7.01.155	Functional Endoscopic Sinus Surgery for Chronic Rhinosinusitis		
Original Policy Date:	December 1, 2016	**Effective Date:**	April 1, 2019
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Policy Statement

The use of functional endoscopic sinus surgery (FESS) in the treatment of chronic rhinosinusitis (CRS) may be considered **medically necessary** for patients with chronic rhinosinusitis when **all** of the following criteria are present:

- Chronic rhinosinusitis symptoms, characterized by **at least two** of the following, **at least one of which is (a) or (b)**, are present for at least 12 continuous weeks:
  a. Mucopurulent nasal drainage
  b. Nasal congestion
  c. Facial pain
  d. Facial pressure
  e. Anosmia or hyposmia
- Appropriate medical therapy has been attempted, including **all** of the following:
  a. Topical nasal steroids for at least 8 consecutive weeks
  b. Nasal lavage for at least 8 consecutive weeks
  c. Consideration for allergic and/or immune evaluation if the patient has symptoms consistent with allergic rhinitis and/or immunodeficiency
- There is objective evidence of mucosal inflammation as demonstrated by **one** of the following:
  a. Sinus computed tomography or magnetic resonance imaging showing significant mucosal thickening or opacification of the paranasal sinuses
  b. Nasal endoscopy with purulent mucus in the middle meatus or ethmoid region OR polyps in the nasal cavity or middle meatus
- There are no serious urgent complications of acute sinusitis that would suggest orbital cellulitis or abscess, intracranial extension of infection, or other complication that would require urgent or emergent surgery such that "appropriate medical therapy" for 8 weeks would not be appropriate

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

Policy Guidelines

Criteria for "maximal medical therapy" used before endoscopic sinus surgery is attempted have been reported in a minority (21%) of published studies of endoscopic sinus surgery (Dautremont & Rudmik, 2015). The criteria used vary across studies, but studies that have reported specific criteria most often report using topical steroids (91.4%; mean duration, 8.4 weeks) and oral antibiotics (87.7%; mean duration, 23 days) (Dautremont & Rudmik, 2015). Systematic reviews of randomized controlled trials have consistently demonstrated improved symptoms of chronic rhinosinusitis with topical steroids. In contrast, weak evidence supports the use of systemic antibiotics in chronic rhinosinusitis.

Coding

Functional endoscopic sinus surgery may be coded using the following CPT codes:

- **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
- **31256**: Nasal/sinus endoscopy, surgical, with maxillary antrostomy
- **31267**: Nasal/sinus endoscopy, surgical, with maxillary antrostomy; with removal of tissue from maxillary sinus
- **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
- **31294**: Nasal/sinus endoscopy, surgical; with optic nerve decompression
- **31295**: Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (e.g., balloon dilation), transnasal or via canine fossa
- **31296**: Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (e.g., balloon dilation)
- **31297**: Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (e.g., balloon dilation)

Effective January 1, 2018, the following CPT codes may be used to describe functional endoscopic sinus surgery:

- **31241**: Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery
- **31253**: Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including frontal sinus exploration, with removal of tissue from frontal sinus, when performed
- **31254**: Nasal/sinus endoscopy, surgical with ethmoidectomy; partial (anterior)
- **31255**: Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior)
- **31257**: Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including sphenoidotomy
- **31259**: Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including sphenoidotomy, with removal of tissue from the sphenoid sinus
- **31276**: Nasal/sinus endoscopy, surgical, with frontal sinus exploration, including removal of tissue from frontal sinus, when performed
- **31298:** Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (e.g., balloon dilation)

Description

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

Related Policies

- Balloon Ostial Dilation for Treatment of Chronic Sinusitis

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

FESS is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

Rationale

Background

Chronic Rhinosinusitis

CRS is a highly prevalent inflammatory disorder of the paranasal sinuses and the mucosa of the nasal passages that affects 3% to 7% of adults.[1,] In adults, CRS is characterized by symptoms related to nasal and sinus obstruction and inflammation, including mucopurulent nasal drainage, nasal congestion, facial pain or pressure, and anosmia or hyposmia, that persist for at least 12 weeks.

