Corporate Medical Policy

Surgical Treatment of Sinus Disease

File Name:	surgical_treatment_of_sinus_disease
Origination:	2/2010
Last CAP Review:	8/2018
Next CAP Review:	8/2019
Last Review:	8/2018

Description of Procedure or Service

Chronic sinusitis is one of the most frequently diagnosed chronic medical conditions, even more so than hypertension and arthritis. Chronic sinusitis 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. 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.

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 tiny 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 conventional 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.

Balloon ostial dilation is considered an alternative to endoscopic sinus surgery for those with chronic sinusitis of the frontal, maxillary, or sphenoid 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. This technique is said to allow improved sinus drainage.

In March 2008, the device "Relieva™ Sinus Balloon Catheter" (Acclarent, Menlo Park, CA) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The 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 granted 510(k) marketing clearance. These include the Relieva Spin Sinus Dilation System® cleared in August 2011, and the Relieva Seeker Balloon Sinuplasty System® cleared in November 2012.

In June 2008, the device, FinESS™ Sinus Treatment (Entellus Medical, Inc, Maple Grove, MN) was cleared for marketing by the 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. The bony sinus

outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures. Two other balloon sinus ostial dilation devices by Entellus Medical, Inc. also received 510(k) approval in August, 2012. These are the ENTrigue® Sinus Dilation System, and the XprESS® Multi-Sinus Dilation Tool.

Some form of sinus packing is generally performed postoperatively. Simple dressings moistened with saline can be inserted manually following surgery. Foam dressings are polysaccharide substances that form a gel when hydrated and can be used as nasal packs for a variety of indications. Middle meatal spacers are splint-like devices that prop open the sinus cavities post-FESS, but are not capable of drug delivery. 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 a plunger 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. 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

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

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

Surgical treatment 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 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,

3. Complications of sinusitis, including extension to adjacent structures,

4. Chronic headache or facial pain caused by a demonstrable anatomic or pathologic sinus disorder,

5. Mucocele (excludes benign, asymptomatic mucus retention cysts),

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),

8. Multidrug resistant organisms identified by culture,

9. Sinonasal benign or malignant tumor (including inverted papilloma),

10. Cerebrospinal fluid leak (CSF leak),

11. Dacryocystorhinostomy (DCR) for disorders of the lacrimal system,

12. Orbital decompression,

13. Repair of choanal atresia.

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

Surgical treatment of sinus disease is not covered in the absence of the above clinical indications.

Optimal medical management, when indicated, must have been attempted, and failed to resolve the patient's condition.

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

Balloon ostial dilation is considered not medically necessary in the following situations:

1. Nasal polyposis (Grade 2 or greater)
2. Samter's triad (aspirin sensitivity)
3. Severe sinusitis secondary to autoimmune or connective tissue disorders (i.e. including, but not limited to, sarcoidosis, Wegener's granulomatosis)
4. Severe sinusitis secondary to ciliary dysfunction, including, but not limited to, cystic fibrosis
5. Contraindication to, or inability to tolerate local and/or topical anesthetic
6. History of failed balloon procedure in the sinus to be treated
7. Sinusitis with extensive fungal disease
8. Isolated ethmoid sinus disease
9. Significant neo-osteogenesis

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.

Balloon ostial dilation 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.

Policy Guidelines

Functional endoscopic sinus surgery (FESS) and balloon ostial dilation 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 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. Systemic and/or topical steroids (at the discretion of the physician)
4. Saline irrigations (optional)
5. Topical and/or systemic decongestants (optional , if not contraindicated)
6. 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.

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
      - Meningocephaloceles
      - 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 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 Stents 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 stent 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 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

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. 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, 31295, 31296, 31297, 31298, J3490, S1090, S2342*

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.

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 7/2012

Specialty Matched Consultant Advisory Panel – 8/2012

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Specialty Matched Consultant Advisory Panel - 8/2013

Medical Director review 8/2013

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Senior Medical Director review 4/2014

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Specialty Matched Consultant Advisory Panel - 8/2016

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Medical Director review 5/2018

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Specialty Matched Consultant Advisory Panel - 8/2018

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Medical Director review 11/2018

Policy Implementation/Update Information

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." 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 Dilation would be considered not medically necessary added to the When Not Covered Section. Definition of optimal medical treatment added. Statement added that "Balloon ostial dilation 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)

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)