

## Corporate Medical Policy

### Surgical Treatment of Sinus Disease

**File Name:** surgical\_treatment\_of\_sinus\_disease  
**Origination:** 2/2010  
**Last CAP Review:** 8/2021  
**Next CAP Review:** 8/2022  
**Last Review:** 8/2021

#### Description of Procedure or Service

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Chronic sinusitis is one of the most frequently diagnosed chronic medical conditions, even more so than hypertension and arthritis. Chronic sinusitis is characterized by 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. Considerable variation exists in the location and shape of these sinus ostia. A course of conservative medical therapy is attempted initially to resolve the symptoms; this treatment may include antibiotics, nasal irrigation, decongestants, and steroids.

In some cases of chronic sinusitis, surgical drainage may be necessary. Functional endoscopic sinus surgery (FESS) is the most commonly used surgical technique to treat medically unresponsive chronic sinusitis and other serious conditions of the nasal sinuses that result in impaired sinus drainage. The use of the endoscope permits a better view of the surgical field. Goals of FESS are to allow for maximum preservation of mucosa, and to open and enlarge the sinus passageways allowing for proper drainage and optimizing access for topical medications.

FESS is performed using a rigid endoscope to view the structures of the nose and sinuses. The endoscope is inserted through the nose, as are the surgical instruments the surgeon uses to perform the surgery. The procedure can be performed under general or local anesthesia on an outpatient basis, and patients usually experience minimal discomfort. The use of FESS allows for a much less invasive and traumatic procedure than open or non-endoscopic sinus surgery. There are shorter surgery and healing times, less postoperative discomfort, and fewer surgical complications with FESS. However, because of the proximity of sinus structures to the eyes and the brain, it is not risk free.

Some form of sinus packing is generally utilized postoperatively. Simple dressings, both absorbable and non-absorbable, can be inserted following surgery. These can serve as both hemostatic agents and/or middle meatal spacers. There is some RCT evidence that middle meatal spacers may reduce the formation of synechiae following FESS, although the available studies have significant heterogeneity in this outcome.

Implantable drug-eluting sinus implants are another option for postoperative management following FESS and other sinus procedures. These implants are inserted under endoscopic guidance to stabilize the sinus openings and the turbinates, reduce edema, and/or prevent obstruction by adhesions. They also deliver medications (e.g. steroids) topically over an extended period of time (e.g. 30 days), and this local delivery of medications may be superior to other treatment options in the postoperative setting. In 2011, the PROPEL™ system (Intersect ENT, Palo Alto, CA) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. This device is a self-expanding, bioabsorbable, steroid-eluting stent intended for use in the ethmoid sinus. It is placed via endoscopic guidance using an applicator included with the device. Steroids (mometasone furoate) are embedded in a polyethylene glycol polymer, which allows sustained release of the drug over an approximate duration of 30 days. The device dissolves over several weeks, and therefore does not require removal.

# Surgical Treatment of Sinus Disease

In 2012, a smaller version of the PROPEL™ device, the PROPEL™ mini Sinus Implant, was approved for use in patients older than age 18 years following ethmoid sinus surgery.

In December 2017, the U.S. Food and Drug Administration (FDA) approved Sinuva (mometasone furoate) Sinus Implant for the treatment of nasal polyps in patients 18 years of age or older who have had ethmoid sinus surgery.

There are numerous other stenting and packing materials commonly used in sinus surgery. This policy does not apply to the use of those materials.

***\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

## Policy

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**BCBSNC will cover surgical treatment of sinus disease when determined to be medically necessary because the medical criteria and guidelines shown below are met.**

## Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## When surgical treatment of sinus disease is covered

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Functional endoscopic sinus surgery (FESS) is considered **medically necessary** for the treatment of sinusitis, polyposis, sinus tumor, or other conditions listed below when **any one or more** of the following circumstances is present:

1. Uncomplicated sinusitis and **all** of the following:
  - a. Either four or more documented episodes of acute rhinosinusitis in one year, or chronic sinusitis that interferes with lifestyle; and,
  - b. Optimal medical therapy has been attempted and failed; and,
  - c. For chronic rhinosinusitis, documentation of coronal CT and/or nasal endoscopy following optimal medical therapy showing persistent sinus pathology; and,
  - d. For recurrent acute rhinosinusitis, coronal CT and nasal endoscopy may be normal after treatment. However, CT and/or nasal endoscopy during acute rhinosinusitis should document sinus pathology amenable to surgical treatment.
2. Multiple or recurrent polyps with symptoms and failure of optimal medical management (including assessment for allergy symptoms and allergy evaluation if indicated) with persistent sinus disease on follow up CT scan and/or nasal endoscopy,
3. Complications of sinusitis, including extension to adjacent structures,
4. Mucocele (excludes benign, asymptomatic mucus retention cysts),
5. Recurrent sinusitis with significant associated comorbid conditions (some examples include immune system disorders, and congenital or acquired ciliary dyskinesia),
6. Recurrent sinusitis which exacerbates significant comorbid conditions (including but not limited to asthma, recurrent bronchitis or pneumonia, diabetes),