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

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

While acute sinusitis is considered a more traditional infectious process, CRS is a chronic inflammatory disease of the upper airways, with multiple underlying causes. Risk factors for CRS with or without nasal polyps include anatomic variations and gastroesophageal reflux. There are conflicting reports about the association between allergy and CRS without nasal polyps, although weak evidence has suggested that allergy may be associated with CRS with nasal polyps. In addition, aspirin sensitivity may be associated with CRS with nasal polyps. The role of bacterial, viral, and fungal microorganisms in CRS has been actively investigated. There is some evidence that CRS is associated with a predominance of anaerobic bacteria.[2,3,] On the other hand, a study that used bacterial ribosomal RNA sequencing to evaluate the sinus microbiome in patients with and without CRS found a quantitative increase in bacterial and fungal RNA

expression in patients with CRS, but no major differences in the types of microorganisms detected.[4,] Bacterial biofilms have been identified in cases of CRS.[5,]

Diagnostic Criteria

Several medical organizations have developed criteria for the diagnosis of CRS, which are summarized in Table 1. Most diagnostic schemas require the presence of the major symptoms of CRS for more than 12 weeks, combined with objective evidence of mucosal inflammation on sinus imaging, endoscopy or rhinoscopy, or both.

Table 1. Chronic rhinosinusitis Diagnostic Criteria

Organization	Chronic Rhinosinusitis Definition
International Consensus Statement on Allergy and Rhinology: Rhinosinusitis (2016)[6]	Sinonasal inflammation persisting for more than 12 weeks. Symptoms must include at least 2 of the following: • Nasal blockage/obstruction/congestion • Nasal discharge (anterior/posterior) • Facial pain/pressure • Reduction/loss of smell Additionally, the diagnosis must be confirmed by: • Evidence of inflammation on paranasal sinus examination or computed tomography (CT) • Evidence of purulence coming from paranasal sinuses or ostiomeatal complex. CRS is divided into CRSwNP or CRSsNP based on the presence or absence of nasal polyps
American Academy of Allergy, Asthma, and Immunology et al (2005)[7,]	Symptoms for 8 weeks or longer of varying severity consisting of the same symptoms as seen in acute sinusitis. In chronic sinusitis there should be abnormal findings on CT or MRI. Some patients with chronic sinusitis might present with vague or insidious symptoms.
European Academy of Allergology and Clinical Immunology and the European Rhinologic Society (2012)[8,]	Rhinosinusitis in adults is defined as: • Inflammation of the nose and the paranasal sinuses characterized by two or more symptoms, one of which should be either nasal blockage/ obstruction/congestion or nasal discharge (anterior/posterior nasal drip): ± Facial pain/pressure ± Reduction or loss of smell and either • Endoscopic signs of: o Nasal Polyps, and/or o Mucopurulent discharge primarily from middle meatus, and/or oedema/mucosal obstruction primarily in middlemeatus and/or • CT changes: o Mucosal changes within the ostiomeatal complex and/or sinuses Chronic rhinosinusitis with nasal polyps (CRSwNP): Chronic rhinosinusitis as defined above and bilateral, endoscopically visualized polyps in middle meatus. Chronic rhinosinusitis without nasal polyps (CRSsNP): Chronic rhinosinusitis as defined above and no visible polyps in middle meatus, if necessary following decongestant.
British Society for Allergy and Clinical Immunology (2008)[9,]	Diagnostic criteria for rhinosinusitis: Major symptoms – two of the following, one to be: • Nasal congestion or obstruction • Nasal discharge (anterior or posterior) ± Facial pain or pressure ± Olfactory disturbance AND either Endoscopic signs (one or more of): • Polyps • Mucopurulent discharge from middle meatus • Oedema/obstruction at middle meatus OR Computerized Tomography (CT) signs
American Academy of Otolaryngology – Head and Neck	[12] weeks or longer of [2] or more of the following signs and symptoms: • Mucopurulent drainage (anterior, posterior, or both) • Nasal obstruction (congestion)

Organization	Chronic Rhinosinusitis Definition
Surgery Foundation (2015)[10,11,]	• Facial pain-pressure-fullness • Decreased sense of smell AND Inflammation is documented by one or more of the following findings: • Purulent (not clear) mucus or edema in the middle meatus or anterior ethmoid region • Polyps in nasal cavity or the middle meatus, and/or radiographic imaging showing inflammation of the paranasal sinuses

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

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

Medical Treatment

Medical therapy for CRS, with or without polyps, is often multimodal, including nasal irrigation, topical and/or systemic corticosteroids, and/or antibiotic therapy.[12,] Guidelines from the American Academy of Otolaryngology-Head and Neck Surgery (2015) have recommended the use of saline nasal irrigation, topical intranasal corticosteroids, or both, for symptom relief of CRS, on the basis of systematic reviews of randomized controlled trials (RCTs).[10,11,] There is a specific recommendation against the use of topical and systematic antifungal therapies. The guidelines do not include a statement specifically addressing the use of systemic antibiotics for CRS; however, in the list of future research needs, the authors included: "Perform additional RCTs to clarify the impact of antibiotic therapy on CRS outcomes."

