Sinus Surgeries and Interventions (for Kansas Only)

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Instructions for Use

Table of Contents **Page**

Related Policy

- Rhinoplasty and Other Nasal Procedures (for Kansas Only)

Application

This Medical Policy only applies to the state of Kansas.

Coverage Rationale

Balloon sinus ostial dilation is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Balloon Ostial Dilation.

Click here to view the InterQual® criteria.

Self-expanding absorptive sinus ostial dilation is unproven and not medically necessary for evaluating or treating sinusitis and all other conditions due to insufficient evidence of efficacy.

Functional Endoscopic Sinus Surgery (FESS) for the ethmoid, frontal, and maxillary sinus is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures:

- Ethmoidectomy
- Sinusotomy, Frontal
- Sinusotomy, Maxillary

Click here to view the InterQual® criteria.

Functional Endoscopic Sinus Surgery (FESS) for the sphenoid sinus is proven and medically necessary when one or more of the following conditions are present:

- Chronic Rhinosinusitis (CRS) which has **all** of the following:
  - Lasted longer than 12 weeks
  - Persistence of symptoms despite recent medical management with administration of full courses of **all** of the following treatments:
    - Intranasal corticosteroids (and/or oral corticosteroids when appropriate); and
    - Antibiotic therapy if bacterial infection is suspected; and
    - Nasal lavage/irrigation if appropriate
  - Confirmation of Chronic Rhinosinusitis on a Recent Computed Tomography (CT) Scan for each sinus to be treated meeting **all** of the following criteria:

        - CT images are obtained after completion of medical management described above; and
        - Documentation of which sinus has the disease and the extent of disease including the percent of opacification or the use of a scale such as the Modified Lund-Mackay Scoring System; and
        - CT findings include one or more of the following:
            - Bony remodeling
            - Bony thickening
            - Opacified sinus
            - Ostial obstruction (outflow tract obstruction) and mucosal thickening
    - Sinonasal symptoms such as pain, pressure, or drainage are present on the same side as CT scan findings of rhinosinusitis
- Recurrent Acute Rhinosinusitis (RARS) with **all** of the following:
    - Four or more episodes per year with distinct symptom free intervals between episodes; and
    - Sinonasal symptoms such as pain, pressure, or drainage are present on the same side as CT scan findings of rhinosinusitis; and
    - Recent Computed Tomography (CT) Scan evidence of one of the following:
        - Both of the following are present:
            - Ostial obstruction (outflow tract obstruction) in the sinus to be treated
            - Mucosal thickening in the sinus to be treated

Functional Endoscopic Sinus Surgery (FESS) for the sphenoid sinus is also proven and medically necessary when any of the following conditions are confirmed on CT:

- Symptomatic mucocele
- Polyposis with obstructive symptoms (for Chronic Rhinosinusitis with polyps, refer to the criteria above)
- Sinonasal tumor

Functional Endoscopic Sinus Surgery (FESS) is also proven and medically necessary for complications of sinusitis such as abscess and for symptomatic concha bullosa confirmed on CT.

Functional Endoscopic Sinus Surgery (FESS) is unproven and not medically necessary for any other condition due to insufficient evidence of efficacy.

Definitions

Acute Rhinosinusitis (ARS): ARS is a clinical condition characterized by inflammation of the mucosa of the nose and paranasal sinuses with associated sudden onset of symptoms of purulent nasal drainage accompanied by nasal obstruction, facial pain/pressure/fullness, or both of up to 4 weeks duration [American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) Clinical Indicators: Endoscopic Sinus Surgery, Adult. 2012, Updated 2021].

Chronic Rhinosinusitis (CRS): An inflammatory process that involves the paranasal sinuses and persists for longer than 12 weeks with two or more of the following signs and symptoms:

- Mucopurulent drainage (anterior, posterior, or both)
- Nasal obstruction (congestion)
- Facial pain-pressure-fullness
- Decreased sense of smell

Diagnosing CRS requires that inflammation be documented (polyps, edema, or purulent mucus) in addition to persistent symptoms. 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 the nasal cavity or the middle meatus, and/or
- Radiographic imaging showing inflammation of the paranasal sinuses (Rosenfeld et al., 2015; Peters et al., 2014)

Draf Classification System for Endoscopic Frontal Sinus Drainage: A classification system to describe degrees of endoscopic surgical interventions used in the management of frontal sinus disorders based on the sinuses accessed (Al Komser et al., 2013).

Type	Description
Draf I	A simple drainage of the cells of the frontal recess without altering the frontal sinus ostium; also known as an anterior ethmoidectomy.

Type	Description
Draf IIa	Extended drainage with resection of the sinus floor from the lamina papyracea to the middle turbinate for the removal of agger nasi and frontal recess cells; also known as a frontal sinusotomy.
Draf IIb	Extended drainage with more extensive resection of the frontal sinus floor from the lamina papyracea to the nasal septum; also known as drilling of the frontal sinus or unilateral frontal sinus drillout.
Draf III	Removal of all of the frontal sinus floor, intersinus septum, the frontal beak and the superior septum; also known as an endoscopic modified Lothrop procedure or a bilateral frontal sinus drillout.