# Surgical Treatment of Sinus Disease

7. Multidrug resistant organisms identified by culture,
8. Sinonasal benign or malignant tumor (including inverted papilloma),
9. Cerebrospinal fluid leak (CSF leak),
10. Dacryocystorhinostomy (DCR) for disorders of the lacrimal system,
11. Orbital or optic nerve decompression,
12. Repair of choanal atresia.
13. Silent Sinus Syndrome
14. Antrochoanal Polyps
15. Fungal ball or mycetoma

The use of a mometasone furoate sinus implant (Propel™) is considered medically necessary following functional endoscopic sinus surgery (FESS) or other sinus procedure when the following criteria are met:

1. Patient is > 18 years of age; AND
2. Ethmoid sinus surgery is planned; AND
3. Patient has one or more of the following conditions:
  - a. Polypoid disease
  - b. Failed prior surgery and/or restenosis
  - c. Absolute or relative contraindication to systemic steroids
4. The functional endoscopic sinus surgery (FESS) or other primary sinus procedure is considered medically necessary.

## **When surgical treatment of sinus disease is not covered**

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Functional endoscopic sinus surgery for sinus disease is considered not medically necessary for the treatment of sinusitis or polyposis when the criteria above are not met.

The use of a mometasone furoate sinus implant (Propel™) is considered not medically necessary when the criteria above are not met.

A mometasone furoate sinus implant (Propel™) is contraindicated when:

- Patient has suspected or confirmed intolerance to mometasone furoate.
- Patient has a known hypersensitivity to lactide, glycolide, or caprolactone copolymers.

The use of a mometasone furoate sinus implant (Sinuva™) in the treatment of sinonasal polyposis is considered investigational.

## **Policy Guidelines**

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### **Optimal medical treatment**

Functional endoscopic sinus surgery (FESS) should be reserved for use in patients in whom optimal medical treatment has failed. The majority of patients with sinusitis do not require surgery. Their sinus

# Surgical Treatment of Sinus Disease

symptoms can usually be successfully treated medically, including antibiotic therapy and other medications, treatment of allergy, and environmental control.

Optimal medical treatment consists of the following:

1. Oral antibiotics of 2-4 weeks duration for patients with chronic rhinosinusitis (culture-directed if possible)
2. Oral antibiotics with multiple 1-3 week courses for patients with recurrent acute rhinosinusitis
3. Intranasal steroids for at least one month
4. Systemic steroids (at the discretion of the physician)
5. Saline irrigations (optional)
6. Topical and/or systemic decongestants (optional, if not contraindicated)
7. Treatment of concomitant allergic rhinitis, including avoidance measures, pharmacotherapy, and/or immunotherapy (at the discretion of the physician)

Note: Imaging studies should be generally obtained after maximal medical therapy. Based on clinical situation (i.e. concern for extrasinus complications or neoplasm), early or emergent imaging may be required to confirm a diagnosis. Early imaging is also indicated in recurrent acute rhinosinusitis.

## Endoscopic Sinus Surgery in the Pediatric Population

Prior to performing endoscopic sinus surgery in the pediatric population, the following must be documented.

1. A comprehensive history
  - a. Failure of medical management for chronic rhinosinusitis or recurrent acute rhinosinusitis, possibly in addition to other disorders, including, but not limited to:
    - Allergy
    - Day care exposure
    - Gastroesophageal reflux contributing to rhinosinusitis
    - Adenoiditis and/or obstructive adenoid hypertrophy
    - Cystic fibrosis
    - Immune deficiency disorders
    - Ciliary dysfunction/dyskinesia
    - Progressively worsening asthma with opaque sinus(es)
    - Nasal polyposis with airway obstruction and/or sinusitis
    - Suspected neoplasm (e.g., juvenile nasopharyngeal angiofibroma)
    - Adenoidectomy should be strongly considered a minimum of three months prior to performing pediatric sinus surgery for any of the above indications
    - Intracranial complications
    - Cavernous sinus thrombosis
    - Mucocoeles and mucopyocoeles
    - Subperiosteal or orbital abscess/periorbital cellulitis
    - Traumatic injury to optic canal (decompression)
    - Dacryocystitis from rhinosinusitis
    - Meningocephalocoeles
    - Cerebrospinal fluid leaks
    - Tumors of the nasal cavity, paranasal sinuses, orbit or skull base
    - Recurrent acute rhinosinusitis (RARS)
2. Physical examination, including complete anterior and posterior nasal examination (rhinoscopy after mucosal decongestion) as possible for patient's age
3. Other tests, including for surgical planning, a coronal CT scan following medical therapy is

