

Corporate Medical Policy

Surgical Treatment of Sinus Disease

Description of Procedure or Service

Sinusitis refers to infection or inflammation of the sinuses, which are small openings in the bones of the face. Symptoms include a stuffy nose, facial pain and discharge from the nose. Most sinus infections will get better without any specific treatment. For some people, sinus symptoms may last for months, and this is called chronic sinusitis. Standard therapy to treat chronic sinusitis may include decongestants, antibiotics, antihistamines, saline irrigation, and the use of nasal spray containing steroids. When chronic sinusitis does not respond to standard medical treatments, then surgery may be the next step. In some cases of chronic sinusitis, surgical drainage may be necessary when symptoms have not responded to medications or other conservative methods. Traditional functional endoscopic sinus surgery is generally considered the clinical standard; however balloon sinus ostial dilation is a recently emerged option that is appropriate for certain clinical circumstances. In both procedures, the sinuses are opened wider to allow for natural drainage of mucus resulting in movement of air through the nasal and sinus pathways.

Background

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, antihistamines, and steroids.

Functional endoscopic sinus surgery (FESS) is a 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 trans illumination 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” was cleared for marketing by the U.S. Food and Drug Administration (FDA). 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 have also been granted clearance. These include the Relieva Spin Sinus Dilation System®, and the Relieva Seeker Balloon Sinuplasty System®, FinESS™ Sinus Treatment, 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.

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. The only U.S. Food and Drug Administration approved drug-eluting sinus implant at this time is Propel™ (mometasone furoate sinus implant). There are numerous other stenting and packing materials commonly used in sinus surgery.

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, as well as the impact of the stent device itself.

Benefit 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.

The clinical coverage policy for rhinoplasty can be found at geha.com.

GEHA considers any surgical procedure (or any portion of a procedure) performed primarily to improve physical appearance through change in bodily form, except repair of accidental injury if repair is initiated promptly or as soon as the member's condition permits, as cosmetic and therefore not a covered benefit.

Regulatory Status

Sinus surgeries are procedures and, as such, are not subject to regulation by the FDA. However, the FDA does regulate manufacturing and dispensing practices and use of devices and drugs for such procedures.

Policy Statement

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

When surgical treatment of sinus disease is covered

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

1. Suspected tumor seen on preferred imaging, physical examination, or endoscopy; **or**
2. Supportive complications, including but are not limited to:
 - A. Sub periosteal abscess; **or**
 - B. Brain abscess; **or**
3. Chronic polyposis with symptoms unresponsive to medical therapy, including, but not limited to the following:
 - A. Oral steroids (unless contraindicated); **and**
 - B. Oral antibiotics (unless contraindicated); **and**
 - C. Topical nasal steroid sprays; **and**
 - D. Allergy evaluation and treatment (where indicated).
4. Allergic fungal sinusitis, as indicated by **all** of the following:
 - A. Specific diagnostic criteria including:
 1. Nasal polyposis; **and**
 2. Positive CT findings; **and**
 3. Eosinophilic mucus; **and**

AND
 - B. Allergy evaluation and treatment that fails to adequately manage the condition

5. Mucocele causing chronic sinusitis; **or**
6. Recurrent sinusitis that triggers or exacerbates comorbidities such as asthma or cystic fibrosis; **or**
7. Uncomplicated sinusitis (for example, sinusitis confined to the paranasal sinuses without adjacent involvement of neurologic, soft tissue, or bony structures) **and all** (A, B, and C) of the following:
 - A. Either of the following:
 1. Four or more documented episodes of acute rhinosinusitis (less than 4 weeks duration) in one year; **or**
 2. Chronic sinusitis (greater than 12 weeks continuously) associated with current functional deficits; **and**
 - B. Maximal medical therapy has been attempted, as indicated by **all** of the following:
 1. Antibiotic therapy for at least 4 consecutive weeks with appropriate antimicrobial therapy; **and**
 2. Trial of antihistamines and steroids and/or topical intranasal steroids; **and**
 3. Nasal lavage; **and**
 4. Allergy testing where indicated; **and**
 - C. Abnormal findings from diagnostic workup, as indicated by **any one** of the following:
 1. CT findings suggestive of obstruction or infection for example, but not limited to, air fluid levels, air bubbles, significant mucosal thickening, pansinusitis, or diffuse opacification; **or**
 2. Nasal endoscopy findings suggestive of significant disease; **or**
8. Fungal mycetoma; **or**
9. Cerebrospinal fluid rhinorrhea; **or**
10. Encephalocele; **or**
11. Posterior epistaxis (refractory to conservative treatment); **or**
12. Persistent facial pain with identified anatomic pathology in the sinuses confirmed by preferred imaging; **or**
13. Cavernous sinus thrombosis caused by chronic sinusitis.