Functional Endoscopic Sinus Surgery (FESS): A minimally invasive, mucosal-sparing surgical technique utilized to treat medically refractory CRS with or without polyps or RARS (Homsi and Gaffey, 2022).

Modified Lund-Mackay Scoring System: A tool used to quantify the severity of CRS based on CT scan findings. The Lund-Mackay System was modified by Zinreich by increasing the scale from 0 to 5. In the Modified Lund-Mackay System, each sinus is assigned a score based on the percentage of opacification from mucosal thickening as follows: 0 = 0%, 1 = 1% to 25%, 2 = 26% to 50%, 3 = 51% to 75%, 4 = 76% to 99%, and 5 = 100% or completely occluded. The ostiomeatal complex is given a score of 0 to 2, depending on whether it is completely patent, partially obstructed, or completely obstructed. Each side is graded, and their sum is the total score out of maximum of 54 (Likness et al., 2014).

Recent Computed Tomography (CT) Scan: For the purpose of this policy, a CT scan is considered recent when performed within 12 months of the planned procedure.

Recurrent Acute Rhinosinusitis (RARS): RARS is defined as four or more episodes per year of acute bacterial rhinosinusitis (ABRS) with distinct symptom free intervals between episodes. Each episode of ABRS should meet the following diagnostic criteria:

- Acute Rhinosinusitis that is caused by, or presumed to be caused by, bacterial infection
- Symptoms or signs of Acute Rhinosinusitis fail to improve within 10 days or more beyond the onset of upper respiratory symptoms, or
- Symptoms or signs of Acute Rhinosinusitis worsens within 10 days after an initial improvement (double worsening)

Confirming a true bacterial episode of rhinosinusitis is preferred for substantiating an underlying diagnosis of RARS. When ABRS is not confirmed through laboratory analysis, examination of the member during an episode of ABRS (among the 4 episodes occurring per year) is needed to substantiate the diagnosis (Rosenfeld et al., 2015).

Rhinitis Medicamentosa (RM): A condition of rebound nasal congestion brought on by extended use of topical decongestants (e.g., oxymetazoline, phenylephrine, xylometazoline, and naphazoline nasal sprays) that constrict blood vessels in the lining of the nose. It classifies as a subset of drug-induced rhinitis (Wahid, 2022).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
31240	Nasal/sinus endoscopy, surgical; with concha bullosa resection
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

CPT Code	Description
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
31295	Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); maxillary sinus ostium, transnasal or via canine fossa
31296	Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); frontal sinus ostium
31297	Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); sphenoid sinus ostium
31298	Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); frontal and sphenoid sinus ostia
31299	Unlisted procedure, accessory sinuses

Description of Services

Individuals who have persistent or Chronic Rhinosinusitis (CRS) that has failed medical therapy may require surgery. CRS is defined as rhinosinusitis lasting longer than 12 weeks (Rosenfeld et al., 2015; Peters et al., 2014). Functional Endoscopic Sinus Surgery (FESS) is an accepted procedure for CRS refractory to medical therapy. FESS is a minimally invasive technique in which the sinus air cells and ostia are opened and drained under direct visualization. Polyps and infected tissue can be removed at the same time.

Balloon sinus ostial dilation, also known as balloon dilation sinuplasty or balloon catheter sinusotomy, has been proposed as an alternative or an addition to traditional endoscopic sinus surgery. Several procedural approaches have been proposed for balloon sinus ostial dilation. The first type of approach is done through the nostrils by inserting a small balloon through a tube placed in the nasal cavity where the blocked sinus is located. Using navigation or endoscopic visualization, the balloon is gradually inflated to compress tissue and bone and widen the sinus ostium or outflow tract. The balloon is then removed, and an endoscope may be used to assess the width of the nasal passage. The second type of approach is the transantral approach which is done by creating a small entry point under the lip. The balloon catheter is then directly inserted into the target sinus. Potential advantages of sinus balloon catheterization include minimal mucosal damage, minimal intraoperative bleeding, and minimal discomfort. Balloon sinus ostial dilation can be performed as a stand-alone procedure or with FESS. When performed with FESS, it may be referred to as a hybrid procedure.

FESS is a set of minimally invasive surgical techniques which allow direct visual examination and opening of the sinuses sometimes used for the treatment of CRS or RARS which have not responded to medical treatment. FESS has also been used to treat other conditions such as complications of sinusitis abscess, concha bullosa, mucocele, polyposis with obstructive symptoms or sinonasal tumor. Compared to other surgeries, the use of FESS allows for a much less invasive and traumatic procedure, resulting in shorter surgery and healing times, less postoperative discomfort, and fewer surgical complications.