A systematic review by Rudmik and Soler (2015) evaluated the evidence for various medical therapies for chronic sinusitis, excluding allergic fungal sinusitis.[1,] Reviewers included 29 studies, with 12 meta-analyses (with a total of >60 RCTs), 13 systematic reviews, and 4 individual RCTs not included in any meta-analyses. Topical corticosteroids were associated, in multiple studies, with improved symptom scores, reduced polyp size, and decreased polyp recurrence after surgery. Saline nasal irrigation was associated, in multiple studies, with significant improvements in symptoms scores. There was some evidence that two systemic therapies (oral corticosteroids, doxycycline), both for three weeks, improved polyp scores in patients with CRS with nasal polyps. Long-term (>3 months) macrolide therapy was associated in an RCT with improved symptoms and QOL in individuals with CRS without nasal polyps, although other studies did not find a benefit with chronic macrolide use.

In 2014, an evidence-based review summarized a series of earlier evidence-based reviews with recommendations related to CRS.[13,] This review concluded that both saline irrigation and topical corticosteroids are well-supported by the available published literature for treatment of CRS, with and without nasal polyps. For CRS with polyps, the evidence demonstrated short-term improvement in symptoms after short-term oral corticosteroid treatment. For CRS with or without nasal polyps, a small number of RCTs have shown improvement in nasal endoscopy scores and some symptoms with oral macrolide therapy. However, for CRS with or without nasal polyps, there was very limited evidence on the use of nonmacrolide oral antibiotics.

A 2011 Cochrane review of studies comparing systemic antibiotics with placebo for CRS in adults identified a study (n=64 patients) judged to be at high-risk of bias.[14,] Reviewers concluded: "Further good quality trials, with large sample sizes, are needed to evaluate the use of antibiotics in chronic rhinosinusitis."

Surgical Treatment

The goals of surgery for CRS include removing polyps and debris that may be sources of inflammatory mediators and prevent the effective delivery of local medical therapies. In addition, to varying degrees, surgical techniques involve the creation of open sinus cavities,

usually via dilation of the sinus ostia, to permit better drainage from the sinus cavities and more effective delivery of local therapies.

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

FESS encompasses a variety of degrees of sinus access and tissue removal and is described based on the sinuses accessed. The Draf classification is used to describe degrees of endoscopic frontal sinusotomy (see Table 2).

Table 2. Draf Classification for Endoscopic Frontal Sinusotomy

Type	Description
Draf I	Anterior ethmoidectomy without altering frontal sinus ostium
Draf IIA	Removal of ethmoid cells that extend into frontal sinus
Draf IIB	Removal of frontal sinus floor between the middle turbinate and the lamina papyracea
Draf III[a]	Removal of frontal sinus floor from orbit to orbit with contiguous portions of the superior nasal septum

[a] Modified Lothrop procedure.

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

Outcomes

To quantify the severity of CRS and to assess treatment response, various outcomes measures can be used, including patient-reported QOL measures, radiologic scores, and endoscopic grading.

The Lund-McKay scoring system uses radiologist-rated information derived from computed tomography scans regarding opacification of the sinus cavities, generating a score ranging from 0 to 12.[15,16,]

Several disease-specific patient-reported QOL scores have been used. Commonly used is the Sino-Nasal Outcome Test-20 (SNOT-20), a validated questionnaire, in which patients complete 20 symptom questions on a categorical scale (0 [no bother] to 5 [worst symptoms can be]). Average rankings can be reported over all 20 symptoms, as well as by 4 subclassified symptom domains. The SNOT-22 is a variation of the SNOT-20 that includes 2 additional questions ("nasal obstruction" and "loss of smell and taste"). The minimal clinically important difference for the SNOT-22 has been estimated to be 8.9 points.[17,]

Additionally, QOL may be reported based on overall health-related QOL scores, such as the 36-Item Short-Form Health Survey. The Survey consists of 8 scales on various health domains, which are transformed into a scale ranging from 0 to 100 (100 corresponding to best health).

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be

relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice. The following is a summary of the key literature to date.

This review focuses on the use of surgical therapies for chronic rhinosinusitis (CRS) with or without nasal polyposis. It focuses on functional endoscopic sinus surgery (FESS).

The primary outcome measures relevant to the treatment of CRS are patient-reported symptoms and QOL. Studies should predefine responder criteria for outcome measures used and assess between-group differences in the proportion of patients considered responders. Examiner evaluation of the nasal and sinus appearance and polyp size may provide some information about treatment outcomes, but these evaluations are limited by the lack of universally accepted standards.

Functional Endoscopic Sinus Surgery for Chronic Rhinosinusitis
Clinical Context and Test Purpose
The purpose of FESS is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as medical management, in patients with CRS with or without nasal polyposis.

