



Louisiana

Functional Endoscopic Sinus Surgery for Chronic Rhinosinusitis

Policy # 00711

Original Effective Date: 12/01/2020

Current Effective Date: 08/14/2023

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: Sinus Ostial Dilatation with Balloon Catheter for Rhinosinusitis is addressed separately in medical policy 00292.

Note: Drug Eluting Sinus Stents and Implants for Postoperative Use Following Endoscopic Sinus Surgery and for Recurrent Sinonasal Polyposis is addressed separately in medical policy 00485.

Note: Balloon Dilation of the Eustachian Tube is addressed separately in medical policy 00613.

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 the use of functional endoscopic sinus surgery for individuals with chronic rhinosinusitis to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for the use of functional endoscopic sinus surgery for individuals with chronic rhinosinusitis may be considered when ALL of the following criteria are met:

- Chronic rhinosinusitis 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; AND
 - Intranasal corticosteroids for at least 8 weeks; AND
 - Two 10-day courses of antibiotics or one prolonged course of oral antibiotic for at least 21 days; AND

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- For revision functional endoscopic sinus surgery requests, certain conditions and findings may not improve with medical therapy (i.e., recirculating issues resulting in mucus stasis, chronic inflammation or infection, or stenosis/obstruction of ostia), therefore failure of 8 weeks of aggressive medical therapy is not required; AND
- Chronic rhinosinusitis of the sinus to be operated on is confirmed with nasal endoscopy or anterior rhinoscopy, 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; AND

Note: Chronic rhinosinusitis with polyposis (confirmed visualization of polyps on nasal endoscopy or anterior rhinoscopy) might require operation on multiple or all sinuses. In the absence of active infection, a trial of antibiotics may not be necessary in individuals with documented polyposis.

- There are no serious urgent complications of acute sinusitis that would suggest orbital cellulitis or abscess, intracranial extension of infection, or other complication that would require urgent or emergent surgery such that “appropriate medical therapy” for 8 weeks would not be appropriate.

When Services Are Considered Investigational

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

The use of functional endoscopic sinus surgery for the treatment of chronic rhinosinusitis when the above patient selection criteria are not met is considered to be **investigational**.*

Policy Guidelines

Classification of rhinosinusitis is based upon symptom duration:

- Acute rhinosinusitis – Symptoms for less than 4 weeks
- Subacute rhinosinusitis – Symptoms for 4 to 12 weeks
- Chronic rhinosinusitis – Symptoms persist greater than 12 weeks

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- Recurrent acute rhinosinusitis – Four or more documented and treated episodes of acute rhinosinusitis in a 12-month period, with interim symptom resolution

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.

For individuals 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 individuals 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 individuals 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

Chronic Rhinosinusitis

Chronic rhinosinusitis (CRS) is a highly prevalent inflammatory disorder of the paranasal sinuses and the mucosa of the nasal passages that affects 3% to 7% of adults. In adults, CRS is characterized by symptoms related to nasal and sinus obstruction and inflammation, including mucopurulent nasal drainage, nasal congestion, facial pain or pressure, and anosmia or hyposmia, that persist for at least 12 weeks.

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Three CRS subtypes exist and may have somewhat different treatment strategies: CRS without nasal polyposis; CRS with nasal polyposis; and allergic fungal sinusitis. The latter is a less common subtype thought to result from chronic allergic inflammation to colonizing nasal fungi. This review focuses on the more common subtypes: CRS with and without nasal polyposis. Both subtypes present with similar symptoms. However, CRS with nasal polyposis is, by definition, associated with nasal polyps that are visible on rhinoscopy or nasal endoscopy. Further, CRS with nasal polyposis is more likely to be associated with asthma and aspirin intolerance; this triad is referred to as Samter syndrome or aspirin-exacerbated respiratory disease.

Chronic rhinosinusitis is associated with impaired quality of life for affected individuals, and with high direct and indirect costs for medical treatments and lost productivity. Most often, the negative health effects of CRS are related to the unpleasant symptoms associated with CRS, including nasal congestion, nasal drainage, and facial pain or pressure. In rare cases, CRS can be associated with serious complications, including orbital cellulitis, osteomyelitis, or intracranial extension of infection.

