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 (Khalil & Nunez, 2006).

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.

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 pericosteal 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 or positive allergy testing to fungus; and
      AND
   B. Allergy evaluation and treatment that fails to adequately manage the condition

5. Mucocele causing chronically obstructed sinus outflow; 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 5-10 days with appropriate antimicrobial therapy; and
      2. Trial of antihistamines and steroids and/or topical intranasal steroids; and
      3. Nasal irrigation; and
      4. Allergy testing is necessary if symptoms are consistent with allergic rhinitis and have not responded to appropriate environmental controls and pharmacotherapy (e.g., antihistamines or intranasal corticosteroids or leukotriene antagonists, etc.); 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 six weeks 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.

Additional debridement may be allowed if records are provided documenting any of the following (not an all-inclusive list):

1. Persistent crusting; or
2. Recurrent polyps; or
3. Allergic mucin; or
4. Retained fungal material; or
5. Synechiae obstructing sinus ostia; or
6. Lateralized middle turbinate with ostial obstruction.

**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 6 weeks 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:
   - Oral steroids and/or nasal steroid sprays (unless contraindicated); **and**
   - Oral antibiotics (unless contraindicated); **and**
   - Nasal irrigation; **and**
   - Allergy testing is necessary if symptoms are consistent with allergic rhinitis and have not responded to appropriate environmental controls and pharmacotherapy (e.g., antihistamines or intranasal corticosteroids or leukotriene antagonists, etc. **and**
   - Abnormal findings from diagnostic workup, as indicated by **any one** of the following:
     - 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**
     - 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 or frontal sinus surgery is planned; **and**
3. Patient has one or more of the following conditions:
   - Polypoid disease
   - Failed prior surgery and/or restenosis
   - Absolute or relative contraindication to systemic steroids; **and**
4. The functional endoscopic sinus surgery (FESS) or other primary sinus procedure is considered medically necessary.

**Policy Guidelines**

In 2015, the American Academy of Otolaryngology-Head and Neck Surgery Foundation provided an update to the guidelines for adult sinusitis. The update group made strong recommendations that clinicians
1. should distinguish presumed ABRS from acute rhinosinusitis (ARS) caused by viral upper respiratory infections and noninfectious conditions and
2. 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.

The update group made recommendations that clinicians
1. should either offer watchful waiting (without antibiotics) or prescribe initial antibiotic therapy for adults with uncomplicated ABRS;
2. should prescribe amoxicillin with or without clavulanate as first-line therapy for 5 to 10 days (if a decision is made to treat ABRS with an antibiotic);
3. should reassess the patient to confirm ABRS, exclude other causes of illness, and detect complications if the patient worsens or fails to improve with the initial management option by 7 days after diagnosis or worsens during the initial management;
4. should distinguish CRS and recurrent ARS from isolated episodes of ABRS and other causes of sinonasal symptoms;
5. should assess the patient with CRS or recurrent ARS for multiple chronic conditions that would modify management, such as asthma, cystic fibrosis, immunocompromised state, and ciliary dyskinesia;
6. should confirm the presence or absence of nasal polyps in a patient with CRS; and
7. should recommend saline nasal irrigation, topical intranasal corticosteroids, or both for symptom relief of CRS.

The update group stated as options that clinicians may
1. recommend analgesics, topical intranasal steroids, and/or nasal saline irrigation for symptomatic relief of viral rhinosinusitis;
2. recommend analgesics, topical intranasal steroids, and/or nasal saline irrigation) for symptomatic relief of ABRS; and
3. obtain testing for allergy and immune function in evaluating a patient with CRS or recurrent ARS.

The update group made recommendations that clinicians
1. should not obtain radiographic imaging for patients who meet diagnostic criteria for ARS, unless a complication or alternative diagnosis is suspected, and
2. should not prescribe topical or systemic antifungal therapy for patients with CRS.