The question addressed in this evidence review is: does FESS improve the net health outcome for patients with CRS?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest are individuals with CRS with or without nasal polyposis.

Interventions
The therapy being considered is FESS.

Comparators
Comparators of interest include medical management. Medical management for CRS includes saline nasal irrigation, corticosteroids, antibiotics, and immunotherapy.

Outcomes
The general outcomes of interest are symptoms, change in disease status, QOL, treatment-related morbidity.

Timing
The existing literature evaluating FESS as a treatment for CRS with or without nasal polyposis has varying lengths of follow-up, ranging from 3- to 12-months. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 12-months of follow-up is considered necessary to demonstrate efficacy.

Setting
Patients with CRS with or without nasal polyposis are actively managed by otolaryngologists and primary care providers in an inpatient clinical setting.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies
c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought

Studies with duplicative or overlapping populations were excluded.

Despite the widespread use of FESS, only a small number of RCTs have directly compared FESS with medical management. To the extent possible, CRS with and without nasal polyposis have been evaluated separately. If studies did not specify that the patient populations included only those with CRS with nasal polyposis, or if studies included both groups, the study was grouped with those addressing CRS with and without nasal polyps.

FESS for CRS

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CRS with or without Polyposis

Two RCTs were identified that compared FESS with medical therapy in patients with CRS, not limited to patients with polyposis, which have been summarized in systematic reviews. Given the small body of RCTs, they are discussed individually first, followed by systematic reviews.

Randomized Controlled Trials

Ragab et al (2004) reported on the results of an RCT comparing medical management with FESS in patients who had CRS with or without nasal polyposis.[18,] Eligible patients had 1 of the following: 8 or more weeks of persistent signs and symptoms and signs at least 2 major or 1 major and 2 minor symptoms (major: nasal congestion obstruction, nasal discharge, facial pain or pressure, headache, olfactory disturbance; minor: fever, halitosis [97% of patients]) or 4 episodes per year of recurrent acute rhinosinusitis each lasting at least 10 days in association with persistent changes on computed tomography for weeks after medical therapy without intervening acute infection (3% of patients). Patients were randomized after demonstrating persistent symptoms following initial medical therapy and subsequently demonstrating persistent changes in computed tomography scan. Patients were randomized to an FESS group, which received FESS performed by 1 of 2 surgeons, followed by a 2-week course of oral erythromycin, topical nasal dexamethasone plus tramazoline, and alkaline nasal douche, followed by a 3-month course of topical nasal fluticasone, or to a medical therapy group, which received a 12-week course of oral erythromycin, alkaline nasal douche, and topical nasal corticosteroids (dexamethasone plus tramazoline for 2 weeks followed by 10 weeks of fluticasone for patients without polyposis and 12 weeks of fluticasone for patients with polyposis).

Of 90 patients randomized, 35 had CRS with polyposis. Both patient-reported (Sino-Nasal Outcome Test-20 [SNOT-20], 36-Item Short-Form Health Survey, subjective symptom assessment on visual analog scale) and objective (nasal examination with scoring, acoustic rhinometry, saccharine clearance time, total nasal nitric oxide levels) outcomes were used, without blinding of outcome assessment. At 6- and 12-month follow-up visits, both groups demonstrated significant improvements in subjective outcomes, but there were no significant between-group differences. For example, the percent change in visual analog scale score at 6 months was 49.7% in the FESS group compared with 45.3% in the medical therapy group ($p>0.05$). There were no significant differences in the change in SNOT-20 or 36-Item Short-Form Survey scores between

groups (p<0.05). There were no significant between-group differences in change in any objective measurements at 6- or 12-month follow-up visits, with the exception of total nasal volume at 6 months in patients without polyposis (mean percent change from baseline, 21.8% in the FESS group vs 3.2% in the medical therapy group; p<0.01).

A second report (Ragab et al [2006]) assessed asthma-related outcomes in the subgroup of 45 patients with asthma,[19] and a third (Ragab et al [2010]) detailed the QOL measurement outcomes in this study.[20]

