7.01.155	Functional Endoscopic Sinus Surgery for Chronic Rhinosinusitis		
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Section:	7.0 Surgery	**Page:**	Page 1 of 21

Policy Statement

I. The use of functional endoscopic sinus surgery may be considered **medically necessary** for individuals with chronic rhinosinusitis when **all** of the following criteria are present:
   A. Chronic rhinosinusitis that negatively impacts quality of life, characterized by at least 2 of the following, at least 1 of which is (a) or (b), present for at least 12 continuous weeks:
      1. Mucopurulent nasal drainage (anterior, posterior, or both);
      2. Nasal obstruction (congestion)
      3. Facial pain-pressure-fullness
      4. Decreased sense of smell
   B. Optimal medical therapy has been attempted and failed, , in the past 12 weeks for the current episode of illness as indicated by **all** of the following:
      1. Allergy evaluation, education, and optimal treatment when indicated
      2. Two 10-day courses of antibiotics or 1 prolonged course of oral antibiotic for at least 21 days
      3. Decongestants when indicated
      4. Topical and/or systemic corticosteroids for at least 8 weeks
      5. Saline nasal irrigations for at least 8 consecutive weeks
      6. Treatment of rhinitis medicamentosa (rebound nasal congestion due to extended use of topical decongestants), when present
      7. Education on environmental irritants including tobacco smoke
   C. Clinical and radiographic documentation of persistent inflammation following optimal medical therapy (see Policy Guidelines)
   D. 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

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Inflammation may be documented by all of the following:

- Nasal endoscopy showing purulent (not clear) mucus or edema in the middle meatus, anterior ethmoid, or sphenoethmoid region.
- Abnormal CT scan of the paranasal sinuses.

According to the 2015 American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) guideline on adult sinusitis, abnormal findings on CT imaging may include moderate-to-severe mucosal thickening, opacification, or air-fluid levels. A subsequent consensus statement on balloon dilation of the sinuses published by the AAO-HNS in 2018 states: "The requirement of objective evidence of inflammation in addition to sinonasal symptoms suggestive of rhinosinusitis is consistent with AAO-HNSF diagnostic criteria for rhinosinusitis. However, evidence of inflammation or other findings on a CT scan was not deemed sufficient alone to make a patient a candidate for balloon dilation. The consensus that both symptoms and objective evidence of sinonasal disease are needed to deem a patient appropriate for a SOD [sinus ostial dilation] procedure is also reflected in many of the randomized clinical trials involving balloon dilation. The inclusion criteria for many of these trials require that the patient be deemed appropriate for conventional sinus surgery, which includes a trial of medical therapy and the presence of sinonasal symptoms in addition to objective evidence of

sinus mucosal inflammation. On the surface, this statement may seem incompatible with the guidelines that mandate the presence of objective findings but do not specify which objective findings those are (i.e., polyps, purulence, or CT findings) for the diagnosis of CRS. However, the panel felt that the transition from diagnosis to management requires additional information. In that vein, a CT scan is necessary before proceeding with surgical management, and the findings of that CT scan would direct which sinuses were to be addressed. It was also agreed that an improved taxonomy for the classification of sinusitis would be helpful to improve the quality of clinical research."

Coding
See the Codes table for details.

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.

Summary of Evidence
For individuals with uncomplicated chronic rhinosinusitis (CRS) with or without nasal polyposis who receive functional endoscopic sinus surgery (FESS), the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, change in disease status, quality of life, 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. 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 that the technology results in an improvement in the net health outcome.

For individuals with uncomplicated CRS refractory to medical therapy who receive FESS, the evidence includes an RCT, a systematic review of non-randomized comparative studies, and additional non-randomized studies published since the systematic review. Relevant outcomes are symptoms, functional outcomes, change in disease status, quality of life, and treatment-related morbidity. One RCT was identified in patients who have failed therapy with nasal irrigation and corticosteroids. This RCT found that FESS was not superior to maximal medical therapy that includes antibiotics along with nasal irrigation and topical or systemic corticosteroids. Although no RCTs have been identified that evaluated FESS in patients with CRS who failed a regimen that included antibiotic therapy, a systematic review of non-randomized comparative cohorts and pre-post studies is available. This meta-analysis suggests that in patients who have failed maximal medical therapy (nasal irrigation, corticosteroids, and antibiotics), FESS can improve symptoms compared to continued medical management. Patients most likely to select and benefit from FESS are those with lower disease-specific quality of life. Multiple additional non-randomized studies further support improvements in quality of life and functional outcomes after FESS in this setting. Surgical treatment of CRS with FESS may thus be appropriate for individuals who meet diagnostic criteria for CRS and have failed maximal medical management. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information
Not applicable.