When nasal or sinus cavity debridement is covered

Nasal or sinus cavity debridement following FESS is considered **medically necessary** for any of the following circumstances:

1. Nasal or sinus cavity debridement is allowed three times during the first 30 days postoperatively; **or**

2. Postoperative loss of vision or double vision; **or**
3. Evidence of cerebrospinal fluid leak such as rhinorrhea; **or**
4. When prompted by physical obstruction of the sinus opening related to:
 - A. Nasal polyps unresponsive to oral or nasal steroids; **or**
 - B. Documented presence of papilloma, carcinoma or other neoplasm; **or**
 - C. Allergic fungal sinusitis.

When surgical treatment of sinus disease is not covered:

1. Functional endoscopic sinus surgery is considered **not medically necessary** for the treatment of sinusitis, polyposis, sinus tumor, or any other condition when the criteria above are not met.
2. Nasal or sinus cavity debridement following FESS is considered **not medically necessary** when criteria above are not met, including additional post-surgical debridement beyond 30 days post-procedure.

When Balloon Sinus Ostial Dilation is covered:

Balloon sinus ostial dilation is medically necessary for treating chronic rhinosinusitis (defined as rhinosinusitis lasting longer than 12 weeks) when the following are met:

1. Chronic rhinosinusitis of the sinus to be dilated is confirmed on computed tomography scan. CT scan findings of chronic rhinosinusitis include one or more of the following: significant mucosal thickening, periosteal remodeling, periosteal thickening, and or obstruction of the ostiomeatal complex.
2. Balloon sinus ostial dilation is limited to the frontal, maxillary and/or sphenoid sinuses
3. Balloon sinus ostial dilation is performed either as a stand-alone procedure or as part of functional endoscopic sinus surgery
4. Balloon sinus ostial dilation is performed in persons older than 12 years of age whose symptoms persist despite medical therapy, as indicated, including all of the following:
 - A. Oral steroids and/or nasal steroid sprays (unless contraindicated); **and**
 - B. Oral antibiotics (unless contraindicated); **and**
 - C. Allergy evaluation and treatment (where indicated).
 - i. Nasal lavage; **and**
 - ii. Allergy testing where indicated; **and**
 - D. Abnormal findings from diagnostic workup, as indicated by **any one** of the following:
 - i. CT findings suggestive of obstruction or infection for example, but not limited to, air fluid levels, air bubbles, significant mucosal thickening, pansinusitis, or diffuse opacification; **or**

- ii. Nasal endoscopy findings suggestive of significant disease.

When Balloon Dilation is not covered:

1. Balloon sinus ostial dilation is considered investigational for treating nasal polyps or tumors.
There is insufficient published clinical evidence to conclude that balloon sinus ostial dilation is safe and effective for treating nasal polyps or tumors.
2. Balloon sinus ostial dilation is considered investigational in children 12 years of age or younger. There is insufficient evidence to support the use of balloon sinus ostial dilation in the management of rhinosinusitis in children. Long-term, well-designed studies using appropriate controls are needed to determine the effectiveness of balloon sinus ostial dilation in this population.

When use of a mometasone furoate sinus implant (Propel™) is covered:

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; **and**
4. The functional endoscopic sinus surgery (FESS) or other primary sinus procedure is
 - A. Considered medically necessary.

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 (directed by culture is preferred).
2. Oral antibiotics with multiple 1-3 week courses for patients with recurrent acute rhinosinusitis.
3. Systemic and/or topical steroids.
4. Saline irrigations.
5. Topical and/or systemic decongestants (if not contraindicated).

6. Treatment of concomitant allergic rhinitis, including avoidance measures, pharmacotherapy, and/or immunotherapy.

Note: Imaging studies should be generally obtained after maximal medical therapy. Based on clinical situation (i.e. concern for extra sinus complications or neoplasm), early or emergent imaging may be required to confirm a diagnosis.