Self-expanding absorptive sinus ostial dilation has been proposed as an alternative to standard balloon sinus ostial dilation. The self-expanding device is inserted into the sinus ostia and starts absorbing moisture and begins to expand providing gradual dilation of the sinus ostia. When the device is fully expanded, it is removed. The SinuSys Vent-OS Sinus Dilation System is a self-expanding device that has been cleared by the FDA. These devices are being studied to determine their safety and effectiveness.

Clinical Evidence

Functional Endoscopic Sinus Surgery (FESS)

In their systematic review and meta-analysis, Fu et al. (2023) sought to determine the mean change in patients' scores on the SNOT-22 test before and after ESS for CRS to evaluate whether ESS improves the QOL in patients with CRS. The

study included 15 multinational, prospective cohort studies with an average follow-up of 25.5 months. The authors reported that all studies demonstrated a statistically significant difference in mean SNOT-22 scores between baseline and post-op time periods ranging from 5.1 to 55.4, and that the mean SNOT-22 changed significantly across all studies by 26.02 with nine studies having a mean change ≥ 26.02 and six studies having a mean change ≤ 26.02. The authors also reported that the risk of bias assessment showed that eight of the studies had a low risk of bias, four had a moderate risk of bias, and three had a high risk of bias. According to the stepwise multivariate analysis conducted by the authors, studies with higher average age and average pre-op SNOT-22 scores had greater changes in SNOT-22 scores following ESS, while the studies with longer average follow-up had less significant changes in SNOT-22 scores post-ESS. Limitations of the study included the scarcity of studies available for inclusion, the heterogeneity of the study design with varied inclusion criteria and duration of follow-up, the use of aggregated data rather than individual participant data, the variability of the delineation of primary outcomes, and the inclusion of studies only written in English. The authors concluded that ESS leads to enhanced QOL outcomes, and that improvement is influenced by the initial SNOT-22 score, the average age of the patients and the duration of the follow-up period.

Lourijsen et al. (2022) conducted an open-label, multicenter RCT to assess the efficacy of ESS plus medical therapy versus medical therapy alone in patients with CRSwNP. Their study included 238 participants with 142 men (61%) with a mean age of 50.4 years who were randomly assigned to either an ESS plus medical therapy group (n = 121) or to a medical therapy only group (n = 117). Adults with CRSwNP and an indication for ESS (failure of appropriate medical treatment) were randomly assigned to receive either the ESS plus medical therapy group or to the medical therapy only group. ESS was performed according to local practice with anterior ethmoidectomy mandatory. CT-sinus Lund-Mackay score was collected at baseline and follow-up. Concurrent medical therapy was prescribed at the patient's otorhinolaryngologist's discretion and consisted of, but was not limited to, nasal corticosteroids, nasal lavage, systemic corticosteroids, or systemic antibiotics. The primary outcome was disease-specific health-related quality of life (HRQoL) at 12 months of follow up, measured with the SNOT-22 test. The study showed that the mean SNOT-22 score in the ESS plus medical therapy group was 27.9 at 12 months and was 31.1 in the medical therapy group; adjusted mean difference of –4·9 (95% CI –9·4 to –0·4). The authors concluded that ESS plus medical therapy is more efficacious than medical therapy alone in patients with CRSwNP even though the minimal clinically important difference was not met in their study. They recommended additional studies with longer-term follow-up to determine whether the effect persists over time.

Authors Alekseenko and Karpischenko (2020) performed a prospective RCT along with a comparative analysis of outcomes in pediatric patients (n = 64) who underwent external sinus surgery with an open approach versus a FESS approach. Examinations of all patients were performed pre-operatively and at six-months post-operatively. The examinations performed were QOL, SNOT-20 questionnaire, an endoscopic examination of nasal mucosa using Lund-Kennedy scoring and a CT of the sinuses using Lund-Mackay scoring. The cohorts were divided into two groups, 30 pediatric patients underwent external sinus surgery and the other 34 underwent FESS. Pre-operative SNOT-20 scores external 46.1 ±8.6 versus FESS 35.0 ±6.8; Lund-Kennedy scores for external (rt) 4.57 ±1.87 and (lt) 4.67 ±2.07 versus FESS (rt) 4.50 ±1.44 and (lt) 4.29 ±1.55; Lund-Mackay scores for external 10.47 ± 3.88 versus FESS 9.56 ±5.61. Post-operative SNOT-20 scores for external 38.6 ±8.9 and FESS 22.0 ±2.5; Lund-Kennedy scores for external (rt) 4.57 ±1.94 and (lt) 4.50 ±2.10 versus FESS (rt) 1.71 ±1.68 and (lt) 1.38 ±1.48; Lund-Mackay scores for external 6.57 ±3.52 versus FESS 3.17 ±2.89. Postoperative total score outcomes for Lund-Mackay sinus opacification in pediatric patients that underwent external sinus surgery and FESS were reduced by 38, 67% as compared to the preoperative values. The authors concluded FESS significantly decreased surgery duration by 15% as compared to external sinus surgery (98.16 ±20.28 vs. 83.08 ±29.89 min; p = 0.024). Both groups that underwent external sinus surgery and FESS resulted in a significant improvement in total Lund-Kennedy, Lund-Mackay, and SNOT-20 scores, but it was more profound in the FESS group and appears to be more effective and safer in children with CRS.

