setting as long as proper precautions are taken and appropriate monitoring is performed.
- Balloon dilation can be performed under local anesthesia with or without sedation.

Outcome:

- Balloon dilation can improve short-term quality-of-life outcomes in patients with limited CRS without polyposis.
- Balloon dilation can be effective in frontal sinusitis.

The AAO-HNS updated its statement on balloon ostial dilation, reaffirming its 2010 position statement: “Sinus ostial dilation … is a therapeutic option for selected patient with chronic rhinosinusitis…. This approach may be used alone... or in conjunction with other instruments….”

In 2015, the Academy’s Foundation updated its 2007 clinical practice guidelines on adult sinusitis, which do not discuss surgical therapy or use of balloon sinuplasty.

National Institute for Health and Care Excellence
In 2008, a guidance on balloon catheter dilation of paranasal sinus ostia from the National Institute for Health and Care Excellence (NICE) stated:

- "Current evidence on the short-term efficacy of balloon catheter dilation of paranasal sinus ostia for chronic sinusitis is adequate and raises no major safety concerns.
- This procedure should only be carried out by surgeons with experience of complex sinus surgery, and specific training in both the procedure and the use of fluoroscopy.
- Publication of long-term outcomes will be helpful in guiding the future use of this technique. NICE may review the procedure upon publication of further evidence."

In 2016, NICE published a recommendation on the use of the XprESS Multi-Sinus Dilation System for the treatment of chronic rhinosinusitis:

1.1 “The case for adopting the XprESS multi-sinus dilation system for treating uncomplicated chronic sinusitis after medical treatment has failed is supported by the evidence. Treatment with XprESS leads to a rapid and sustained improvement in chronic symptoms, fewer acute episodes and improved quality of life which is comparable to FESS.

1.2 XprESS should be considered in patients with uncomplicated chronic sinusitis who do not have severe nasal polyposis. In these patients, XprESS works as well as FESS, is associated with faster recovery times, and can more often be done under local anaesthesia.”

The recommendation was based on the results of the REMODEL study: the committee "considered that the evidence from REMODEL demonstrated that balloon dilation (with either XprESS or FinESS) is clinically non-inferior to FESS in terms of alleviating symptoms in patients with

uncomplicated chronic sinusitis." Single-arm observational studies were of lower quality but were consistent with the findings of the REMODEL study.

American Rhinologic Society
A position statement, revised in 2017, from the American Rhinologic Society, stated that sinus ostial dilation is "a therapeutic option for selected patients with chronic rhinosinusitis (CRS) … who have failed appropriate medical therapy."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in December 2019 did not identify any ongoing or unpublished trials that would likely influence this review.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Balloon Ostial Dilation for Treatment of Chronic Sinusitis", Policy 7.01.105, 03:2021.
2. Zinreich, James S. Imaging for Staging of Rhinosinusitis. Ann Otol Rhinol Laryngol. 2004; 113:19-23.
3. Langille, Morgan M.D. et al. Frontal sinus cells: Identification, prevalence, and association with frontal sinus mucosal thickening. American Journal of Rhinology and Allergy. 2012; 26:e107-e110.
4. Rak, Kevin M. et al. Paranasal Sinuses on MR Images of the Brain: Significance of Mucosal Thickening. AJNR:11 1990:1211-1214.
5. Piccirillo, Jay F. et al. Clinical ConsensusStatement: Balloon Dilation of the Sinuses. Clinical Consensus Statement. Otolaryngology-Head and Neck Surgery. 2018 158(2) 203-214.
6. U.S. Food and Drug Administration. Establishment Registration and Device Listing. 08/03/2020.

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04/07/2011 Medical Policy Committee review

04/13/2011 Medical Policy Implementation Committee approval. New policy.

02/15/2012 Policy Retired.

09/03/2015 Medical Policy Committee review

09/23/2015 Medical Policy Implementation Committee approval. Title change, patient selection criteria added. Policy rewritten. Policy returned to active status.