Hartog et al (1997) reported on results of an RCT comparing FESS plus sinus irrigation with sinus irrigation alone in patients with chronic maxillary sinusitis.[21] Eligible patients had at least two of the following three CRS symptoms: purulent rhinitis, nasal obstruction, and headache, with confirmation of maxillary sinusitis on sinus radiographs. Patients were randomized to sinus irrigation, with a second irrigation a week after the first if needed, or to FESS within three days of enrollment. Randomization techniques were not described. The trial enrolled 89 patients (45 in each group), with 77 patients included in data analysis; 11 patients were nonevaluable (7 with early dropout due to treatment failure; 5 for other reasons). An additional 14 patients were lost to follow-up. Symptom scores and mucosal appearance on nasal endoscopy (scored on a 1-4 scale) were evaluated at baseline and 2, 6, 12, and 52 weeks after enrollment. Sinus radiographs were reevaluated at 12 weeks. For patient-reported symptoms, the prevalence of purulent rhinitis decreased from 91% to 40% after sinus irrigation alone and from 86% to 16% after sinus irrigation plus FESS (p=0.027), while the prevalence of loss of smell decreased from 49% to 18% after sinus irrigation and from 51% to 11% after sinus irrigation plus FESS (p=0.026). Changes in other patient-reported outcomes, including snoring, nasal obstruction, headache, and dry mouth on waking, did not differ significantly between groups. Nasoendoscopy-based scores of mucosal swelling and the prevalence of middle turbinate purulence did not differ significantly between groups at any follow-up time point. The proportion of patients in each group with specific findings on sinus radiographs (complete opacity, fluid level, mucosal swelling of at least 50% of the mediolateral diameter of the maxillary sinus) or with normal sinus radiographs at 12-week follow-up did not differ significantly between groups.

A 2006 Cochrane review summarized the evidence on FESS for CRS.[22] This review was updated in 2010, with a literature search through November 2008, with no change to reviewers' conclusions. Reviewers included RCTs comparing FESS alone or FESS plus other therapies with medical treatment and/or other types of sinus surgery. Three RCTs (total n=212 patients) met reviewers' inclusion criteria, one of which was unpublished: one compared FESS plus sinus irrigation and medical treatment (antibiotics) with medical treatment alone; another compared endoscopic middle meatal antrostomy with conventional inferior meatal antrostomy; and a third compared FESS plus medical treatment (antibiotics, combination steroid and decongestant nasal spray, and nasal irrigation, followed by steroid nasal spray and saline nasal irrigation) with medical treatment alone. For the risk of bias assessment, reviewers reported: "It was unclear whether allocation concealment was carried out in any of the trials. There was no blinding applied in any of the included studies. Intention-to-treat analysis was applied in two of the studies." Two trials reported no between-group differences in symptom scores at follow-up, and the third reported no between-group differences in overall cure rates. No major complications were reported across the three studies.

Vlastarakos et al (2013) reported on results of a systematic review and meta-analysis of FESS for CRS with or without nasal polyps in children, which included any interventional studies.[23] Reviewers selected 4 prospective, 5 retrospective comparative, and 6 retrospective studies (total n=1301 treated patients); no RCTs were identified. Although reviewers concluded that FESS was associated with improvements in patients' QOL, the conclusions that can be drawn from retrospective studies are limited.

Patel et al (2017) conducted a systematic review with meta-analysis comparing appropriate medical therapy with endoscopic sinus surgery in adults who had CRS, including only moderate-

to high-quality prospective studies.[24] Six observational or before/after studies were selected; no RCTs were included. For the pooled analysis of disease-specific QOL measures, 2 studies (n=106 patients) were included. The studies used different outcome measures, the Rhinosinusitis Disability Index and SNOT-22, and were therefore pooled using the standardized mean difference. There was significant heterogeneity (p<0.001, I^2=97%) but both studies favored surgery. For the pooled analysis of endoscopic grading scores, 2 studies (n=182 patients) were combined, again with significant heterogeneity (p=0.004, I^2=88%). Mean scores in both studies favored surgery.

Systematic Reviews

Goldstein and Kennedy (2013) reported on results of a systematic review of the long-term (>1 year) outcomes after surgical therapy for sinusitis, including endoscopic sinus surgery, balloon ostial dilation, and hybrid procedures.[25] Reviewers included 56 studies, 30 of which reported on follow-up beyond 1 year. They did not report specifically on study quality or design; however, they described noncomparative studies that reported high rates of improvement in symptoms (>75%) after 1 year.

CRS with Polyposis

Surgical approaches may include a simple polypectomy (defined as the removal of polyps without intentionally entering the sinuses or enlarging the natural ostia), polypectomy with FESS (removing polyps and other causes of obstruction from the ethmoid sinuses and lateral or nasal wall), or more radical nasalization of the ethmoid sinuses. We focus on studies comparing FESS with medical therapy for the management of CRS with nasal polyps.

Randomized Controlled Trials

Two RCTs identified are relevant to the use of FESS in patients with CRS with polyposis. In the Ragab et al (2004) trial (described above), 39% of patients had nasal polyposis.[18] No significant differences were reported between FESS and medical treatment for change in subjective or objective outcome measures.