Singh et al. (2020) conducted a prospective, single institution study of 30 patients with CRS that failed maximum medical treatment and underwent FESS. All the patients with CRS had undergone medical management with antibiotics, nasal decongestants and steroids for 4-8 weeks. Each patient had a CT of the paranasal sinuses prior to FESS provides an objective means of evaluation supporting the clinical findings and scoring using the Lund Mackay CT classification system. There was a total mean Lund Mackay CT preoperative score of 13.16 ±4.5. Using the scoring the patients were divided into two groups. Group A had a Lund Mackay score ≤ 13.1 and Group B ≥ 13.1. A statistically significant improvement in symptoms with good long-term prognosis was recorded in Group-B only. The authors concluded that using a CT scan with Lund Mackay scoring with patients that have a minimum score of 13.1 or greater is a good long-term predictor for determining the efficacy of FESS for the treatment of CRS.

Zhang et al. (2020) conducted a five-year prospective, cohort study of 81 patients who had CRSwNP and asthma. The aim of the study was to compare the long-term clinical outcomes of surgical interventions such as FESS, Radical Endoscopic Sinus Surgery (RESS) and RESS + Draf 3 in these patients. The study used data from January 1, 2010, and October 31, 2013, that included patients with bilateral CRSwNP scheduled to undergo ESS. The CRSwNP diagnosis was

confirmed based on criteria of the European Position Paper on Rhinosinusitis and Nasal Polyps guidelines (EPOS). The asthma diagnosis was confirmed by a pulmonologist according to Global Initiative for Asthma (GINA) guidelines. The 81 patients were randomized to undergo a FESS, RESS or RESS + Draf 3 surgery. The randomization was 1:1:1 that was completely computer generated. After surgery patient each patient underwent a 10-day course of antibiotics and a three-week tapering of oral methylprednisolone. Post-operative data was gathered at one, three- and five-year intervals. The patients were monitored for polyp recurrence; the polyp score was graded for each nasal cavity on a scale of 0-3 for each side, and the bilateral polyp grade of (maximum, 6); symptom scoring was according to the Lund-Kennedy with assessment of edema, nasal discharge, scarring, and crusting; endoscopic results were postoperative and measured by CT of paranasal sinuses, a baseline was performed in all patients preoperatively and were scored using the Lund-Mackay system; Sinus-specific quality of life (QoL) was assessed using the SNOT-22 test; CRSwNP was graded using the EPOS 2012 guidelines; and clinical control of asthma was evaluated by pulmonary function testing using the percentage forced expiratory volume in 1 second (FEV1%) assessed by spirometer and a FEV1% of < 80% was graded as abnormal. The authors concluded that FESS had a higher short-term recurrence rate than RESS and RESS + Draf 3 for patients with CRSwNP and asthma. Both RESS and RESS + Draf 3 demonstrated a lower revision rate than FESS in the long-term. Patients with CRSwNP and asthma had poorer outcomes and higher recurrence rate after FESS for patients with CRSwNP and asthma. It is recommended for further studies, larger cohorts, longer follow-up duration and stricter standardization of medications used.

Smith et al. (2019) conducted an observational case series of 59 adult patients with CRS electing ESS. Long-term, disease-specific QOL outcomes, health utility values (HUV), revision surgery rate, development of asthma, and patient expectations/satisfaction with outcomes of ESS were examined using descriptive statistics and simple fixed-effects linear modeling. Fifty-nine adult patients were followed for an average of 10.9 years. Mean QOL significantly improved between baseline and 6 months and remained durable to 10 years. HUV improved to normal. A 17% revision surgery rate within the 10-year follow-up period was observed with a 25% revision rate in CRSwNP. New-onset asthma after ESS occurred at a rate of 0.8%/year. Patient satisfaction with ESS outcomes was generally high. The authors concluded that the ten-year prospective outcomes of ESS for CRS demonstrate that the initial clinically significant improvements in QOL seen 6 months postoperatively are durable over the long term.

Ni et al. (2018) conducted a systematic review and meta-analysis on studies using the SN-5 which is a validated symptom questionnaire in pediatric CRS. A total of 10 studies, consisting of 13 separate treatment arms of either medical therapy, adenoidectomy, balloon catheter sinuplasty (BCS), or FESS were included in the review. The investigators limited inclusion of studies to pre/post studies that reported changes in SN-5 scores. Despite the multiple interventions under consideration in this meta-analysis, no treatment comparisons were conducted. Two of the 10 studies that met inclusion criteria for the meta-analysis reported SN-5 improvement following treatment with FESS. In the FESS-stratified meta-analysis of these 2 studies that included 22 total patients, the mean SN-5 score decreased by 1.83 points (95% CI, 1.47 to 2.19), which the authors report as a statistically significant improvement ($p < 0.00001$).