Related Policies

- Balloon Dilation of the Eustachian Tube

- Balloon Ostial Dilation for Treatment of Chronic and Recurrent Acute Rhinosinusitis
- Steroid-Eluting Sinus Stents and Implants

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

Functional endoscopic sinus surgery is a surgical procedure and, as such, is not subject to regulation by the FDA.

Rationale

Background

Chronic Rhinosinusitis

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.

Chronic rhinosinusitis is associated with impaired quality of life 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,]

Medical Therapy

Medical therapy for CRS, with or without polyps, is often multimodal, including nasal irrigation, topical and/or systemic corticosteroids, monoclonal antibodies, and/or antibiotic therapy.[6,] Guidelines from the American Academy of Otolaryngology-Head and Neck Surgery (2015; affirmed in 2020 by the American Academy of Family Physicians) 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).[7,8,] There is a specific recommendation against the use of topical and systemic 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 symptom scores. There was some evidence that 2 systemic therapies (oral corticosteroids, doxycycline), both for 3 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 quality of life 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.[9,] 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 non-macrolide oral antibiotics.

A 2016 Cochrane review of studies evaluating systemic and topical antibiotics for CRS included 5 RCTs (N=293), all of which compared systemic antibiotics with placebo or another pharmacological intervention.[10,] Reviewers found "very little evidence that systemic antibiotics are effective in patients with chronic rhinosinusitis" and that "more research in this area, particularly evaluating longer-term outcomes and adverse effects, is required."

In 2019, the U.S. Food and Drug Administration (FDA) approved the first treatment for CRS with nasal polyps - dupilumab (Dupixent®). Results from clinical trials revealed that patients who received dupilumab "had statistically significant reductions in their nasal polyp size and nasal congestion compared to the placebo group" and also "reported an increased ability to smell and required less nasal polyp surgery and oral steroids."[11,] This was followed by the approval of omalizumab (Xolair®) in 2020 as add-on maintenance treatment for adults with nasal polyps with an inadequate response to nasal corticosteroids.[12,] In 2021, mepolizumab (Nucala®) was also approved as an add-on maintenance treatment in adults with CRS with nasal polyps.[13,]

Surgery

The goals of surgery for CRS include removing polyps and debris that may be sources of inflammatory mediators and preventing 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. Functional endoscopic sinus surgery 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). Functional endoscopic sinus surgery 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 (Table 1).

Table 1. 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.

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

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, 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, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 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. Randomized controlled trials 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Functional Endoscopic Sinus Surgery for Uncomplicated Chronic Rhinosinusitis Eligible for Medical Therapy

Clinical Context and Test Purpose

The purpose of functional endoscopic sinus surgery (FESS) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as medical management, in individuals with uncomplicated chronic rhinosinusitis (CRS) with or without nasal polyposis.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with uncomplicated CRS with or without nasal polyposis eligible for medical therapy.

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

To quantify the severity of CRS, various measures can be used, including patient-reported quality of life 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.[14,15,] Several disease-specific patient-reported quality of life 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.[16,17,] The Questionnaire of Olfactory Dysfunction (QOD) is a validated, olfactory-specific survey that summarizes Likert scale responses from 0 ("Disagree") to 3 ("Agree"), where higher total scores (range: 0 to 51) represent higher global impacts of olfactory impairment. Additionally, quality of life may be reported based on overall health-related quality of life 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).

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 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 12 months of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- 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.

Review of Evidence

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.

Chronic Rhinosinusitis With or Without Polyposis

Systematic Reviews

A 2006 Cochrane review summarized the evidence on FESS for CRS.[18,] 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 (N=212) met reviewers' inclusion criteria, 1 of which was unpublished: 1 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 2 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 3 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.[19,] Reviewers selected 4 prospective, 5 retrospective comparative, and 6 retrospective studies (N=1301); no RCTs were identified. Although reviewers concluded that FESS was associated with improvements in patients' quality of life, the conclusions that can be drawn from retrospective studies are limited.

Randomized Controlled Trial

One RCT from 1997 compared FESS plus sinus irrigation to sinus irrigation alone in patients with CRS, not limited to patients with polyposis.[20,] Patients were randomized to sinus irrigation, with a second irrigation a week after the first if needed, or to FESS within 3 days of enrollment. Randomization techniques were not described. The trial enrolled 89 patients (45 in each group), with 77 patients included in the data analysis. A major limitation of this trial is that a single sinus irrigation is not the current standard of medical therapy.

Symptom scores and mucosal appearance on nasal endoscopy (scored on a 1 to 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=.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=.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.

Chronic Rhinosinusitis 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.