In an evidence based review of early postoperative care following ESS, Rudmik et. al. (2011), representing the American Rhinologic Society-American Academy of Otolaryngic Allergy, it concluded, based on the available evidence, use of nasal saline irrigation, sinus cavity debridement, and standard topical nasal steroid spray are recommended early postoperative care interventions. Postoperative antibiotic, systemic steroid, nonstandard topical nasal steroid solution, and/or drug-eluting spacers/stents are options in postoperative management. These evidence-based recommendations should not necessarily be applied to all postoperative patients and clinical judgment, in addition to evidence, is critical to determining the most appropriate care.
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. (American Academy of Otolaryngology-Head and Neck Surgery, Endoscopic sinus surgery clinical indicators for pediatrics, 2012.)

Physician documentation

Origination Date: Feb 2019  Peer Reviewed: Feb 2020  Next Review Date: Feb 2021
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.

**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.

Chronic sinusitis may be caused by persistent allergic rhinitis. Allergic rhinitis is an inflammation of the nasal membranes that is characterized by sneezing, nasal congestion, nasal itching, and rhinorrhea, in any combination. Nasal features of allergic rhinitis can include the following: a horizontal crease across the lower half of the bridge of the nose; caused by repeated upward rubbing of the tip of the nose by the palm of the hand; thin, watery nasal secretions and possible deviation or perforation of the nasal septum which may be associated with chronic rhinitis.

**Functional endoscopic sinus surgery (FESS)**

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**

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.

Gould et. al. (2014) conducted a multicenter study to assess 1-year changes in sinonasal symptoms and health care use after office-based multisinus balloon dilation. Adults diagnosed with chronic or recurrent acute rhinosinusitis per the 2007 adult sinusitis guidelines were enrolled in this Institutional Review Board-approved study. Balloon dilation of the maxillary sinuses/ethmoid infundibula with or without frontal or sphenoid ostial dilation was performed in the physician's office under local anesthesia. Intraoperative procedure technical success and subject procedure tolerance were recorded. Efficacy was assessed using the patient-reported 20-item Sino-Nasal Outcome Test (SNOT-20) and Rhinosinusitis Symptom Inventory (RSI). Complications and revision surgeries were also recorded. A total of 313 ostial dilations were attempted and 307 were successfully completed in 81 subjects. Mean procedure tolerance was 2.8 ± 2.2 (0 = no pain; 10 = severe pain). Clinically meaningful and statistically significant (p < 0.0001) mean SNOT-20 symptom improvement was observed at 1 and 6 months and sustained through 1 year. The RSI treatment effect for all major rhinosinusitis symptoms was "large" and improvement in each was significant (p < 0.0001). Compared with the previous 1-year period, patients reported an average of 2.3 fewer acute sinus infections (p < 0.0001), 2.4 fewer antibiotic courses taken (p < 0.0001), and 3.0 fewer sinus-related physician visits (p < 0.0001) after balloon dilation. No serious device or procedure-related adverse events occurred. One subject (1.3%) underwent revision surgery. In conclusion, in-office, multisinus balloon dilation is safe, effective, and well tolerated. Patients reported significant reductions in both sinonasal symptoms and health care use after balloon dilation. Efficacy observed at 1 and 6 month follow-up was sustained through 1 year with a very low rate of revision surgery.