# Surgical Treatment of Sinus Disease

required. A complete axial CT scan is recommended in cases with complex disease. MRI, culture and sensitivity, and allergy testing are optional.

4. Optimal medical therapy, including
  - a. Evaluation and management for all medical conditions listed above
  - b. Treatment of rhinitis medicamentosa, when present
  - c. Parental education of environmental factors including allergens, irritants, or secondhand tobacco smoke
  - d. Antibiotic therapy consisting of four to six consecutive weeks of appropriate antibiotic drugs
  - e. Appropriate topical and/or systemic steroids when indicated

## **Steroid-Eluting Sinus Stents as an Adjunct to Endoscopic Sinus Surgery**

Drug-eluting sinus implants have been used post-FESS with the intent of maintaining patency of the sinuses and delivering local steroids. Two RCTs have compared the Propel™ device with steroids to the same device without steroids, and reported that the steroid-eluting device reduced postoperative inflammation, reduced the need for oral steroids, and reduced the need for postoperative re-interventions. These trials evaluate the benefit of local steroid delivery in addition to standard care. The improvements reported in these trials reflect the impact of local steroid delivery, which was withheld in the control arm.

## **Steroid-Eluting Sinus Implant (Sinuva) for Recurrent Polyposis**

Han et al (2014) reported on results from RESOLVE, a sham-controlled randomized trial evaluating the use of office-based placement of a mometasone-eluting nasal implant (Sinuva) for patients with recurrent nasal polyposis after endoscopic sinus surgery. Eligible patients had chronic rhinosinusitis, had undergone prior bilateral total ethmoidectomy more than 3 months earlier, had endoscopically confirmed recurrent bilateral ethmoid sinus obstruction due to polyposis that was refractory to medical therapy, and were considered candidates for repeat surgery based on the judgment of the surgeon and patient. Patients and those who administered symptom questionnaires at follow-up visits were blinded to treatment group. The trial was powered to detect a between-group difference of at least a 0.6-point change in polyp grade from baseline, and at least a 1.0-point change in nasal obstruction/congestion score. One hundred subjects were randomized to treatment (n=53) or control (n=47). For endoscopically measured outcomes, at 90 days of follow-up, the treatment group had a greater reduction in polyp grade than the control group (-1.0 vs -0.1; p=0.016) and a greater reduction in percent ethmoid obstruction on a 100-mm VAS (-21.5 mm vs 1.3 mm; p=0.001), both respectively. For patient-reported outcomes, there were no significant differences in change in nasal obstruction/congestion scores between groups. Compared with controls, fewer treatment group patients required oral steroids for ethmoid obstruction (11% vs 26%) and fewer treatment group patients were indicated for sinus surgery at 3 months based on established criteria (47% vs 77%), although statistical comparisons were not reported.

Forwith et al (2016) reported six month follow-up results from the RESOLVE trial. Treated patients experienced improvement in Nasal Obstruction Symptom Evaluation (NOSE) score (p=0.02) and greater than 2 fold improvement in mean nasal obstruction/congestion score (p=0.12). Endoscopically, treated patients showed reduction in ethmoid sinus obstruction (p=0.01) and a two-fold improvement in bilateral polyp grade (p=0.099).

The RESOLVE trial had a high risk of bias due to unblinded outcome assessment. Although avoidance of repeat endoscopic sinus surgery and oral steroids may be relevant outcomes for this indication, it would be more important if decisions about repeat surgery or other treatments were standardized and, in the trial setting, if decisions were prespecified or made by a clinician blinded to treatment group.