Systematic Review

A Cochrane review by Rimmer et al (2014), compared surgical interventions with medical interventions for CRS with nasal polyps.[21,] Reviewers identified 4 studies (N=231), 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, n=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 quality of life scores (e.g., SNOT-22), or overall health-related quality of life 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 to 3 point scale) were significantly better in the FESS group (mean difference, -1.5; 95% confidence interval [CI], -1.8 to -1.2; corresponds to large effect size). In the RCT (n=34) comparing FESS plus topical steroid to antibiotics plus topical steroids, the percentage improvement in polyp size did not differ significantly between groups, but the estimate was limited due to the small sample size. Overall, reviewers concluded: "Evidence relating to the effectiveness of different types of surgery versus medical treatment for adults with CRS with nasal polyps is of very low quality. The evidence does not show that 1 treatment is better than another in terms of patient-reported symptom scores and quality of life measurements."

Randomized Controlled Trial

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 quality of life.[22,] 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 6 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, $p<.05$), loss of smell scores (0.9 for FESS vs. 0.5 for medical therapy, $p<.05$), and polyp size score (2.3 for FESS vs. 0.8 for medical therapy, $p<.05$).

Section Summary: Functional Endoscopic Sinus Surgery for Uncomplicated Chronic or Acute Recurrent Rhinosinusitis Eligible for Medical Therapy

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 maximal medical therapy.

Functional Endoscopic Sinus Surgery for Uncomplicated Chronic Rhinosinusitis Refractory to Medical Therapy

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 individuals with uncomplicated CRS refractory to medical therapy.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with uncomplicated CRS refractory to maximal medical therapy.

Interventions
The therapy being considered is FESS.

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

Outcomes
The general outcomes of interest are symptoms, change in disease status, quality of life, and treatment-related morbidity. Subjective scales are the SNOT-20 or SNOT-22, SF-36, QOD, visual analog scale (VAS), and "sniffin' stick pens", that evaluate odorant threshold, discrimination, and identification (TDI).

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 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 12 months of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- 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.

Review of Evidence
Systematic Reviews
Patel et al (2017) conducted a systematic review of cohort and crossover studies to compare appropriate medical therapy with endoscopic sinus surgery in adults with CRS who had undergone at least 3 weeks of antibiotics, with or without corticosteroids (Table 2).[23,] Six observational or crossover studies were selected; no RCTs were available for analysis. Included in the meta-analysis were studies by Smith et al (2011, n=130), Smith et al (2014, n=31), and Luk et al (2015, n=212). In Smith et al (2011) patients self-selected continued medical therapy (n=55) or surgical therapy (n=75). Smith et al (2014) was a crossover study of patients who failed medical therapy. Luk et al (2015) included 40 patients in their medical cohort and 152 patients in their surgical cohort.

For the pooled analysis of disease-specific quality of life measures, the 2 studies by Smith et al (2011, 2014; n=180 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 ($p<.001$, $I^2=97\%$), but both studies favored surgery. For the pooled analysis of endoscopic grading scores, 2 studies by Smith et al and Luk et al (n=241 patients) were

combined, again with significant heterogeneity (p=.004, I^2=88%). Mean scores in both studies favored surgery. For missed days of work, there was no significant difference between the medical therapy and surgical groups (the same 3 studies). Other studies assessed olfaction, health utility quality of life, and economic impact. No studies evaluated adverse events. A limitation of the cohort studies included in this systematic review is the lack of comparable groups; patients who selected surgery had a lower disease-specific quality of life at baseline.

Table 2. Systematic Review and Meta-analyses Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Patel et al (2017)[23,]	2005-2016	6	Patients with CRS who had undergone ≥3 weeks of antibiotics, with or without corticosteroids, and received continued medical therapy or surgery	(31 to 280)	Analysis of prospective cohorts and crossover studies that compared surgery to continued medical therapy. Meta-analysis was conducted on 3 studies.	6- to 12-month follow-up

CRS: chronic rhinosinusitis.

Other systematic reviews with meta-analyses have summarized pre- and post data from cohort studies, finding improvements in sleep quality[24,], fatigue[25,], and SNOT-22 outcomes[17,] following FESS. However, these systematic reviews did not describe whether patients included in the primary studies had failed maximal medical therapy, limiting their interpretation. Criteria for "maximal medical therapy" used before endoscopic sinus surgery is attempted have been reported in a minority (21%) of published studies of FESS.[6,] 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) systemic corticosteroids (61% mean duration 18 days), saline irrigations (39%), oral antihistamines (11%), oral mucolytics (10%), and topical/oral decongestants (10%)

Randomized Controlled Trial

Ragab et al (2004) reported on the results of an RCT comparing medical management to FESS in 90 patients who had CRS, with or without nasal polyposis, who had failed initial medical management (6-week regimen of a corticosteroid spray and an alkaline nasal douche).[26,] 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. Patients who had persistent symptoms and changes in computed tomography scan following initial medical therapy were randomized to a FESS group, which received FESS performed by 1 of 2 surgeons, or to a medical therapy group, which received a 12-week course of oral erythromycin, alkaline nasal douche, and topical nasal corticosteroids.