Within the same year, Bikhazi et. al. (2014) performed a prospective, multicenter, randomized trial was to evaluate and compare 1-year outcomes from the REMODEL study between office balloon dilation and functional endoscopic sinus surgery (FESS). Adults with maxillary chronic rhinosinusitis (CRS), including those with anterior ethmoid disease, who failed medical management and were surgical candidates for FESS, underwent either standalone balloon dilation or FESS in a 1:1 randomization scheme and were followed through a minimum of 1 year. Sinonasal symptom improvement was assessed using the validated 20-item Sino-Nasal Outcome Test (SNOT-20) survey. Standardized effect sizes were computed to further assess clinical significance. Ostial patency rate, rhinosinusitis episode frequency, impact of sinus disease on activity and work productivity using the validated Work Productivity and Activity
Impairment survey, complications, and revision rate were also compared between the two groups. Ninety-two patients (50 balloon dilation; 42 FESS) were treated and 89 (96.7%) completed 1-year follow-up. Both groups showed clinically meaningful and statistically significant ($p < 0.0001$) improvement in mean overall SNOT-20 scores and in all four SNOT-20 subscales. The 1-year mean change in SNOT-20 after balloon dilation (-1.64) was noninferior to FESS (-1.65; $p < 0.001$). The standardized effect size was large, showing clinically significant improvement for both interventions. Ostial patency was 96.7 and 98.7% after balloon dilation and FESS, respectively, and each group reported significant reductions ($p < 0.0001$) in rhinosinusitis episodes (mean decrease, 4.2 for balloon dilation and 3.5 for FESS). Overall work productivity and daily activity impairment due to chronic sinusitis were significantly improved ($p < 0.001$) in both groups. There were no complications and revision surgery rate was 2% in each arm through 1 year. In conclusion, with 1-year follow-up, standalone balloon dilation is as effective as FESS in the treatment of CRS in patients with maxillary sinus disease with or without anterior ethmoid disease who failed medical therapy and met the criteria for medically necessary FESS.

**Nasal irrigation**

Nasal irrigation (also known as nasal douche, wash or lavage) is a procedure that rinses the nasal cavity with isotonic or hypertonic saline solutions. The patient instills saline into one nostril and allows it to drain out of the other nostril, bathing the nasal cavity.

Freeman et. al. (2008) conducted a preliminary randomized controlled trial evaluating the efficacy of saline douching following endoscopic sinus surgery. Participants consisted of twenty three adults undergoing bilateral ESS for chronic rhinosinusitis or nasal polyposis. Saline douching of one side of the nasal cavity was performed three times per day for 6 weeks. Attendance was 22 patients at 3 weeks and 17 patients at 3 months. At 3 weeks saline douching significantly improved the presence of discharge and non-significantly improved the presence of edema with minimal difference with regard to polyps and no difference with adhesions or crusting.

In 2011, Rotenberg et. al. performed a double-blinded, randomized controlled trial to compare three different standardized medication regimens prescribed to chronic rhinosinusitis patients with polyposis (CRSwP) after ESS. Patients with Samter’s triad undergoing ESS were postoperatively randomized into three medication regimens, those being saline irrigation alone (control group A), saline irrigation plus separate budesonide nasal spray (group B), and saline irrigation mixed with budesonide nasal spray (group C). Outcome measures were Sino-Nasal Outcome Test scores, Lund-Mackay computed tomography scores, and Lund-Kennedy endoscopic scores taken at preoperative baseline, and then at 6 months and 1 year postoperatively. Side effect profiles were also measured (adrenocorticotropic hormone blood level ranges and intraocular pressure at the same interval points). Analysis of variance and two analyses were conducted using a Bonferroni correction method and routine descriptive statistics. Inter- and intragroup comparisons were made. Sixty subjects were recruited. All groups were equivalent at baseline in all outcomes. All intragroup analyses showed statistically and clinically significant improvement in disease status as compared to baseline, with a sustained but lessened improvement at 1 year. However, no statistically or clinically significant differences were observed between groups at any time point. There was no treatment effect noted. It was concluded that nasal steroids did not confer any additional benefit over saline alone as post-ESS care for the Samter’s triad CRSwP patient population.

**Sinus packing**

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.