The National Cancer Database was queried for cases of sinonasal squamous cell carcinoma (SNSCC) without cervical or distant metastases that were treated surgically between 2010 and 2014. They were divided into 2 groups based on surgical approach: open or endoscopic. Cox proportional hazard analysis was performed. Propensity score matching (PSM) was used to mimic an RCT. A total of 1,483 patients were identified: 353 (23.8%) received endoscopic and 1,130 (76.2%) received open surgery. Age, gender, race, geographic region, tumor size, surgical margins, post-operative chemoradiation, and 30-day readmissions did not vary significantly between the 2 groups. Open surgery was more common in academic centers (62.8% vs. 54.2%; $p = 0.004$), less common for tumors of the ethmoid and sphenoid sinus ($p < 0.0001$), less common for stage IVB tumors, and associated with longer hospital stay. Five-year overall survival (5Y-OS) was not significantly different between the 2 approaches ($p = 0.953$; open: 5Y-OS, 56.5%; 95% confidence interval, 51.3% to 61.6%; endoscopic: 5Y-OS, 46.0%; 95% confidence interval, 33.2% to 58.8%). In the PSM cohort of 652 patients, there was also no significant difference in overall survival ($p = 0.850$). The investigators concluded that endoscopic surgery is an effective alternative to open surgery, even after accounting for confounding factors that may favor its use over the open approach (Kılıç et al., 2018).

Kim and Kwon (2017) conducted a meta-analysis to evaluate recurrence of sinonasal inverted papilloma (IP) based on the type of surgical approach. Fourteen retrospective cohort studies involving a total of 696 endoscopic approaches and 444 non-endoscopic approaches were included in the review. The pooled risk ratio (RR) for IP recurrence (endoscopic vs. external approach) was 0.56 (95% CI: 0.36-0.85, I2 = 48.3%). The investigators concluded that surgical management of IP via an endoscopic approach reduces the risk of recurrence compared to an external approach. Although further data are needed, early-stage IP requires endoscopic or endoscopic-assisted surgery to reduce the risk of tumor recurrence.

In a systematic review and meta-analysis, Patel et al. (2017) examined the literature regarding management of CRS patient's refractory to appropriate medical therapy (AMT). Adult patients with CRS who received AMT and then underwent

either medical or surgical therapy in moderate to high level prospective studies were included. Six observational or before/after studies were included in the systematic review with 5 included in the meta-analysis. On meta-analysis, for patients with CRS refractory to AMT, ESS significantly improves objective endoscopic scoring outcomes vs. continued medical therapy alone. In patients with refractory CRS who had significant reductions in baseline QOL, ESS resulted in significant improvements. Continued medical therapy appeared to maintain outcomes in patients with less severe baseline QOL. Unpooled analysis demonstrated improvement in health utility and olfaction following ESS compared to continued medical therapy alone, in medically refractory CRS.

Wood et al. (2017) conducted a prospective case series to assess treatment outcomes of CRS patients undergoing FESS and post-operative medical treatment over a prolonged follow-up period. The study included 200 non-consecutive patients in the tertiary referral practice of a single surgeon. Symptoms were scored by patients pre-operatively and over a minimum follow-up period of 12 months. The median pre-operative symptom score was 16 (out of a maximum of 25). Symptom scores reduced to a median of 7 after 12 months of follow up. The median symptom score improved for all symptoms and across all patient subgroups. The authors concluded that extensive FESS offers significant and durable symptom improvement in patients with CRS refractory to medical treatment and that prolonged medical therapy is recommended after FESS. The findings are however limited by lack of comparison group undergoing a different treatment approach.

Djukic et al. (2015) evaluated the clinical outcomes and QoL in patients with nasal polyposis (NP) after FESS. The prospective study included 85 consecutive adult patients (≥ 18 years) with NP who were operated on using FESS after failure of the medical treatment and in certain cases of surgical treatment. The objective finding was presented as endoscopic and CT score. The intensity of each symptom, the values of symptom scores (major, minor and total), the values of dimension scales and summary scales of the QOL, as well as the values of endoscopic score through three periods of time (pre-surgery, 6 and 12 months after the surgery) were analyzed. Following FESS, mean intensity values of all individual symptoms and symptom scores were significantly lower and the values of all dimension scales and summary scales of QoL were significantly higher ($p < 0.05$). There was no statistically significant difference in symptom intensity and QoL after 6 and 12 months of surgical treatment ($p > 0.05$). Endoscopic score was on average significantly lower after 6 and 12 months of FESS ($p < 0.05$), but the mean score value after 12 months of operation was significantly higher in relation to that after 6 months of surgery ($p < 0.05$). Nevertheless, the recurrence of NP was observed in 28 patients (32.9%) in the follow-up period. In conclusion, FESS in patients with NP resulted in significant improvement of symptom intensity, QOL and endoscopic score. While the intensity of symptoms and QOL showed a tendency to maintain between 6 and 12 months after surgery, endoscopic score showed a tendency of exacerbation in the same period. The findings were limited by lack of comparison group.