Both patient-reported (SNOT-20, SF-36, and VAS) 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, with no significant between-group differences. For example, the percent change in VAS score at 6 months was 49.7% in the FESS group compared with 45.3% in the medical therapy group (p>.05). There were no significant differences between the 2 groups in the change in SNOT-20 or SF-36 scores or 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<.01).

A second report (Ragab et al [2006]) assessed asthma-related outcomes in the subgroup of 45 patients with asthma,[27,] and a third (Ragab et al [2010]) detailed the quality of life measurement outcomes in this study.[28,]

Non-Randomized Comparative Study

A National Institutes of Health-funded multicenter study by Mattos et al (2021) evaluated improvements in olfactory function in patients undergoing FESS after failed medical therapy.[29,] Pre- and postoperative scores of 113 patients from "sniffin' stick pens" were compared with 164 non-affected volunteers of similar age and gender. Secondary outcomes included the QOD and olfactory cleft endoscopy scores. TDI scores pre-operatively were 6.8 (95% CI, 4.9 to 8.7) points lower than controls. There was an improvement of 3.7 (95% CI, 2.2 to 5.2) points postoperatively, with post-operative TDI scores of 25.7 (8.6 standard deviation) compared to 28.8 (7.0 standard deviation) in controls. Secondary outcomes showed similar improvements, and about half of patients had post-operative scores that were at least as good as the controls. Multivariate regression found decreased odds of improvement in patients with nasal polyposis and previous FESS, while septoplasty increased the odds of improvement.

Non-Randomized Observational Studies

A single-center prospective cohort study by Verma et al (2022) evaluated pre- and postoperative quality of life measures in patients undergoing FESS following failure of medical treatment for CRS (oral and topical corticosteroids for at least 3 months), including VAS scoring of symptom intensity (nasal obstruction and discharge, sneezing, facial pain/pressure) and SNOT-22.[30,] Among 40 patients enrolled, mean total SNOT-22 score at baseline was 46.25 ± 20.44; at 3- and 6-month follow-up post-FESS, mean total SNOT-22 scores were 14.5 ± 4.90 and 22.38 ± 7.93, respectively (p<.0001 for each compared to baseline). Significant improvements from baseline were noted in 15 of 22 SNOT-22 items at 6-month follow-up; items without significant improvement included cough (p=1.0), post-nasal discharge (p=.13), dizziness (p=.063), facial pain/pressure (p=.13), decreased sense of smell/taste (p=.94), fatigue (p=.10), and feeling embarrassed (p=.08). At 6-month follow-up, significant improvements were noted in VAS scores for all queried symptoms compared to baseline (p<.001 for each).

As part of a multicenter, multicohort prospective observational study, Miglani et al (2022) sought to indirectly compare outcomes associated with FESS to those of monoclonal antibodies recently approved for management of CRS.[31,] Investigators enrolled a cohort of patients undergoing FESS for CRS with nasal polyposis refractory to daily saline irrigation, at least 1 course of topical (at least 3 weeks) or oral corticosteroids (at least 5 days), and at least 1 course (at least 2 weeks) of antibiotics. Quality of life outcomes were evaluated at preoperative baseline and at 24 and 52 weeks postoperatively, including total SNOT-22 score and nasal congestion subscale score, and were compared to historical control data derived from phase 3 clinical trials for dupilumab, omalizumab, and mepolizumab employing similar inclusion criteria, outcomes, and assessment timelines. Notably, among 111 patients enrolled, 59% had undergone previous FESS; this proportion was similar to those in the historical monoclonal antibody clinical trial cohorts, with the exception of the phase 3 trial of mepolizumab, which required patients to have CRS refractory to prior surgical intervention. At 24 weeks and 52 weeks following FESS, mean total SNOT-22 scores were reduced by 33.0 ± 18.7 points and 33.9 ± 21.1 points, respectively, representing mean improvements from baseline of approximately 59% at both timepoints. Mean nasal congestion subscale scores were reduced from baseline by 1.9 ± 0.9 points and 1.2 ± 0.16 points at 24 weeks and 52 weeks following FESS, respectfully, representing mean improvements from baseline of approximately 66% and 59%. Trials with 24-week outcome assessments included 2 dupilumab clinical trials and 2 omalizumab clinical trials; compared to these historical cohorts, patients undergoing FESS experienced significantly greater improvement in total SNOT-22 score at 24 weeks than patients in 1 dupilumab trial (p<.05) and both omalizumab trials