Alobid et al (2005) reported on an RCT comparing FESS with oral steroids for individuals who had nasal polyposis, with a focus on nasal symptoms, polyp size, and QOL.[26] Eligible patients had nasal polyposis, defined by the presence of both of the following: visualization of polyps under endoscopic examination and bilateral opacification of paranasal sinuses on computed tomography scan. Patients were randomized to 14 days of oral prednisone (n=52) or to FESS (n=56). All patients received 1 year of intranasal budesonide for 12 months. Symptoms were patient-reported on a 0-to-3 scale, while nasal polyp score was endoscopically assessed on a scale ranging from 0 to 3. At the 6- and 12-month follow-ups, patients in both groups reported improvements in nasal symptoms. At six months, the FESS group had greater improvements than the medical therapy group in nasal symptom scores (1.6 for FESS vs 1.2 for medical therapy, p<0.05), loss of smell scores (0.9 for FESS vs 0.5 for medical therapy, p<0.05), and polyp size score (2.3 for FESS vs 0.8 for medical therapy, p<0.05).

Systematic Reviews

Two Cochrane reviews published in 2014 addressed the use of surgical therapies for CRS with nasal polyps. Rimmer et al (2014), compared surgical interventions with medical interventions for CRS with nasal polyps.[27] Sharma et al (2014), compared the value of nasal polypectomy plus additional sinus dissection with polypectomy alone for CRS with nasal polyps.[28]

The Rimmer et al (2014) review selected RCTs comparing any surgical intervention with any medical treatments, including placebo, in adults with CRS with nasal polyps.[27] Reviewers identified 4 studies (total n=231 randomized participants), none of which was considered at low-risk of bias. In all trials, topical steroids were used in both arms, but the trials otherwise varied by comparison groups; 1 study (n=109 enrolled, 95 analyzed) compared FESS with systemic steroids, 2 studies (combined n=87) compared polypectomy with systemic steroids, and 1 study (n=35) compared FESS plus a topical steroid (usual dose) with antibiotics plus high-dose topical steroid. Across trials, there were no important differences between treatment groups in terms of patient-

reported disease severity scores, disease-specific QOL scores (e.g., SNOT-22), or overall health-related QOL scores. Two trials reported on endoscopic sinus mucosal appearance, although there is no single accepted endoscopic grading system. In the RCT (n=95 analyzed) comparing FESS with systemic steroids, polyp size scores (graded on a 0-3, point scale) were significantly better in the FESS group (mean difference, -1.5; 95% confidence interval, -1.8 to 0 -1.2; corresponds to large effect size). In the RCT (n=34) comparing FESS plus topical steroid with antibiotics plus topical steroids, polyp size was also graded on a scale from 0 to 3 but reported as a percentage improvement from baseline in each group. The percentage improvement did not differ significantly between groups (mean difference=2.3%; 95% confidence interval, -17.4% to 12.8%), but the estimate for this improvement was limited due to the small sample size. Overall, reviewers concluded: "Evidence relating to the effectiveness of different types of surgery vs medical treatment for adults with CRS with nasal polyps is of very low quality. The evidence does not show that one treatment is better than another in terms of patient-reported symptom scores and quality of life measurements."

The Sharma et al (2014) review included RCTs and quasi-RCTs comparing nasal polypectomy with surgeries that involved more extensive sinus clearance in adults with CRS with nasal polyps.[28] Reviewers identified no studies that met their inclusion criteria. Six studies were excluded after full-text review, for a variety of reasons, including the use of a "split-nose" design, lack of randomization, the use of patient populations that did not necessarily have nasal polyps or the use of surgical techniques not included in reviewers' criteria. Reviewers concluded: "We are unable to reach any conclusions as to whether isolated nasal polypectomy or more extensive sinus surgery is a superior surgical treatment modality for chronic rhinosinusitis with nasal polyps."

Other evidence-based reviews, such as those on adult CRS reported by Orlandi et al (2014),[13] on surgery for CRS with or without nasal polyps reported by Georgalas et al (2014),[29] and on CRS with nasal polyps by Schlosser and Soler (2013),[30] did not describe their search and selection criteria.

Section Summary: FESS for CRS
The evidence from RCTs comparing FESS with medical management in individuals who had CRS with or without nasal polyposis is limited. Multiple observational studies and single-arm trials, with methodologic limitations, generally have not reported clinically significant differences in symptom improvements with FESS compared with medical therapy. Controlled trials with low-risk of bias are important to determine the efficacy of FESS compared with the alternatives.