In a systematic review, Vlastarakos et al. (2013) evaluated the quality of evidence in the use of FESS for the treatment of CRS in children, regarding the respective changes in their QOL and the outcome that follows the operation. Fifteen studies were systematically analyzed. Four represented Level II, 5 Level III, and 6 Level IV evidence. The total number of treated patients was 1,301. Thirteen research groups reported that pediatric FESS was an effective treatment for CRS; the respective positive outcome ranged between 71 and 100% of operated children. Five studies concluded that this treatment modality was associated with significant improvement in the children's postoperative QOL. Systemic diseases and environmental factors may have unfavorable prognostic effects; cystic fibrosis was associated with at least 50% recurrence rate. The rate of major complications following pediatric FESS was 0.6%, and the respective rate of minor complications was 2%. The authors concluded that surgical management with FESS in children with CRS is effective when optimal medical treatment proves unsuccessful (grade B strength of recommendation) and was associated with improvement in the children's QOL (grade B strength of recommendation). FESS also improved the sinusitis-associated symptoms and QOL in children with cystic fibrosis (grade C strength of recommendation). According to the authors, most complications of pediatric FESS reported in the literature were minor and associated with difficulties in the postoperative assessment and care of pediatric patients.

Scangas et al. (2013) conducted a retrospective case series at a university tertiary referral center to characterize the natural history, clinical characteristics, management principles, and outcomes of paranasal sinus mucoceles. A chart review was performed on 102 patients with a total of 133 paranasal sinus mucoceles. Patients were diagnosed with a mucocele on average 5.3 years following prior FESS, 17.7 years following prior paranasal sinus trauma, and 18.1 years following prior open sinus surgery. The most common presenting symptoms were headache (42.1%) and maxillofacial pressure (28.6%). The most common sites were the frontal, frontoethmoidal, and ethmoid sinuses. Fifty-seven mucoceles (44.9%) had intraorbital extension, intracranial extension, or both. Out of 133 mucoceles, 114 underwent ESS without complication. The authors concluded that the endoscopic approach can be safely used for the management of mucoceles.

Higgins et al. (2011) conducted a systematic review with a pooled-data analysis to compare outcomes of endoscopic versus craniofacial resection of sinonasal malignancies. The review included 15 case series with individual data on 226

patients. The 5Y-OS for the sample was 56.5%. Because of the paucity of data with endoscopic resection of high-stage malignancies, the outcome results were highly variable, and no useful comparison could be made. Among low-stage malignancies (T1-2 or Kadish A-B), the endoscopic and open approaches demonstrated no statistically significant difference in outcome results. The 5Y-OS was 87.4% in the endoscopic group versus 76.8% for open approaches; disease-specific survival was 94.7% versus 87.7%; and locoregional control rate was 89.5% versus 77.2%. The authors concluded that transnasal endoscopic resection appears to be a reasonable alternative to craniofacial resection in the management of low stage sinonasal malignancies.

Toros et al. (2007) compared the outcomes of ESS in patients with CRSsNP and those with nasal polyps (NP). The investigators also determined the correlation between preoperative CT findings and postoperative endoscopy and symptom score improvement. Data were collected from two groups of patients diagnosed as CRSwNP and CRSsNP that underwent FESS with a 1-year postoperative follow up. Preoperative symptoms, CT scores, and endoscopic scores were recorded. Assessment of symptoms was performed subjectively using VAS. CT scan findings were scored using the Lund-Mackay system. The correlations between the CT score, endoscopic scores and VAS scores were calculated. There was a statistically significant correlation between the pre-operative CT, symptom, and endoscopic scores. Post-operative symptom and endoscopic scores also showed a significant correlation. Total CT scores of the CRSsNP group were significantly lower than the scores of the NP group. Also, preoperative endoscopy and symptom scores were statistically lower in CRSsNP group compared to NP group. Endoscopy total scores and symptom total scores of both groups were significantly decreased at post-operative 12th month. Statistically significant difference was observed between the pre-operative and post-operative symptom and endoscopy scores. The patients with polyps had higher symptom scores and worse objective findings compared to the patients with CRSsNP. In all patients' groups, objective and subjective scores seemed to correlate well pre-operatively and post-operatively. These data suggest that ESS provides significant symptomatic relief and endoscopic healing in patients with CRSsNP and NP.

Maru and Gupta (1999) conducted a study of 150 patients with chronic sinusitis, who underwent CT scan of the paranasal sinuses prior to FESS. The CT scans were evaluated to detect the incidence of concha bullosa and its types, the significance of concha bullosa in the formation of ostiomeatal complex disease and the relation between type of concha bullosa and ostiomeatal complex disease. All patients underwent FESS. According to the investigators, FESS is the technique of choice for management of inflammatory disease of middle meatus and concha bullosa so as to restore the normal function of the middle turbinate.