(p<.001 for each), similar improvement in total SNOT-22 score at 24 weeks to patients in the other dupilumab trial (p=.225), and significantly greater improvement in nasal congestion subscale score at 24 weeks than patients in all 4 trials (p<.05 for each). Trials with 52-week outcome assessments included 1 dupilumab trial and 1 mepolizumab trial; compared to these historical cohorts, patients undergoing FESS experienced similar improvement in total SNOT-22 score at 52 weeks to those in clinical trials for dupilumab (p=.105) and mepolizumab (p=.244), but significantly greater improvements in nasal congestion subscale scores than patients in both trials (p<.001 for each).
In another study by this group, Pandrangi et al (2022) described Work Productivity and Activity Impairment-Specific Health Problem (WPAI-SHP) survey-derived outcomes in patients undergoing FESS for refractory CRS with or without nasal polyposis.[32,] Outcomes evaluated in the survey included work absenteeism due to CRS (as percentage of work hours missed due to CRS over total anticipated work hours in preceding 7 days) and the impact of CRS symptoms on work productivity and on daily non-work activities (as integer responses ranging from 0 to 10, with 10 indicating complete prevention of work or performing daily activities due to CRS, converted to percentages) at preoperative baseline and approximately 6 months postoperatively. Among 176 patients enrolled who completed follow-up surveys, at approximately 6 months postoperatively, significant improvements from baseline were noted in work absenteeism (mean reduction 6.8% ± 2.0%, p<.001), work productivity impairment (mean reduction 20.0% ± 2.9%, p<.001), and non-work activity impairment (mean reduction 20.5% ± 2.1%, p<.001). Minimal clinically important differences, defined as improvement by at least half of the standard deviation of the preoperative mean work productivity and non-work activity impairment scores at the time of the 6-month follow-up survey, were reported for work productivity in 48.1% of the 106 patients employed during the follow-up period and 53.4% of patients for non-work activity impairment.

In a prospective observational cohort study by Hintschich et al (2022), SNOT-20 and TDI were assessed preoperatively and 4 months postoperatively in patients undergoing FESS for refractory CRS with nasal polyposis.[33,] Among 88 patients enrolled, 41% had previously undergone FESS. At 4-month postoperative follow-up, mean improvement from baseline in total SNOT-20 score was 18.4 ± 15.5 points (p<.001), with 59% of patients experiencing a minimum clinically important improvement of 16 points and no patients experiencing deterioration from baseline. In the analysis of "sniffin' stick pens" olfaction testing, mean TDI score improved from 17.3 ± 10.1 points preoperatively to 22.7 ± 8.5 points 4 months postoperatively, with 44% experiencing a minimum clinically important improvement of 5.5 points and 7% experiencing a minimum clinically important deterioration.

Section Summary: Functional Endoscopic Sinus Surgery for Uncomplicated Chronic or Acute Recurrent Rhinosinusitis Refractory to Medical Therapy

One RCT was identified in patients who have failed therapy with nasal irrigation and corticosteroids. This RCT found that FESS was not superior to maximal medical therapy that includes antibiotics along with nasal irrigation and topical or systemic corticosteroids. No RCTs have been identified that evaluated FESS in patients with CRS who failed this regimen. One systematic review of patients who had failed a treatment regimen that included antibiotic therapy identified non-randomized comparative cohorts and pre-post studies. These and other non-randomized studies published since the RCT and systematic review indicate that in patients who have failed maximal medical therapy (nasal irrigation, corticosteroids, and antibiotics), FESS can improve symptoms compared to continued medical therapy. Patients most likely to select and benefit from FESS are those with lower disease-specific quality of life.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US

representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Guidelines on the diagnosis and management of CRS are described in Tables 3 through 5.

Table 3. Chronic Rhinosinusitis Diagnostic Criteria

Organization	Chronic Rhinosinusitis Definition
International Consensus Statement on Rhinology and Allergy: Rhinosinusitis (2021)[34,]	"Greater than or equal to 12 weeks of: Two or more of the following symptoms: • Nasal discharge (rhinorrhea or post-nasal drip) • Nasal obstruction or congestion • Hyposmia • Facial pressure or pain • Cough AND One or more of the following objective findings: • Evidence of inflammation on nasal endoscopy or computed tomography • Evidence of purulence coming from paranasal sinuses or ostiomeatal complex AND CRS is divided into CRSsNP or CRSwNP based on the presence or absence of nasal polyps"
American Academy of Otolaryngology – Head and Neck Surgery Foundation (2015)[7,8,]	"Twelve weeks or longer of 2 or more of the following signs and symptoms: • Mucopurulent drainage (anterior, posterior, or both), • Nasal obstruction (congestion) • Facial pain-pressure-fullness, or • Decreased sense of smell. AND inflammation is documented by 1 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.