Berlucchi et. al. (2009) conducted a multicenter prospective randomized controlled study examining the endoscopic outcomes of resorbable nasal packing after FESS. A total of 66 patients for 88 nasal cavities were randomized to receive either hyaluronan resorbable packing (MeroGel) or standard non-resorbable nasal dressing after FESS. All underwent preoperative rhinoscopy, CT of sinuses, and, after surgery, were reassessed by rhinoscopy at 2, 4, and 12 weeks in blinded fashion. A total of 44 nasal cavities (MeroGel-group) received resorbable packing, whereas the remaining 44 were packed with non-resorbable nasal dressing. At follow-up endoscopic visit, the presence of nasal synechia was evaluated as primary outcome. Moreover, the tolerability and surgical handling properties of MeroGel and its comfort were assessed by surgeons and patients. Preoperative severity of rhinosinusitis was similar in both groups. No significant adverse events were observed in all patients. Follow-up endoscopy showed a lower proportion of nasal adhesions in MeroGel-group. Moreover, an improvement of other endoscopic nasal findings such as re-epithelialization, presence of granulation tissue, and appearance of nasal mucosa of nasal cavities after FESS was observed in the MeroGel-group. Tolerability and surgical handling properties of MeroGel were positively rated by clinicians and the overall patient judged comfort of MeroGel was favorable. In conclusion, MeroGel can be considered a valid alternative to standard non-resorbable nasal dressings. It is safe, well-accepted, well-tolerated, and has significant advantage of being resorbable. Moreover, it may favor improved healing in patients undergoing FESS and reduce formation of adhesions.

Drug-eluting sinus implants

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 U.S. Food and Drug Administration has approved drug-eluting sinus implant Propel™ (mometasone furoate sinus implant). There are numerous FDA approved 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.

A randomized, double-blind, placebo-controlled study by Cote & Wright (2010) analyzes Triamcinolone-impregnated nasal dressing following endoscopic sinus surgery. Chronic rhinosinusitis patients with polyposis who were to undergo bilateral endoscopic sinus surgery were recruited and randomized to receive triamcinolone-impregnated bioresorbable dressing in one nasal cavity and saline-impregnated dressing contralaterally. Postoperative healing assessments of edema, crusting, secretions, and scarring were done at postoperative days 7, 14, 28 and at 3 and 6 months using validated Lund-Kennedy and Perioperative Sinus Endoscopy (POSE) scores. Analysis of 19 enrolled patients having completed observation shows no significant difference between the cavity scores preoperatively using both the POSE and Lund-Kennedy scores. There was, however, a statistically significant difference at day 7 and 14.
in both the Lund-Kennedy and POSE scores for the treatment and control groups, and a significant difference was also detected between the groups at 3- and 6-month observations.

Murr et. al. (2011) sought to explore the safety and efficacy of bioabsorbable, steroid-eluting sinus stents. A prospective, multicenter, randomized, double-blind clinical trial, enrolled 43 patients in 2 groups. One group (n = 38) used an intrapatient control design comparing drug-eluting to non-drug-eluting stents. The other group (n = 5) received bilateral drug-eluting stents to assess systemic safety. Endoscopic follow-up was performed for 60 days. Efficacy endpoints included assessment of inflammation, polyp formation, adhesions, and middle turbinate position. Stents were successfully deployed in all 86 sinuses. Compared to the control stent, the drug-eluting stent provided statistically significant reduction in inflammation at days 21 to 45, frequency of polyp formation, and frequency of significant adhesion. Reduced frequency of middle turbinate lateralization was also apparent though not statistically significant. No device-related adverse events occurred. Eluted steroid was unquantifiable systemically and there was no evidence of adrenal cortical suppression. This study demonstrates the safety and efficacy of a novel bioabsorbable, steroid-eluting stent for use in chronic rhinosinusitis patients. The steroid-eluting stent is effective in improving wound healing by preserving sinus patency, reducing inflammation, and minimizing adhesions via controlled local steroid delivery without measurable systemic exposure.

In a follow up study, Marple et. al. (2012) investigate the safety and effectiveness of controlled delivery of mometasone furoate to the sinus mucosa via bioabsorbable implants deployed at the time of ESS. The study enrolled 105 patients with CRS undergoing bilateral ethmoidectomy to compare the effect of drug-releasing to non-drug-releasing implants using an intrapatient control design. Postoperative interventions, polyposis, and adhesions were assessed postoperatively. Efficacy was determined through independent analysis of randomized video-endoscopies by 3 blinded sinus surgeons. Safety assessments included ocular examinations. Implants were successfully deployed in all 210 ethmoid sinuses. Compared with control sinuses with non-drug-releasing implants, the drug-releasing implant provided a 29.0% relative reduction in postoperative interventions and a 52% decrease in lysis of adhesions. The relative reduction in frank polyposis was 44.9%. Similar reductions were observed in real-time grading performed by the clinical investigators. No clinically significant changes from baseline in intraocular pressure or cataracts were observed. This study provides a high level of evidence that use of steroid-releasing implants that apply a sustained release of corticosteroid improves surgical outcomes by reducing synechiae formation, polyposis, and the need for postoperative interventions, with no observable ocular safety risk.