Clinical Practice Guidelines

American Academy of Otolaryngology − Head and Neck Surgery (AAO-HNS)

In a 2015 Clinical Practice Guideline (update) for Adult Sinusitis, the AAO-HNS indicates that clinicians should recommend saline nasal irrigation, topical intranasal corticosteroids, or both for symptom relief of CRS. CT of the paranasal sinuses should be obtained when ESS is considered or planned in patients with CRS or RARS. In addition to demonstrating abnormal mucosa and opacified sinuses, CT will provide the anatomic detail necessary to guide the surgery. Surgical management of CRS is not discussed "because of insufficient evidence (e.g., RCTs) for evidence-based recommendations" (Rosenfeld et al. 2015).

The AAO-HNS clinical indicators for ESS for adults states that the indications for ESS include a history of one of more of the following:

- CRS with or without nasal polyps with persistent symptoms and objective evidence of disease by endoscopic and/or CT imaging that is refractory to medical treatment
- Allergic fungal rhinosinusitis
- Unilateral paranasal sinus opacification, symptomatic or asymptomatic, consistent with CRS with or without nasal polyps, fungus ball, or benign neoplasm (i.e., inverted papilloma)
- Complications of sinusitis, including extension to adjacent structures such as orbit or skull base
- Sinonasal polyposis with nasal airway obstruction or suboptimal asthma control
- Mucocele
- RARS

The AAO-HNS clinical indicators for ESS also indicate that imaging studies should generally be obtained after optimal medical therapy [American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) Clinical indicators: Endoscopic sinus surgery, adult 2012, Updated 2021].

The AAO-HNS clinical pediatric CRS expert consensus statement concluded that the effectiveness of balloon sinuplasty compared to traditional ESS-line surgical procedure for children aged 13 years and older with CRS (AAO-HNS, 2014).

In the 2021 clinical indicators for pediatric ESS, the AAO-HNS states that adenoidectomy should be strongly considered a minimum of three months prior to performing pediatric sinus surgery when there is failure of medical management for CRS or RARS.

American Academy of Allergy, Asthma, and Immunology (AAAAI)/American College of Allergy, Asthma, and Immunology (ACAAI)/Joint Council of Allergy, Asthma, and Immunology (JCAAI)

In a 2014 practice parameter for the diagnosis and management of rhinosinusitis, the AAAA, ACAAI, and JCAAI recommends that although medical therapy is the mainstay of disease management, FESS should be considered when medical therapy fails. According to the AAAA, ACAAI, and JCAAI, indications for surgical intervention include the following:

- When nasal polyps obstruct sinus drainage and persist despite appropriate medical treatment
- When there is recurrent or persistent infectious rhinosinusitis despite adequate trials of medical management that at least includes topical nasal steroids and nasal irrigations
- For biopsy of sinonasal tissue to rule out granulomatous disease, neoplasm, ciliary dyskinesia, or fungal infections
- When maxillary antral puncture is required (as for culture-directed therapy)
- When anatomic defects obstruct the sinus outflow tract, particularly the ostiomeatal complex (and adenoidal tissues in children)
- For rhinosinusitis with threatened complications (such as threat of brain abscess, meningitis, cavernous sinus thrombosis, or frontal bone osteomyelitis)

Regarding medical management for CRS, the AAAA, ACAAI, and JCAAI indicate that the role of antibiotics in CRS is controversial. For CRS associated with suspected bacterial infection, a longer duration of therapy beyond the usual 10 to 14 days is suggested; the choice of appropriate antibiotic therapy may need to consider the possible presence of anaerobic pathogens. Because CRS is an inflammatory disease, intranasal corticosteroids (INSs) are indicated for treatment. Other adjunctive therapy, such as intranasal antihistamines, decongestants, saline irrigation, mucolytics, and expectorants, might provide symptomatic benefit in select cases.

American College of Radiology (ACR)

The ACR Appropriateness Criteria for Sinonasal Disease (ACR 2017, revised 2021) indicates the following):

- Most cases of uncomplicated acute and subacute rhinosinusitis are diagnosed clinically and should not require any imaging procedure.
- CT of the sinuses without contrast is the imaging method of choice in patients with RARS or CRS, or to define sinus anatomy prior to surgery.
- Immunocompromised patients are at high risk for invasive fungal sinusitis.
- In patients with suspected sinonasal mass or suspected orbital and/or intracranial complication of sinusitis, MRI and CT are complementary studies.

European Forum for Research and Education in Allergy and Airway Diseases (EUFOREA)

The 2020 EUFOREA evidence-based position paper makes the following recommendations regarding ESS surgery for CRS:

- A CT scan showing evidence of disease is mandatory.
- For adult patients with uncomplicated CRSsNP ESS could be appropriately offered when:
  - The CT Lund-Mackay score is ≥ 1.
  - A minimum trial of at least eight weeks' duration of a topical intranasal corticosteroid plus either a short-course of a broad spectrum/culture-directed systemic antibiotic or the use of a prolonged course of systemic low dose anti-inflammatory antibiotic with a post-treatment total SNOT-22 score ≥ 20.