Kern et al (2018) reported on results from RESOLVE II, a sham-controlled, double-blind, randomized trial evaluating mometasone-eluting sinus implants in patients with recurrent

# Surgical Treatment of Sinus Disease

polyposis after sinus surgery. Three hundred patients with refractory chronic rhinosinusitis with nasal polyps who were candidates for repeat surgery, were randomized to in-office bilateral placement of implants or sham procedure. Treated patients experienced reductions in both nasal obstruction/congestion score ( $p=0.007$ ) and bilateral polyp grade ( $p=0.007$ ), compared to controls. There was a 61% reduction in the need for repeat sinus surgery at 90 days in the treatment group versus 37% reduction among sham patients. Limitations to the study included absence of a defined medical regimen prior to enrollment, and the clinical investigators who performed the endoscopic grading and assessment for indication for repeat surgery at day 90 were not blinded to treatment assignment. Additional trials with longer follow-up beyond 90 days are needed to assess duration of the effect of the stent on recurrent nasal polyps.

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: 0406T, 0407T, 31241, 31253, 31254, 31255, 31256, 31257, 31259, 31267, 31276, 31287, 31288, J7402, S1091, S2342*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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Medical Director review 2/2010

Medical Director review 7/2010

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Rudmik L, Soler ZM, Orlandi RR et al. Early postoperative care following endoscopic sinus surgery: an evidence-based review with recommendations. *Int Forum Allergy Rhinol* 2011; 1(6):417-30.

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Medical Director review 7/2012

Specialty Matched Consultant Advisory Panel – 8/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.134, 6/13/13

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Medical Director review 8/2013

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Senior Medical Director review 4/2014

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Specialty Matched Consultant Advisory Panel - 8/2017

Medical Director review 5/2018

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Kern RC, Stolovitzky JP, Silvers SL, Singh A, Lee JT, Yen DM, Iloretta AMC Jr, Langford FPJ, Karanfilov B, Matheny KE, Stambaugh JW, Gawlicka AK; RESOLVE II study investigators. [A phase 3 trial of mometasone furoate sinus implants for chronic sinusitis with recurrent nasal polyps.](#) Int Forum Allergy Rhinol. 2018 Apr;8(4):471-481.

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Medical Director review 11/2018

Specialty Matched Consultant Advisory Panel – 9/2019

Medical Director review 7/2020

Specialty Matched Consultant Advisory Panel – 8/2020

Specialty Matched Consultant Advisory Panel – 8/2021

## Policy Implementation/Update Information

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- 3/30/2010 New policy issued. BCBSNC will cover functional endoscopic sinus surgery (FESS) when determined to be medically necessary because the medical criteria and guidelines outlined in the policy are met. Notification given 3/30/10 for effective date 7/1/10. (adn)
- 7/6/2010 Specialty Matched Consultant Advisory Panel review 5/24/10. No change to policy statement or coverage criteria. (adn)
- 7/20/2010 Minor changes in *Description* section. In the *When FESS is covered* section: Revised Item 1.c. to read “[For chronic rhinosinusitis](#), documentation of coronal CT and/or nasal endoscopy following optimal medical therapy showing persistent sinus pathology.” Added item 1.d. which reads “For recurrent acute rhinosinusitis, coronal CT and nasal endoscopy may be normal after treatment. However, CT and/or nasal endoscopy during acute rhinosinusitis should document sinus pathology amenable to surgical treatment.” Revised Item 2 to read “Multiple or recurrent polyps with airway obstruction and failure of optimal medical management (including [assessment for allergy symptoms](#), and allergy evaluation if indicated) with persistent sinus disease on follow up CT scan and/or nasal endoscopy.”

# Surgical Treatment of Sinus Disease

Revised Item 4 to read “Chronic ~~anterior~~ headache or facial pain...” Inserted new items 6, 7 and 8 which read “6) Recurrent sinusitis with significant associated comorbid conditions (some examples include immune system disorders, and congenital or acquired ciliary dyskinesia), 7) Recurrent sinusitis which exacerbates significant comorbid conditions (including but not limited to asthma, recurrent bronchitis or pneumonia, diabetes), and 8) Multidrug resistant organisms identified by culture. Revised newly numbered Item 9 to read “Sinonasal benign or malignant tumor (including inverted papilloma).” In the *Policy Guidelines* section, revised item 3.f. to read “antibiotic therapy consisting of three consecutive weeks of appropriate antibiotic drugs, OR multiple two to three week courses of appropriate antibiotic drugs during the symptomatic periods.” CPT Codes 31237 and 31240 deleted from the *Billing/Coding* section. (adn)