While acute sinusitis is considered a more traditional infectious process, CRS is a chronic inflammatory disease of the upper airways, with multiple underlying causes. Risk factors for CRS with or without nasal polyps include anatomic variations and gastroesophageal reflux. There are conflicting reports about the association between allergy and CRS without nasal polyps, although weak evidence has suggested that allergy may be associated with CRS with nasal polyps. In addition, aspirin sensitivity may be associated with CRS with nasal polyps. The role of bacterial, viral, and fungal microorganisms in CRS has been actively investigated. There is some evidence that CRS is associated with a predominance of anaerobic bacteria. On the other hand, a study that used bacterial ribosomal RNA sequencing to evaluate the sinus microbiome in individuals with and without CRS found a quantitative increase in bacterial and fungal RNA expression in individuals with CRS, but no major differences in the types of microorganisms detected. Bacterial biofilms have been identified in cases of CRS.

Medical Therapy

Medical therapy for CRS, with or without polyps, is often multimodal, including nasal irrigation, topical and/or systemic corticosteroids, monoclonal antibodies, and/or antibiotic therapy. Guidelines from the American Academy of Otolaryngology-Head and Neck Surgery (2015; affirmed in 2020 by the American Academy of Family Physicians) have recommended the use of saline nasal

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irrigation, topical intranasal corticosteroids, or both, for symptom relief of CRS, on the basis of systematic reviews of randomized controlled trials (RCTs). There is a specific recommendation against the use of topical and systemic antifungal therapies. The guidelines do not include a statement specifically addressing the use of systemic antibiotics for CRS; however, in the list of future research needs, the authors included: "Perform additional RCTs to clarify the impact of antibiotic therapy on CRS outcomes."

A systematic review by Rudmik and Soler (2015) evaluated the evidence for various medical therapies for chronic sinusitis, excluding allergic fungal sinusitis. Reviewers included 29 studies, with 12 meta-analyses (with a total of >60 RCTs), 13 systematic reviews, and 4 individual RCTs not included in any meta-analyses. Topical corticosteroids were associated, in multiple studies, with improved symptom scores, reduced polyp size, and decreased polyp recurrence after surgery. Saline nasal irrigation was associated, in multiple studies, with significant improvements in symptom scores. There was some evidence that 2 systemic therapies (oral corticosteroids, doxycycline), both for 3 weeks, improved polyp scores in individuals with CRS with nasal polyps. Long-term (>3 months) macrolide therapy was associated in an RCT with improved symptoms and quality of life in individuals with CRS without nasal polyps, although other studies did not find a benefit with chronic macrolide use.

In 2014, an evidence-based review summarized a series of earlier evidence-based reviews with recommendations related to CRS. This review concluded that both saline irrigation and topical corticosteroids are well-supported by the available published literature for treatment of CRS, with and without nasal polyps. For CRS with polyps, the evidence demonstrated short-term improvement in symptoms after short-term oral corticosteroid treatment. For CRS with or without nasal polyps, a small number of RCTs have shown improvement in nasal endoscopy scores and some symptoms with oral macrolide therapy. However, for CRS with or without nasal polyps, there was very limited evidence on the use of non-macrolide oral antibiotics.

A 2016 Cochrane review of studies evaluating systemic and topical antibiotics for CRS included 5 RCTs (N=293), all of which compared systemic antibiotics with placebo or another pharmacological intervention. Reviewers found "very little evidence that systemic antibiotics are effective in individuals with chronic rhinosinusitis" and that "more research in this area, particularly evaluating longer-term outcomes and adverse effects, is required."

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In 2019, the U.S. Food and Drug Administration (FDA) approved the first treatment for CRS with nasal polyps - dupilumab (Dupixent^{®†}). Results from clinical trials revealed that individuals who received dupilumab "had statistically significant reductions in their nasal polyp size and nasal congestion compared to the placebo group" and also "reported an increased ability to smell and required less nasal polyp surgery and oral steroids." This was followed by the approval of omalizumab (Xolair^{®†}) in 2020 as add-on maintenance treatment for adults with nasal polyps with an inadequate response to nasal corticosteroids. In 2021, mepolizumab (Nucala^{®†}) was also approved as an add-on maintenance treatment in adults with CRS with nasal polyps.

Surgery

The goals of surgery for CRS include removing polyps and debris that may be sources of inflammatory mediators and preventing the effective delivery of local medical therapies. In addition, to varying degrees, surgical techniques involve the creation of open sinus cavities, usually via dilation of the sinus ostia, to permit better drainage from the sinus cavities and more effective delivery of local therapies.

Techniques for functional endoscopic sinus surgery (FESS), in which an endoscope is used to access the sinus cavities and varying degrees of tissue are removed and the sinus ostia are opened, have evolved since the development of the nasal endoscope in the 1960s. Functional endoscopic sinus surgery has largely replaced various open techniques for CRS (eg, Caldwell-Luc procedure), although open procedures may have a role in complicated sinus pathologies (eg, endonasal tumors).