Summary of Evidence
For individuals with CRS with or without nasal polyposis who receive FESS, the evidence includes RCTs and systematic reviews. The relevant outcomes are symptoms, change in disease status, QOL, and treatment-related morbidity. A small number of trials, with methodologic limitations, generally have not reported clinically significant differences in symptom improvement with FESS compared with medical therapy. Two Cochrane reviews evaluating FESS for CRS with and without nasal polyposis have reported that FESS can be accomplished safely, but clinical trials have not demonstrated significant improvements with FESS compared with standard medical therapy. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information
Clinical Input From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests from Blue Cross Blue Shield Association, input was received from 2 specialty societies and 3 academic medical centers (4 responses), for a total of 6 responses in 2016. Input was consistent that the use of functional endoscopic sinus surgery is medically necessary for the treatment of chronic rhinosinusitis (CRS). Opinions about specific criteria for the diagnosis of CRS differed, although most reviewers provided some for diagnosis of CRS and failure of medical management.

Practice Guidelines and Position Statements

The American Academy of Otolaryngology-Head and Neck Surgery (2015) updated its clinical practice guidelines on the management of sinusitis in adults, which recommended the following on the diagnosis and treatment of CRS (see Table 3).[11,]

Table 3. Guidelines on Management of CRS in Adults

Guideline	Type of Recommendation	Aggregate Evidence Quality	Confidence in Evidence
The clinician should confirm a clinical diagnosis of CRS with objective documentation of sinonasal inflammation, which may be accomplished using anterior rhinoscopy, nasal endoscopy, or computed tomography.	Strong recommendation	B (cross-sectional studies)	Medium
Clinicians should assess the patient with chronic rhinosinusitis or recurrent acute rhinosinusitis for multiple chronic conditions that would modify management such as asthma, cystic fibrosis, immunocompromised state, and ciliary dyskinesia.	Recommendation	B (1 systematic review, multiple observational studies)	Medium
The clinician may obtain testing for allergy and immune function in evaluating a patient with chronic rhinosinusitis or recurrent acute rhinosinusitis.	Option	C (systematic review of observational studies)	Medium
The clinician should confirm the presence or absence of nasal polyps in a patient with CRS.	Recommendation	A (systematic review of RCTs)	Medium
Clinicians should recommend saline nasal irrigation, topical intranasal corticosteroids, or both for symptom relief of CRS.	Recommendation	A (systematic reviews of RCTs)	High
Clinicians should not prescribe topical or systemic antifungal therapy for patients with CRS.	Recommendation (against therapy)	A (systematic reviews of RCTs)	High

CRS: chronic rhinosinusitis; RCT: randomized controlled trial.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in January 2019 did not identify any ongoing or unpublished trials that would likely influence this review.

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Documentation for Clinical Review

Please provide the following documentation (if/when requested):

- History and physical and/or consultation notes including:
  - Clinical findings (i.e., pertinent symptoms and duration)
  - Comorbidities
  - Activity and functional limitations
  - Family history if applicable
- Reason for procedure/test/device, when applicable
- Pertinent past procedural and surgical history
- Past and present diagnostic testing and results
- Prior conservative treatments, duration, and response
- Treatment plan (i.e., surgical intervention)
- Consultation and medical clearance report(s), when applicable
- Radiology report(s) and interpretation (i.e., MRI, CT, discogram)
- Laboratory results
- Other pertinent multidisciplinary notes/reports: (e.g., psychological or psychiatric evaluation, physical therapy, multidisciplinary pain management) when applicable

Post Service

- Results/reports of tests performed
- Procedure report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

MN/IE

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or

when the code describes application of a product in the position statement that is investigational.

Type	Code	Description
CPT®	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
	31253	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including frontal sinus exploration, with removal of tissue from frontal sinus, when performed
	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 maxillary antrostomy
	31257	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including sphenoidotomy
	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
	31294	Nasal/sinus endoscopy, surgical; with optic nerve decompression
	31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (e.g., balloon dilation), transnasal or via canine fossa
	31296	Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (e.g., balloon dilation)
	31297	Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (e.g., balloon dilation)
	31298	Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (e.g., balloon dilation)