- 9/13/11 Specialty Matched Consultant Advisory Panel review 8/31/11. No change to policy statement or medical criteria. (adn)
- 6/29/12 Code S1090 added to policy. “The use of a Propel sinus implant may be considered medically necessary when the following criteria are met. 1. Implanted at the time of approved functional endoscopic sinus surgery, and 2. Implanted in the ethmoid sinus only” added to the When Covered section. “Use of the Propel sinus implant is considered not medically necessary if inserted at any surgical setting other than the FESS procedure, or for any sinus cavities other than the ethmoid” added to the When Not Covered section. (sk)
- 7/24/12 Added information regarding implantable sinus stents/spacers for postoperative use following endoscopic sinus surgery to the Description section and to the Policy Guidelines section. Added “The use of implantable sinus stents/spacers for postoperative treatment following endoscopic sinus surgery is considered investigational. BCBSNC does not cover investigational services or supplies” to the When Not Covered section. References added. (sk)
- 11/13/12 Specialty Matched Consultant Advisory Panel review 8/15/12. Additional pediatric information added to Policy Guidelines. No change to policy statement. (sk)
- 11/12/13 Reference added. Existing references updated. Specialty Matched Consultant Advisory Panel review 8/21/13. Medical Director review. No change to policy statement. (sk)
- 2/25/14 Reference added. The word “spacer removed from its association with the word “stent” throughout the policy. No change to Policy intent. (sk)
- 7/15/14 Description section updated to include general information on drug-eluting sinus implants and specific information on the Propel™ sinus implant. Medical necessity criteria for use of a mometasone furoate sinus implant added to When Covered section. Not medically necessary criteria for use of a mometasone furoate sinus implant added to When Not Covered section. Policy Guidelines updated. (sk)
- 11/25/14 References added and updated. Specialty Matched Consultant Advisory Panel review 10/2014. Medical Director review. Policy title changed from Functional Endoscopic Sinus Surgery (FESS) to Surgical Treatment of Sinus Disease. Conditions in which Balloon Ostial Dilatation would be considered not medically necessary added to the When Not Covered Section. Definition of optimal medical treatment added. Statement added that “Balloon ostial dilatation as a standalone procedure in an ambulatory setting must be performed by a board eligible/board certified otolaryngologist who has admitting privileges at a local hospital.” (sk)

# Surgical Treatment of Sinus Disease

- 10/1/15 Specialty Matched Consultant Advisory Panel review 8/26/15. (sk)
- 12/30/15 Codes 0406T and 0407T added to Billing/Coding section. (sk)
- 9/30/16 Specialty Matched Consultant Advisory Panel review 8/31/2016. Reference added and updated. (sk)
- 12/29/17 Reference added. Policy Guidelines updated with inclusion of pediatric criteria. Specialty Matched Consultant Advisory Panel review 8/30/2017. Codes 31241, 31253, 31257, 31259, and 31298 added to Billing/Coding section for effective date 1/1/2018. (sk)
- 5/25/18 Medical Director review. The following statement added to the Billing/Coding section for additional clarity: “Balloon sinuplasty (codes 31295, 31296, 31297) performed in conjunction with functional endoscopic sinus surgery (FESS) within the same sinus cavity, is considered incidental to the major service and not eligible for separate reimbursement.” (sk)
- 11/30/18 Specialty Matched Consultant Advisory Panel review 8/22/2018. References added. Policy Guidelines updated. Information related to Sinuva™ mometasone furoate implant added to policy. Sinuva™ is considered investigational in the treatment of sinonasal polyposis. Code J3490 added to Billing/Coding section. Medical Director review. Notification given 11/30/2018 for effective date 1/29/2019. (sk)
- 10/01/19 Specialty Matched Consultant Advisory Panel review 9/20/2019. (sk)
- 6/30/20 New code C9122 added to Billing/Coding section. (sk)
- 7/14/20 Medical Director review. Criteria for balloon ostial dilation (BOD) moved to a separate medical policy. Silent sinus syndrome and antrochoanal polyps added to list of covered indication. (sk)
- 12/8/20 Specialty Matched Consultant Advisory Panel review 8/19/2020. Description section updated. Removed “Chronic headache or facial pain caused by a demonstrable anatomic or pathologic sinus disorder” from coverage criteria. Policy Guidelines updated. (sk)
- 3/31/21 New HCPCS codes J7402 and S1091 added to Billing/Coding section, effective 4/1/2021. Codes C9122, J3490, and S1090 deleted from Billing/Coding section, effective 4/1/2021. (sk)
- 12/14/21 Specialty Matched Consultant Advisory Panel review 8/18/2021. Added Fungal ball or mycetoma to list of covered indications. (sk)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.