Prior to performing endoscopic sinus surgery in the pediatric population, the physician must consider the following specific to the pediatric patient:

1. A comprehensive historical assessment that evaluates chronic rhinosinusitis or recurrent acute rhinosinusitis that is collateral to or in addition to one of the following (this list is not all inclusive):
 - a) Allergy
 - b) Day care exposure
 - c) Gastroesophageal reflux contributing to rhinosinusitis
 - d) Adenoiditis and/or obstructive adenoid hypertrophy
 - e) Cystic fibrosis
 - f) Immune deficiency disorders
 - g) Ciliary dysfunction/dyskinesia
 - h) Progressively worsening asthma with opaque sinus(es)
 - i) Nasal polyposis with airway obstruction and/or sinusitis
 - j) Suspected neoplasm (e.g., juvenile nasopharyngeal angiofibroma)
 - k) Adenoidectomy should be strongly considered a minimum of three months prior to performing pediatric sinus surgery for any of the above indications
 - l) Intracranial complications
 - m) Cavernous sinus thrombosis
 - n) Mucocoeles and mucopyocoeles
 - o) Subperiosteal or orbital abscess/periorbital cellulitis
 - p) Traumatic injury to optic canal (decompression)
 - q) Dacryocystitis from rhinosinusitis
 - r) Meningocephaloceles
 - s) Cerebrospinal fluid leaks
 - t) Tumors of the nasal cavity, paranasal sinuses, orbit or skull base
 - u) Recurrent acute rhinosinusitis (RARS)
2. 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.
3. Optimal medical therapy, including

- A. Management for any of the identified medical conditions listed above in number 1.
- 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.

Physician documentation

The following documentation must be provided for medical necessity review:

- Completed GEHA Nasal Surgeries Authorization form (can be found on geha.com)
- A history and physical within 12 months from request of authorization
- Relative office notes to include pre-procedure examination including the extent of the member's symptoms, pathology report and testing reports not already listed
- For post procedure submissions, include operative and/or procedure reports
- Imaging report(s)
- A letter of medical necessity including statement of unilateral or bilateral procedure. If unilateral, indicate right or left.
- Clinical documentation of medical management for the last 12 months with the name of the pharmacological interventions, date prescribed, and length of time each has been taken.

Additional documentation must be provided for pediatric patients:

- Documentation of evaluation and results for the conditions listed within the guidelines of this policy.
- Documentation of pre-procedure anterior and posterior nasal examination (rhinoscopy after mucosal decongestion) as possible for patient's age.
- A coronal CT scan performed following medical therapy.

Applicable codes include but are not limited to:

S1090 Mometasone furoate sinus implant, 370 micrograms

30130 Excision inferior turbinate, partial or complete, any method

30140 Submucous resection inferior turbinate, partial or complete, any method

30520 Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft

- 30620 Septal or other intranasal dermatoplasty (does not include obtaining graft)
- 31231 Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)
- 31233 Nasal/sinus endoscopy, diagnostic with maxillary sinusoscopy (via inferior meatus or canine fossa puncture)
- 31235 Nasal/sinus endoscopy, diagnostic with sphenoid sinusoscopy (via puncture of sphenoidal face or cannulation of ostium)
- 31237 Nasal/sinus endoscopy, surgical; with biopsy, polypectomy or debridement (separate procedure)
- 31238 Nasal/sinus endoscopy, surgical; with control of nasal hemorrhage
- 31239 Nasal/sinus endoscopy, surgical; with dacryocystorhinostomy
- 31240 Nasal/sinus endoscopy, surgical; with concha bullosa resection
- 31241 Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery
- 31254 Nasal/sinus endoscopy, surgical with ethmoidectomy; partial (anterior)
- 31255 Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior)
- 31256 Nasal/sinus endoscopy, surgical, with sphenoidotomy; with removal of tissue from the sphenoid sinus
- 31259 Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including sphenoidotomy, with removal of tissue from the sphenoid sinus
- 31267 Nasal/sinus endoscopy, surgical, with maxillary antrostomy; with removal of tissue from maxillary sinus
- 31276 Nasal/sinus endoscopy, surgical, with frontal sinus exploration, including removal of tissue from frontal sinus, when performed
- 31287 Nasal/sinus endoscopy, surgical, with sphenoidotomy
- 31288 Nasal/sinus endoscopy, surgical, with sphenoidotomy; with removal of tissue from the sphenoid sinus
- 31290 Nasal/sinus endoscopy, surgical, with repair of cerebrospinal fluid leak; ethmoid region
- 31291 Nasal/sinus endoscopy, surgical, with repair of cerebrospinal fluid leak; sphenoid region
- 31292 Nasal/sinus endoscopy, surgical; with medial or inferior orbital wall decompression
- 31293 Nasal/sinus endoscopy, surgical; with medial orbital wall and inferior orbital wall decompression