International Consensus Statement on Allergy and Rhinology: Rhinosinusitis 2021 (ICAR-RS)

The 2021 ICAR-RS executive summary provides a compilation of evidenced-based recommendations for medical and surgical treatments for CRS, CRSwNP acute rhinosinusitis (ARS) and RARS (Orlandi et al. 2021). The summary states that ESS is recommended for rhinologic diseases that demonstrate a "failure of maximal medical therapy" (MMT). Criteria used to confirm MMT and eligibility for ESS, but not limited to:

- Presence of two specific cardinal symptoms for ≥ 12 weeks which may vary for the following conditions CRS, CRSwNP, ARS or RARS
- SNOT-22 test preoperative score ≥ 20
- Sinus inflammation and/or purulence on nasal endoscopy
- Sinus inflammation on CT

Modified Lund-Mackay Scoring System

In a prospective, multicenter study, Likness et al. (2014) evaluated CT scans of CRS patients using a novel objective 3D computerized system and compared results with a novel 2D computerized analysis of a single coronal slice through the ostiomeatal complex (OMC) and subjective methods including Lund-Mackay and Zinreich's modified Lund-Mackay. Forty-six adults with a diagnosis of CRS underwent CT examination and received an intramuscular triamcinolone injection, dosage weight dependent, followed by CT scan 4 to 5 weeks later. Scans were evaluated with all four scoring methods over 5 months. The Lin's concordance class correlation (CCC) of the OMC method revealed the best correlation to the 3D volumetric computerized values (0.915), followed by the Zinreich (0.904) and Lund-Mackay methods (0.824). Post-treatment results demonstrated that both the OMC (0.824) and Zinreich's (0.778) methods had strong agreement with the 3D volumetric methods and were very sensitive to change, whereas the Lund-Mackay (0.545) had only moderate agreement. The authors concluded that computerized CT analysis provides the most comprehensive, objective, and reproducible method of measuring disease severity and is very sensitive to change induced by treatment intervention. The authors stated that a 2D coronal image through the OMC provides a valid, user-friendly method of assessing CRS and is representative of CRS severity in all sinuses. According to the authors, Zinreich's subjective method correlated well overall, but the Lund-Mackay method lagged behind in disease representation and sensitivity to change.

Self-Expanding Absorptive Sinus Ostial Dilation

The evidence is insufficient to support the use of self-expanding absorptive sinus ostial dilation devices. Studies with control groups are needed to demonstrate the efficacy of these devices.

Hathorn et al. (2014) conducted a pilot study to determine the safety and performance of a maxillary sinus ostium (MSO) self-dilation device. Twelve CRS patients presenting with maxillary sinus inflammation requiring FESS were enrolled. The device was inserted into the MSO at the start of surgery and removed after 60 minutes. Endoscopic evaluation for patency was performed immediately after removal, and at 1 week, 1 month, and 3 months. Adverse events were recorded intraoperatively and at each subsequent visit. The device was successfully inserted in 100% of cases attempted (19/19 MSOs, 12 patients). Seventeen (89%) devices remained in the MSO for 60 minutes and dilated to a mean diameter of 4.8 ±0.5 mm. One patient was withdrawn from the study. No adverse events occurred during insertion or removal of the device. At 3 months postinsertion 14 of 15 MSO dilated (93%) were confirmed patent. The investigators concluded that the placement of an osmotic self-dilating expansion device in human MSO is safe, achievable, and effective at dilating the ostia. This study is limited by a small sample size and lack of a comparison group.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The FDA classifies devices used for balloon catheter dilation for treating CRS under product code LRC (instrument, ENT, manual surgical). This is a broad product code category that includes a variety of devices used in ear, nose, and throat surgeries (e.g., knives, hooks, injection systems, dilation devices). Additionally, this product code is 510(k)-exempt. Although manufacturers may voluntarily submit product information via the 510(k) process, it is not a requirement. All manufacturers are, however, required to register their establishment and submit a "Device Listing" form; these records can be viewed in the Registration and Device Listing Database (search by product code, device, or manufacturer name). Refer to the following website for more information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm. (Accessed March 27, 2024)

In 2013, the FDA granted 510k clearance to the SinuSys Vent-OS Sinus Dilation System for dilation of the maxillary sinus ostia and associated spaces in adults. Refer to the following for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf13/K133016.pdf. (Accessed March 27, 2024)

To view all 510(k) substantial equivalence summaries for ENT manual surgical instruments, search (Product Code: LRC) at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed March 27, 2024)

FESS is a procedure and, therefore, not subject to FDA regulation. However, any medical devices, drugs, biologics, or tests used as a part of this procedure may be subject to FDA regulation.

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Policy History/Revision Information

Date	Summary of Changes
06/01/2025	• New Medical Policy

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its policies and guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) criteria for substance use disorder (SUD) services, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies that have been approved by the Kansas Department of Health and Environment. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.