Table 4. American Academy of Otolaryngology-Head and Neck Surgery 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

Guideline	Type of Recommendation	Aggregate Evidence Quality	Confidence in Evidence
"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

* Adapted from Rosenfeld et al (2015)[8,]
CRS: chronic rhinosinusitis; RCT: randomized controlled trial.

Table 5. Joint Task Force on Practice Parameters Guidelines for the Medical Management of CRS with Nasal Polyposis*

Recommendation	Strength of Recommendation	Certainty of Evidence
Treatment with INCS is suggested (rather than no INCS) in people with CRSwNP	Conditional	Low
Treatment with biologics is suggested (rather than no biologics) in people with CRSwNP	Conditional	Moderate
Treatment with ATAD is suggested (rather than no ATAD) in people with AERD	Conditional	Moderate

*Adapted from Rank et al (2023)[35,]
AERD: aspirin (or nonsteroidal anti-inflammatory drug)-exacerbated respiratory disease; ATAD: aspirin therapy after desensitization; CRSwNP: chronic rhinosinusitis with nasal polyposis; INCS: intranasal corticosteroids.

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 currently unpublished trial that might influence this review is listed in Table 6.

Table 6. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05598814	Optimisation of Treatment in Patients with CRSwNP. An RCT of Mepolizumab and Surgical Treatment With FESS and Mepolizumab Versus Only Mepolizumab Over a 6- and 12-month Follow-up	52	Aug 2025

References

1. Rudmik L, Soler ZM. Medical Therapies for Adult Chronic Sinusitis: A Systematic Review. JAMA. Sep 01 2015; 314(9): 926-39. PMID 26325561
2. Finegold SM, Flynn MJ, Rose FV, et al. Bacteriologic findings associated with chronic bacterial maxillary sinusitis in adults. Clin Infect Dis. Aug 15 2002; 35(4): 428-33. PMID 12145727

3. Brook I. Bacteriology of chronic maxillary sinusitis in adults. Ann Otol Rhinol Laryngol. Jun 1989; 98(6): 426-8. PMID 2729825
4. Aurora R, Chatterjee D, Hentzleman J, et al. Contrasting the microbiomes from healthy volunteers and patients with chronic rhinosinusitis. JAMA Otolaryngol Head Neck Surg. Dec 2013; 139(12): 1328-38. PMID 24177790
5. Singhal D, Psaltis AJ, Foreman A, et al. The impact of biofilms on outcomes after endoscopic sinus surgery. Am J Rhinol Allergy. 2010; 24(3): 169-74. PMID 20537281
6. Dautremont JF, Rudmik L. When are we operating for chronic rhinosinusitis? A systematic review of maximal medical therapy protocols prior to endoscopic sinus surgery. Int Forum Allergy Rhinol. Dec 2015; 5(12): 1095-103. PMID 26201538
7. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (update): Adult Sinusitis Executive Summary. Otolaryngol Head Neck Surg. Apr 2015; 152(4): 598-609. PMID 25833927
8. 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
9. Orlandi RR, Smith TL, Marple BF, et al. Update on evidence-based reviews with recommendations in adult chronic rhinosinusitis. Int Forum Allergy Rhinol. Jul 2014; 4 Suppl 1: S1-S15. PMID 24889751
10. Head K, Chong LY, Piromchai P, et al. Systemic and topical antibiotics for chronic rhinosinusitis. Cochrane Database Syst Rev. Apr 26 2016; 4(4): CD011994. PMID 27113482
11. Food and Drug Administration. FDA approves first treatment for chronic rhinosinusitis with nasal polyps. June 26, 2019. https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-chronic-rhinosinusitis-nasal-polyps. Accessed January 3, 2025.
12. Xolair prescribing information. South San Francisco, CA: Genentech, Inc.; 2023. https://www.gene.com/download/pdf/xolair_prescribing.pdf. Accessed January 3, 2025
13. Nucala prescribing information. Research Triangle Park, NC: GlaxoSmithKline; 2023. https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Nucala/pdf/NUCALA-PI-PIL-IFU-COMBINED.PDF. Accessed January 3, 2025.
14. Hopkins C, Browne JP, Slack R, et al. The Lund-Mackay staging system for chronic rhinosinusitis: how is it used and what does it predict?. Otolaryngol Head Neck Surg. Oct 2007; 137(4): 555-61. PMID 17903570
15. Lund VJ, Kennedy DW. Staging for rhinosinusitis. Otolaryngol Head Neck Surg. Sep 1997; 117(3 Pt 2): S35-40. PMID 9334786
16. Hopkins C, Gillett S, Slack R, et al. Psychometric validity of the 22-item Sinonasal Outcome Test. Clin Otolaryngol. Oct 2009; 34(5): 447-54. PMID 19793277
17. Soler ZM, Jones R, Le P, et al. Sino-Nasal outcome test-22 outcomes after sinus surgery: A systematic review and meta-analysis. Laryngoscope. Mar 2018; 128(3): 581-592. PMID 29164622
18. Khalil HS, Nunez DA. Functional endoscopic sinus surgery for chronic rhinosinusitis. Cochrane Database Syst Rev. Jul 19 2006; (3): CD004458. PMID 16856048
19. Vlastarakos PV, Fetta M, Segas JV, et al. Functional endoscopic sinus surgery improves sinus-related symptoms and quality of life in children with chronic rhinosinusitis: a systematic analysis and meta-analysis of published interventional studies. Clin Pediatr (Phila). Dec 2013; 52(12): 1091-7. PMID 24146231
20. Hartog B, van Benthem PP, Prins LC, et al. Efficacy of sinus irrigation versus sinus irrigation followed by functional endoscopic sinus surgery. Ann Otol Rhinol Laryngol. Sep 1997; 106(9): 759-66. PMID 9302908
21. Rimmer J, Fokkens W, Chong LY, et al. Surgical versus medical interventions for chronic rhinosinusitis with nasal polyps. Cochrane Database Syst Rev. 2014; 2014(12): CD006991. PMID 25437000
22. Alobid I, Benítez P, Bernal-Sprekelsen M, et al. Nasal polyposis and its impact on quality of life: comparison between the effects of medical and surgical treatments. Allergy. Apr 2005; 60(4): 452-8. PMID 15727575