Functional endoscopic sinus surgery encompasses a variety of degrees of sinus access and tissue removal and is described based on the sinuses accessed. The Draf classification is used to describe degrees of endoscopic frontal sinusotomy (Table 1).

Table 1. Draf Classification for Endoscopic Frontal Sinusotomy

Type	Description
Draf I	Anterior ethmoidectomy without altering frontal sinus ostium
Draf IIA	Removal of ethmoid cells that extend into frontal sinus
Draf IIB	Removal of frontal sinus floor between the middle turbinate and the lamina papyracea

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Draf III^a

Removal of frontal sinus floor from orbit to orbit with contiguous portions of the superior nasal septum

^a Modified Lothrop procedure.

This procedure can also be used to access the ethmoid sinuses, which may involve creation of drainage into the maxillary sinuses (maxillary antrostomy).

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Functional endoscopic sinus surgery is a surgical procedure and, as such, is not subject to regulation by the FDA.

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.

Chronic rhinosinusitis (CRS) is a common chronic condition associated with significant morbidity. Functional endoscopic sinus surgery (FESS) involves the removal of varying amounts of tissue and the opening of sinus ostia to treat CRS.

Summary of Evidence

For individuals with uncomplicated chronic rhinosinusitis (CRS) with or without nasal polyposis who receive functional endoscopic sinus surgery (FESS), the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, change in disease status, quality of life, and treatment-related morbidity. A small number of trials, with methodologic limitations, generally have not reported clinically significant differences in symptom improvement with FESS compared with medical therapy. Cochrane reviews evaluating FESS for CRS with and without nasal polyposis have reported that FESS can be accomplished safely, but clinical trials have not demonstrated significant improvements with FESS compared with

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standard medical therapy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with uncomplicated CRS refractory to medical therapy who receive FESS, the evidence includes an RCT, a systematic review of non-randomized comparative studies, and additional non-randomized studies published since the systematic review. Relevant outcomes are symptoms, functional outcomes, change in disease status, quality of life, and treatment-related morbidity. One RCT was identified in individuals who have failed therapy with nasal irrigation and corticosteroids. This RCT found that FESS was not superior to maximal medical therapy that includes antibiotics along with nasal irrigation and topical or systemic corticosteroids. Although no RCTs have been identified that evaluated FESS in individuals with CRS who failed a regimen that included antibiotic therapy, a systematic review of non-randomized comparative cohorts and pre-post studies is available. This meta-analysis suggests that in individuals who have failed maximal medical therapy (nasal irrigation, corticosteroids, and antibiotics), FESS can improve symptoms compared to continued medical management. Individuals most likely to select and benefit from FESS are those with lower disease-specific quality of life. Multiple additional non-randomized studies further support improvements in quality of life and functional outcomes after FESS in this setting. Surgical treatment of CRS with FESS may thus be appropriate for individuals who meet diagnostic criteria for CRS and have failed maximal medical management. The evidence is sufficient 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.

Guidelines on the diagnosis and management of CRS are described in Tables 2 and 3.

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Table 2. Chronic Rhinosinusitis Diagnostic Criteria

Organization	Chronic Rhinosinusitis Definition
International Consensus Statement on Rhinology and Allergy: Rhinosinusitis (2021)	"Greater than or equal to 12 weeks of: Two or more of the following symptoms: <ul style="list-style-type: none">• Nasal discharge (rhinorrhea or post-nasal drip)• Nasal obstruction or congestion• Hyposmia• Facial pressure or pain• Cough AND One or more of the following objective findings: <ul style="list-style-type: none">• Evidence of inflammation on nasal endoscopy or computed tomography• Evidence of purulence coming from paranasal sinuses or ostiomeatal complex AND CRS is divided into CRSsNP or CRSwNP based on the presence or absence of nasal polyps"
American Academy of Otolaryngology – Head and Neck Surgery Foundation (2015)	"Twelve weeks or longer of 2 or more of the following signs and symptoms: <ul style="list-style-type: none">• Mucopurulent drainage (anterior, posterior, or both),• Nasal obstruction (congestion)• Facial pain-pressure-fullness, or• Decreased sense of smell. AND inflammation is documented by 1 or more of the following findings: <ul style="list-style-type: none">• purulent (not clear) mucus or edema in the middle meatus or anterior ethmoid region,• polyps in nasal cavity or the middle meatus, and/or• radiographic imaging showing inflammation of the paranasal sinuses."