**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.

The following list of codes are intended for reference purposes only, is not an all-inclusive code listing, and does not imply that the service is covered or non-covered. Applicable codes include but are not limited to:

<table>
<thead>
<tr>
<th>CPT/HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>Functional endoscopic sinus surgery</td>
<td>Nasal/sinus endoscopy, diagnostic with maxillary sinusoscopy (via inferior meatus or canine fossa puncture)</td>
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Origination Date: Feb 2019 Peer Reviewed: Feb 2020 Next Review Date: Feb 2021
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>31235</td>
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<td>31237</td>
<td>Nasal/sinus endoscopy, surgical; with biopsy, polypectomy or debridement (separate procedure)</td>
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<td>Nasal/sinus endoscopy, surgical; with concha bullosa resection</td>
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<td>Nasal/sinus endoscopy, surgical with ethmoidectomy; partial (anterior)</td>
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<td>31255</td>
<td>Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior)</td>
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<td>31256</td>
<td>Nasal/sinus endoscopy, surgical, with sphenoidotomy; with removal of tissue from the sphenoid sinus</td>
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<td>31259</td>
<td>Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including sphenoidotomy, with removal of tissue from the sphenoid sinus</td>
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<td>31267</td>
<td>Nasal/sinus endoscopy, surgical, with maxillary antrostomy; with removal of tissue from maxillary sinus</td>
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<td>Nasal/sinus endoscopy, surgical, with frontal sinus exploration, including removal of tissue from frontal sinus, when performed</td>
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<td>31287</td>
<td>Nasal/sinus endoscopy, surgical, with sphenoidotomy</td>
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<td>31288</td>
<td>Nasal/sinus endoscopy, surgical, with sphenoidotomy; with removal of tissue from the sphenoid sinus</td>
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**Balloon sinus ostial dilation**

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<th>Code</th>
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<td>Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa</td>
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<tr>
<td>31296</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation)</td>
</tr>
<tr>
<td>31297</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation)</td>
</tr>
<tr>
<td>31298</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (eg, balloon dilation)</td>
</tr>
</tbody>
</table>

**Drug eluting implant**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0406T</td>
<td>Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant</td>
</tr>
<tr>
<td>0407T</td>
<td>Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant; with biopsy, polypectomy or debridement</td>
</tr>
<tr>
<td>J7401</td>
<td>Mometasone furoate sinus implant, 10 mcg</td>
</tr>
</tbody>
</table>

**Other applicable codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>31238</td>
<td>Nasal/sinus endoscopy, surgical; with control of nasal hemorrhage</td>
</tr>
<tr>
<td>31239</td>
<td>Nasal/sinus endoscopy, surgical; with dacryocystorhinostomy</td>
</tr>
<tr>
<td>31241</td>
<td>Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery</td>
</tr>
<tr>
<td>31290</td>
<td>Nasal/sinus endoscopy, surgical, with repair of cerebrospinal fluid leak; ethmoid region</td>
</tr>
<tr>
<td>31291</td>
<td>Nasal/sinus endoscopy, surgical, with repair of cerebrospinal fluid leak; sphenoid region</td>
</tr>
<tr>
<td>31292</td>
<td>Nasal/sinus endoscopy, surgical; with medial or inferior orbital wall decompression</td>
</tr>
</tbody>
</table>
Nasal/sinus endoscopy, surgical; with medial orbital wall and inferior orbital wall decompression

Scientific references


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.

2/2020    Updates to policy guidelines, coverage clarification, formatting and references.