23. Patel ZM, Thamboo A, Rudmik L, et al. Surgical therapy vs continued medical therapy for medically refractory chronic rhinosinusitis: a systematic review and meta-analysis. Int Forum Allergy Rhinol. Feb 2017; 7(2): 119-127. PMID 27863163
24. Sukato DC, Abramowitz JM, Boruk M, et al. Endoscopic Sinus Surgery Improves Sleep Quality in Chronic Rhinosinusitis: A Systematic Review and Meta-analysis. Otolaryngol Head Neck Surg. Feb 2018; 158(2): 249-256. PMID 29065273
25. Chester AC, Sindwani R, Smith TL, et al. Fatigue improvement following endoscopic sinus surgery: a systematic review and meta-analysis. Laryngoscope. Apr 2008; 118(4): 730-9. PMID 18216743
26. Ragab SM, Lund VJ, Scadding G. Evaluation of the medical and surgical treatment of chronic rhinosinusitis: a prospective, randomised, controlled trial. Laryngoscope. May 2004; 114(5): 923-30. PMID 15126758
27. Ragab S, Scadding GK, Lund VJ, et al. Treatment of chronic rhinosinusitis and its effects on asthma. Eur Respir J. Jul 2006; 28(1): 68-74. PMID 16510462
28. Ragab SM, Lund VJ, Scadding G, et al. Impact of chronic rhinosinusitis therapy on quality of life: a prospective randomized controlled trial. Rhinology. Sep 01 2010; 48(3): 305-11. PMID 21038021
29. Mattos JL, Soler ZM, Schlosser RJ, et al. Olfactory Function After Surgical Treatment of CRS: A Comparison of CRS Patients to Healthy Controls. Am J Rhinol Allergy. May 2021; 35(3): 391-398. PMID 32954837
30. Verma P, Rawat DS, Aseri Y, et al. A prospective longitudinal study of clinical outcome and quality of life assessment in patients with chronic rhinosinusitis after functional endoscopic sinus surgery using sino nasal outcome test-22. Indian J Otolaryngol Head Neck Surg. Oct 2022; 74(Suppl 2): 792-799. PMID 36452849
31. Miglani A, Soler ZM, Smith TL, et al. A comparative analysis of endoscopic sinus surgery versus biologics for treatment of chronic rhinosinusitis with nasal polyposis. Int Forum Allergy Rhinol. Feb 2023; 13(2): 116-128. PMID 35980852
32. Pandrangi VC, Mace JC, Kim JH, et al. Work productivity and activity impairment in patients with chronic rhinosinusitis undergoing endoscopic sinus surgery-A prospective, multi-institutional study. Int Forum Allergy Rhinol. Mar 2023; 13(3): 216-229. PMID 35938699
33. Hintschich CA, Pade J, Petridis P, et al. Presurgical olfactory function as an indicator of the outcome of functional endoscopic sinus surgery in chronic rhinosinusitis with nasal polyps. Eur Arch Otorhinolaryngol. Dec 2022; 279(12): 5727-5733. PMID 35748932
34. Orlandi RR, Kingdom TT, Smith TL, et al. International consensus statement on allergy and rhinology: rhinosinusitis 2021. Int Forum Allergy Rhinol. Mar 2021; 11(3): 213-739. PMID 33236525
35. Rank MA, Chu DK, Bognanni A, et al. The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. J Allergy Clin Immunol. Feb 2023; 151(2): 386-398. PMID 36370881