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CRS: chronic rhinosinusitis; CRSsNP: chronic rhinosinusitis without nasal polyps; CRSwNP: chronic rhinosinusitis with nasal polyps; CT: computed tomography; MRI: magnetic resonance imaging.

Evaluation of individuals for allergic disorders, immunodeficiencies, or both, may be indicated depending on the presence of associated symptoms.

Table 3. American Academy of Otolaryngology-Head and Neck Surgery Guidelines on Management of CRS in Adults*

Guideline	Type of Recommendation	Aggregate Evidence Quality	Confidence in Evidence
“The clinician should confirm a clinical diagnosis of CRS with objective documentation of sinonasal inflammation, which may be accomplished using anterior rhinoscopy, nasal endoscopy, or computed tomography.”	Strong recommendation	B (cross-sectional studies)	Medium
“Clinicians should assess the patient with chronic rhinosinusitis or recurrent acute rhinosinusitis for multiple chronic conditions that would modify management such as asthma, cystic fibrosis, immunocompromised state, and ciliary dyskinesia.”	Recommendation	B (1 systematic review, multiple observational studies)	Medium
“The clinician may obtain testing for allergy and immune function in evaluating a patient with chronic rhinosinusitis or recurrent acute rhinosinusitis.”	Option	C (systematic review of observational studies)	Medium

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Guideline	Type of Recommendation	Aggregate Evidence Quality	Confidence in Evidence
“The clinician should confirm the presence or absence of nasal polyps in a patient with CRS.”	Recommendation	A (systematic review of RCTs)	Medium
“Clinicians should recommend saline nasal irrigation, topical intranasal corticosteroids, or both for symptom relief of CRS.”	Recommendation	A (systematic reviews of RCTs)	High
“Clinicians should not prescribe topical or systemic antifungal therapy for patients with CRS.”	Recommendation (against therapy)	A (systematic reviews of RCTs)	High

* Adapted from Rosenfeld et al (2015)

CRS: chronic rhinosinusitis; RCT: randomized controlled trial.

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 currently unpublished trial that might influence this review is listed in Table 4.

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Table 4. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT05598814	Optimisation of Treatment in Patients with CRSwNP. An RCT of Mepolizumab and Surgical Treatment With FESS and Mepolizumab Versus Only Mepolizumab Over a 6- and 12-month Follow-up	52	Jun 2024

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Policy # 00711

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Policy History

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|------------|---|
| 09/03/2020 | Medical Policy Committee review |
| 09/09/2020 | Medical Policy Implementation Committee approval. New policy. |
| 10/06/2020 | Coding update |
| 03/04/2021 | Medical Policy Committee review |
| 03/10/2021 | Medical Policy Implementation Committee approval. Added a <i>Note</i> in the Patient Selection Criteria that “ <i>Chronic rhinosinusitis with polyposis (confirmed visualization of polyps on nasal endoscopy) might require operation on multiple or all sinuses.</i> ” |
| 07/01/2021 | Medical Policy Committee review |
| 07/14/2021 | Medical Policy Implementation Committee approval. For the use of functional endoscopic sinus surgery for patients with chronic rhinosinusitis, added a forth open bullet to the Patient Selection Criteria as follows: <ul style="list-style-type: none">○ For revision functional endoscopic sinus surgery requests, certain conditions and findings may not improve with medical therapy (i.e., recirculating issues resulting in mucus stasis, inflammation or infection, osteitis, or stenosis of ostia), therefore failure of 8 weeks of aggressive medical therapy is not required; AND Added anterior rhinoscopy as a procedure option to confirm chronic rhinosinusitis to the second Patient Selection Criteria bullet. Revised the <i>Note in the Patient Selection Criteria as follows: Chronic rhinosinusitis with polyposis (confirmed</i> |

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visualization of polyps on nasal endoscopy or anterior rhinoscopy) might require operation on multiple or all sinuses. In the absence of active infection, a trial of antibiotics may not be necessary in patients with documented polyposis.

07/07/2022 Medical Policy Committee review

07/13/2022 Medical Policy Implementation Committee approval. Removed osteitis from the criteria bullet for the list of findings that may not improve with medical therapy for revision of functional endoscopic sinus surgery requests. Added classification of rhinosinusitis based upon symptom duration to the Policy Guidelines section. Coverage intent unchanged.

07/06/2023 Medical Policy Committee review

07/12/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 07/2024

Coding

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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	31253, 31254, 31255, 31256, 31257, 31259, 31267, 31276, 31287, 31288
HCPCS	No codes
ICD-10 Diagnosis	J32.0-J32.9

***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 technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

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

- A. In accordance with nationally accepted standards of medical practice;

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

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

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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.

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