Type	Code	Description
HCPCS	None	
ICD-10 Procedure	095P4ZZ	Destruction of Accessory Sinus, Percutaneous Endoscopic Approach
	095Q4ZZ	Destruction of Right Maxillary Sinus, Percutaneous Endoscopic Approach
	095R4ZZ	Destruction of Left Maxillary Sinus, Percutaneous Endoscopic Approach
	095S4ZZ	Destruction of Right Frontal Sinus, Percutaneous Endoscopic Approach
	095T4ZZ	Destruction of Left Frontal Sinus, Percutaneous Endoscopic Approach
	095U4ZZ	Destruction of Right Ethmoid Sinus, Percutaneous Endoscopic Approach
	095V4ZZ	Destruction of Left Ethmoid Sinus, Percutaneous Endoscopic Approach
	095W4ZZ	Destruction of Right Sphenoid Sinus, Percutaneous Endoscopic Approach
	095X4ZZ	Destruction of Left Sphenoid Sinus, Percutaneous Endoscopic Approach
	099P40Z	Drainage of Accessory Sinus with Drainage Device, Percutaneous Endoscopic Approach
	099P4ZZ	Drainage of Accessory Sinus, Percutaneous Endoscopic Approach
	099Q40Z	Drainage of Right Maxillary Sinus with Drainage Device, Percutaneous Endoscopic Approach
	099Q4ZZ	Drainage of Right Maxillary Sinus, Percutaneous Endoscopic Approach
	099R40Z	Drainage of Left Maxillary Sinus with Drainage Device, Percutaneous Endoscopic Approach
	099R4ZZ	Drainage of Left Maxillary Sinus, Percutaneous Endoscopic Approach
	099S40Z	Drainage of Right Frontal Sinus with Drainage Device, Percutaneous Endoscopic Approach
	099S4ZZ	Drainage of Right Frontal Sinus, Percutaneous Endoscopic Approach
	099T40Z	Drainage of Left Frontal Sinus with Drainage Device, Percutaneous Endoscopic Approach
	099T4ZZ	Drainage of Left Frontal Sinus, Percutaneous Endoscopic Approach
	099U40Z	Drainage of Right Ethmoid Sinus with Drainage Device, Percutaneous Endoscopic Approach
	099U4ZZ	Drainage of Right Ethmoid Sinus, Percutaneous Endoscopic Approach
	099V40Z	Drainage of Left Ethmoid Sinus with Drainage Device, Percutaneous Endoscopic Approach
	099V4ZZ	Drainage of Left Ethmoid Sinus, Percutaneous Endoscopic Approach
	099W40Z	Drainage of Right Sphenoid Sinus with Drainage Device, Percutaneous Endoscopic Approach
	099W4ZZ	Drainage of Right Sphenoid Sinus, Percutaneous Endoscopic Approach
	099X40Z	Drainage of Left Sphenoid Sinus with Drainage Device, Percutaneous Endoscopic Approach
	099X4ZZ	Drainage of Left Sphenoid Sinus, Percutaneous Endoscopic Approach
	09BP4ZZ	Excision of Accessory Sinus, Percutaneous Endoscopic Approach
	09BQ4ZZ	Excision of Right Maxillary Sinus, Percutaneous Endoscopic Approach
	09BR4ZZ	Excision of Left Maxillary Sinus, Percutaneous Endoscopic Approach
	09BS4ZZ	Excision of Right Frontal Sinus, Percutaneous Endoscopic Approach
	09BT4ZZ	Excision of Left Frontal Sinus, Percutaneous Endoscopic Approach

Type	Code	Description
	09BU4ZZ	Excision of Right Ethmoid Sinus, Percutaneous Endoscopic Approach
	09BV4ZZ	Excision of Left Ethmoid Sinus, Percutaneous Endoscopic Approach
	09BW4ZZ	Excision of Right Sphenoid Sinus, Percutaneous Endoscopic Approach
	09BX4ZZ	Excision of Left Sphenoid Sinus, Percutaneous Endoscopic Approach
	09TP4ZZ	Resection of Accessory Sinus, Percutaneous Endoscopic Approach
	09TQ4ZZ	Resection of Right Maxillary Sinus, Percutaneous Endoscopic Approach
	09TR4ZZ	Resection of Left Maxillary Sinus, Percutaneous Endoscopic Approach
	09TS4ZZ	Resection of Right Frontal Sinus, Percutaneous Endoscopic Approach
	09TT4ZZ	Resection of Left Frontal Sinus, Percutaneous Endoscopic Approach
	09TU4ZZ	Resection of Right Ethmoid Sinus, Percutaneous Endoscopic Approach
	09TV4ZZ	Resection of Left Ethmoid Sinus, Percutaneous Endoscopic Approach
	09TW4ZZ	Resection of Right Sphenoid Sinus, Percutaneous Endoscopic Approach
	09TX4ZZ	Resection of Left Sphenoid Sinus, Percutaneous Endoscopic Approach

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
12/01/2016	BCBSA Medical Policy adoption	Medical Policy Committee
04/01/2017	Policy revision without position change	Medical Policy Committee
01/01/2018	Coding update	Administrative Review
04/01/2018	Policy revision without position change	Medical Policy Committee
04/01/2019	Policy revision without position change Coding Update	Medical Policy Committee

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.