Documentation for Clinical Review

- 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
- Specific Details of Prior conservative treatments (Optimal Medical Treatment), 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) after Optimal Medical Treatment
- Laboratory results
- Other pertinent multidisciplinary notes/reports: (e.g., psychological or psychiatric evaluation, physical therapy, multidisciplinary pain management) when applicable

Post Service (in addition to the above, please include the following):

- 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.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

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

Type	Code	Description
	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)
HCPCS	None	

Policy History

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

Effective Date	Action
12/01/2016	BCBSA Medical Policy adoption
04/01/2017	Policy revision without position change
01/01/2018	Coding update
04/01/2018	Policy revision without position change
04/01/2019	Policy revision without position change Coding Update
05/01/2024	Policy reactivated. Previously archived from 05/01/2020 to 04/30/2024.
04/01/2025	Annual review. Policy statement, guidelines and literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

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 and Feedback (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 at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

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.

Appendix A

POLICY STATEMENT	
BEFORE Red font: Verbiage removed	**AFTER** Blue font: Verbiage Changes/Additions
Functional Endoscopic Sinus Surgery for Chronic Rhinosinusitis 7.01.155 **Policy Statement:** I. The use of functional endoscopic sinus surgery may be considered **medically necessary** for individuals with chronic rhinosinusitis when **all** of the following criteria are present: A. Chronic rhinosinusitis that negatively impacts quality of life, characterized by at least 2 of the following, at least 1 of which is (a) or (b), present for at least 12 continuous weeks: 1. Mucopurulent nasal drainage (anterior, posterior, or both); 2. Nasal obstruction (congestion) 3. Facial pain-pressure-fullness 4. Decreased sense of smell B. Optimal medical therapy has been attempted and failed, as indicated by **all** of the following: 1. Allergy evaluation, education, and optimal treatment when indicated 2. Two 10 day courses of antibiotics or 1 prolonged course of oral antibiotic for at least 21 days 3. Decongestants when indicated 4. Topical and/or systemic corticosteroids for at least 8 weeks 5. Saline nasal irrigations for at least 8 consecutive weeks 6. Treatment of rhinitis medicamentosa (rebound nasal congestion due to extended use of topical decongestants), when present 7. Education on environmental irritants including tobacco smoke C. Clinical and radiographic documentation of persistent inflammation following optimal medical therapy (see Policy Guidelines) D. 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	**Functional Endoscopic Sinus Surgery for Chronic Rhinosinusitis 7.01.155** **Policy Statement:** I. The use of functional endoscopic sinus surgery may be considered **medically necessary** for individuals with chronic rhinosinusitis when **all** of the following criteria are present: A. Chronic rhinosinusitis that negatively impacts quality of life, characterized by at least 2 of the following, at least 1 of which is (a) or (b), present for at least 12 continuous weeks: 1. Mucopurulent nasal drainage (anterior, posterior, or both); 2. Nasal obstruction (congestion) 3. Facial pain-pressure-fullness 4. Decreased sense of smell B. Optimal medical therapy has been attempted and failed, , in the past 12 weeks for the current episode of illness as indicated by **all** of the following: 1. Allergy evaluation, education, and optimal treatment when indicated 2. Two 10 day courses of antibiotics or 1 prolonged course of oral antibiotic for at least 21 days 3. Decongestants when indicated 4. Topical and/or systemic corticosteroids for at least 8 weeks 5. Saline nasal irrigations for at least 8 consecutive weeks 6. Treatment of rhinitis medicamentosa (rebound nasal congestion due to extended use of topical decongestants), when present 7. Education on environmental irritants including tobacco smoke C. Clinical and radiographic documentation of persistent inflammation following optimal medical therapy (see Policy Guidelines) D. There are no serious urgent complications of acute sinusitis that would suggest orbital cellulitis or abscess, intracranial extension

POLICY STATEMENT	
BEFORE **Red font: Verbiage removed**	**AFTER** **Blue font: Verbiage Changes/Additions**
emergent surgery such that "appropriate medical therapy" for 8 weeks would not be appropriate	of infection, or other complication that would require urgent or emergent surgery such that "appropriate medical therapy" for 8 weeks would not be appropriate
II. The use of functional endoscopic sinus surgery is considered **investigational** for the treatment of chronic rhinosinusitis when the above criteria are not met.	