02/04/2016 Medical Policy Committee review

02/17/2016 Medical Policy Implementation Committee approval. Added the requirement of at least 2 weeks of antibiotics and significant mucosal thickening of at least 2 mm prior to approval. Also clarified age of children 12 years and under is considered to be investigational.

06/02/2016 Medical Policy Committee review

06/20/2016 Medical Policy Implementation Committee approval. Patient selection criteria revised to this:

Coverage eligibility will be met when the following criteria are present:

- Chronic rhinosinusitis in an adult which has persisted for a minimum of 12 weeks despite failure of aggressive medical therapy. This should include documentation of treatment with all of the following:
  - Saline nasal irrigations
  - Intranasal corticosteroids for at least 8 weeks
  - Two courses of antibiotics
- Chronic rhinosinusitis of the sinus to be dilated is confirmed on computed tomography as evidenced by significant mucosal thickening of 4 mm or greater, opacification or air-fluid levels as evidenced by a formal CT scan report from an independent radiologist.

09/08/2016 Medical Policy Committee review

09/21/2016 Medical Policy Implementation Committee approval. Criteria revised to:

Patient Selection Criteria for chronic rhinosinusitis

Coverage eligibility will be met when the following criteria are present:

- Chronic rhinosinusitis in an adult which has persisted for a minimum of 12 weeks despite failure of aggressive medical therapy. This should include documentation of treatment with all of the following:
  - Saline nasal irrigations or saline nasal spray
  - Intranasal corticosteroids for at least 8 weeks
  - Two courses of antibiotics or one prolonged course of oral antibiotic for at least 21 days
- Chronic rhinosinusitis of the sinus to be dilated is confirmed on computed tomography as evidenced by significant mucosal thickening of greater than 3 mm, opacification, or air-fluid levels documented by a formal CT scan report from an independent radiologist.

Recurrent acute rhinosinusitis criteria added to the policy. "Chronic" removed from title.

01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
06/01/2017 Medical Policy Committee review
06/21/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/07/2018 Medical Policy Committee review
06/20/2018 Medical Policy Implementation Committee approval. No change to coverage.
06/06/2019 Medical Policy Committee review
06/19/2019 Medical Policy Implementation Committee approval. No change to coverage.
08/06/2020 Medical Policy Committee review
08/12/2020 Medical Policy Implementation Committee approval. Added the following changes under the Patient Selection Criteria for chronic rhinosinusitis section:

- Chronic rhinosinusitis without nasal polyps in an adolescent or adult patient, which has persisted for a minimum of 12 weeks despite aggressive medical therapy. This should include documentation of treatment with all of the following:
  - Saline nasal irrigation for at least 8 consecutive weeks
  - Two 10-day courses of antibiotics or one prolonged course of oral antibiotic for at least 21 days; AND
- Chronic rhinosinusitis of the sinus to be dilated is confirmed with nasal endoscopy and computed tomography as evidenced by:
  - Purulent (not clear) mucus OR edema in the middle meatus, anterior ethmoid, or sphenoethmoid region; AND

Added the following changes under the Patient Selection Criteria for recurrent acute rhinosinusitis section:

- Nasal endoscopy performed during the fourth episode showing purulent (not clear) mucus OR edema in the middle meatus, anterior ethmoid, or sphenoethmoid region;

Added the following investigational statements:
The use of sinus ostial dilatation with balloon catheter when patient selection criteria are not met is considered to be investigational. and
Based on review of available data, the Company considers dilation of sinus ostia using a device other than balloon catheter, including but not limited to reusable dilators (e.g. Simplicity®‡ Dilators), to be investigational.
Policy guidelines added to policy.

08/05/2021 Medical Policy Committee review
08/11/2021 Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date: 08/2022

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 2020 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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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	31295, 31296, 31297, 31298, 31299
HCPCS	C1726
ICD-10 Diagnosis	C30.0, C31.0-C31.9, J32.0-J32.9, J33.0-J33.9, J34.0-J34.9, R09.81

*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.

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

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

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

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

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.