31295 Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa

31296 Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation)

31297 Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation)

31298 Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (eg, balloon dilation)

0406T Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant

0407T Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant; with biopsy, polypectomy or debridement

Scientific references

- Berlucchi M, Castelnuovo P, Vincenzi A et al. Endoscopic outcomes of resorbable nasal packing after functional endoscopic sinus surgery: a multicenter prospective randomized controlled study. *Eur Arch Otorhinolaryngol* 2009; 266(6):839-45.
- Cote DW, Wright ED. Triamcinolone-impregnated nasal dressing following endoscopic sinus surgery: a randomized, double-blind, placebo-controlled study. *Laryngoscope* 2010; 120(6):1269-73.
- Freeman SR, Sivayoham ES, Jepson K et al. A preliminary randomised controlled trial evaluating the efficacy of saline douching following endoscopic sinus surgery. *Clin Otolaryngol* 2008; 33(5):462-5.
- Rotenberg BW, Zhang I, Arra I et al. Postoperative care for Samter's triad patients undergoing endoscopic sinus surgery: a double-blinded, randomized controlled trial. *Laryngoscope* 2011; 121(12):2702-5.
- Lee JM, Grewal A. Middle meatal spacers for the prevention of synechiae following endoscopic sinus surgery: a systematic review and meta-analysis of randomized controlled trials. *Int Forum Allergy Rhinol* 2012
- Marple BF, Smith TL, Han JK et al. Advance II: a prospective, randomized study assessing safety and efficacy of bioabsorbable steroid-releasing sinus implants. *Otolaryngol. Head Neck Surg.* 2012; 146(6):1004-11.
- Murr AH, Smith TL, Hwang PH et al. Safety and efficacy of a novel bioabsorbable, steroid-eluting sinus stent. *Int Forum Allergy Rhinol* 2011; 1(1):23-32.
- Forwith KD, Chandra RK, Yun PT et al. ADVANCE: a multisite trial of bioabsorbable steroid-eluting sinus implants. *Laryngoscope* 2011; 121(11):2473-80.

- Catalona PJ, Thong M, Weiss R, Rimash T. The MicroFlow Spacer: a drug-eluting stent for the ethmoid sinus. *Indian J Otolaryngol Head Neck Surg* 2011; 63(3):279-84.
- 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.
- Han JK, Marple BF, Smith TL. Effect of steroid-releasing sinus implants on postoperative medical and surgical interventions: an efficacy meta-analysis. *Int Forum Allergy Rhinol* 2012; 2(4):271-9.
- Gould J, Alexander I, Tomkin E, Brodner D. In-office, multisinus balloon dilation: 1-Year outcomes from a prospective, multicenter, open label trial. *Am J Rhinol Allergy* 2014; 28(2): 156-163.
- Bikhazi N, Light J, Truitt T, et.al. Standalone balloon dilation versus sinus surgery for chronic rhinosinusitis: A prospective, multicenter, randomized, controlled trial with 1-year follow-up. *Am J Rhinol Allergy* 2014; 28(4): 323-329.
- Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (update): adult sinusitis. *Otolaryngol Head Neck Surg*. Apr 2015;152(2 Suppl):S1-S39. PMID 25832968
- American Academy of Otolaryngology-Head and Neck Surgery. Clinical Indicators: Endoscopic Sinus Surgery, Pediatric. 2012
- Rosenfeld RM, Andes D, Bhattacharyya N, et al. (June 2007). Clinical practice guidelines: Adult sinusitis. *Otolaryngol Head Neck Surg*, 2007;137(3S):S1-S31.
- American Academy of Otolaryngology-Head and Neck Surgery. Policy statement for Sinus Endoscopy.
- Slack R, Bates G. (Sept 1998). Functional Endoscopic Sinus Surgery
- Rudmik L, Mace J, Mechor B. Effect of a dexamethasone SinuFoam™ middle meatal spacer on endoscopic sinus surgery outcomes: A randomized, double-blind, placebo-controlled trial. *Int Forum Allergy Rhinol* 2012; 2(3):248-251.

Policy implementation and updates

02/2019 New policy issued. GEHA will cover sinus surgery when determined to be medically necessary because the medical criteria and guidelines outlined in the policy are met.