

UnitedHealthcare[®] Commercial and Individual Exchange Medical Policy

Functional Endoscopic Sinus Surgery (FESS)

Policy Number: 2023T05780 Effective Date: October 1, 2023

Instructions for Use

Table of Contents	Page
Application	1
Coverage Rationale	1
Documentation Requirements	
<u>Definitions</u>	
Applicable Codes	
Description of Services	
Clinical Evidence	
U.S. Food and Drug Administration	
References	
Policy History/Revision Information	
Instructions for Use	

Related Commercial/Individual Exchange Policy

- Balloon Sinus Ostial Dilation
- Rhinoplasty and Other Nasal Procedures

Community Plan Policy

• Functional Endoscopic Sinus Surgery (FESS)

Application

UnitedHealthcare Commercial

This Medical Policy applies to all UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans in all states except for Colorado.

Coverage Rationale

<u>Functional Endoscopic Sinus Surgery (FESS)</u> is proven and medically necessary when one or more of the following conditions are present:

- Chronic Rhinosinusitis (CRS) with or without polyps which has all of the following:
 - Lasted longer than 12 weeks
 - Persistence of symptoms despite 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 <u>Recent Computed Tomography (CT) Scan</u> 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 <u>Modified Lund-Mackay Scoring System</u>; and
 - CT findings include one or more of the following:
 - Bony remodeling
 - Bony thickening

- Opacified sinus
- Ostial obstruction (outflow tract obstruction) and mucosal thickening
- Sino nasal 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
 - o Recent Computed Tomography (CT) Scan evidence of one of the following:
 - For the maxillary, frontal, or sphenoid sinuses, 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
 - For the ethmoid sinus, mucosal thickening is present
- Any of the following conditions confirmed on CT:
 - Complications of sinusitis such as abscess
 - Symptomatic concha bullosa
 - Symptomatic mucocele
 - o Polyposis with obstructive symptoms (for Chronic Rhinosinusitis with polyps refer to the above criteria)
 - Sinonasal tumor

<u>Functional Endoscopic Sinus Surgery (FESS)</u> is unproven and not medically necessary for cases of CRS or RARS that do not meet the criteria above due to insufficient evidence of efficacy.

Documentation Requirements

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

CPT Codes*	Required Clinical Information			
Functional Endoscopic Sinus Surgery (FESS)				
31240	Medical notes documenting the following, when applicable:			
31253	Diagnosis			
31254	History of illness			
31255	Recent physical exam			
31256	Signs and symptoms			
31257	• Treatments tried, failed, or contraindicated; include the dates and reason for discontinuation (e.g.,			
31259	intranasal corticosteroids, antibiotic therapy, nasal lavage/irrigation)			
31267	Recent CT Scan report, including the date of scan, documenting the following:			
31276	 Which sinus has the disease, including side 			
31287	The extent of disease including the percent of opacification or the use of a scale such as the			
31288	Modified Lund-Mackay Scoring System			
0.200	Whether the images were taken pre- or post-medical management			
	Upon request, Recent CT Scan images: That all any the all requestions are upon in larger and the formula in larger a			
	That show the abnormality for which surgery is being requested			
	o Are the optimal images to show the abnormality of the affected area including, when applicable			
	the use of a scale such as the Modified Lund-Mackay Scoring System to define the severity			
	 Labeled with the date taken and the applicable case number obtained at time of notification, or member's name and ID number 			
	o Note : CT images can be submitted via the external portal at www.uhcprovider.com/paan ; faxes			
	will not be accepted			
	For Recurrent Acute Rhinosinusitis, also include the number of episodes per year of Acute			
	Rhinosinusitis			

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 for endoscopic sinus surgery for adults. 2012, Updated 2015).

Chronic Rhinosinusitis (CRS): CRS is one of the more prevalent chronic illnesses in the United States and is an inflammatory process that involves the paranasal sinuses and persists for longer than 12 weeks (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).

Туре	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
Draf Ila	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): FESS is a minimally invasive, mucosal-sparing surgical technique utilized to treat medically refractory CRS with or without polyps or Recurrent Acute Rhinosinusitis (Homsi and Gaffey, 2022).

Modified Lund-Mackay Scoring System: A tool used to quantify the severity of Chronic Rhinosinusitis based on computed tomography (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 has been defined as four episodes per year of Acute Rhinosinusitis with distinct symptom free intervals between episodes (Rosenfeld et al., 2015).

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 the member specific benefit plan document 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 Coverage Determination 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
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

CPT° is a registered trademark of the American Medical Association

Description of Services

Functional Endoscopic Sinus Surgery (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 Chronic Rhinosinusitis (CRS) or Recurrent Acute Rhinosinusitis (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.

Clinical Evidence

Lourijsen et al. (2022) conducted an open-label, multi-center randomized controlled trial (RCT) to assess the efficacy of endoscopic sinus surgery (ESS) plus medical therapy versus medical therapy alone in patients with chronic rhinosinusitis with nasal polyps (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. Computed tomography (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 Sinonasal Outcome Test 22 (SNOT-22). 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.

Saltagi et al. (2021) performed a systematic review of the literature on the management of recurrent acute rhinosinusitis (RARS). A total of 1022 titles/abstracts possibly related to RARS were identified. Of these, 10 publications met inclusion criteria (five with level 4 evidence, four with level 3 evidence, one with level 2 evidence). The studies included a total of 890 participants (age range 5.8 to 53.5 years), with follow up ranging from 1 to 19 months. The outcomes were primarily based on symptomatic improvement, although some articles also reported post-treatment endoscopic and radiographic findings. Management options included medical therapy (intranasal steroids, antibiotics, nasal saline irrigations, N-acetylcysteine, allergy treatment, and

decongestants), balloon sinus dilation (BSD), and ESS. ESS was assessed in 6 publications, all with evidence level 3 or 4. Surgical patients (BSD and ESS) had a trend towards greater symptom control than medically treated patients, but meta-analysis was not possible. Although there are study limitations, the author's note that until better evidence can be obtained, current recommendations are based on expert opinion. Recommendations include considering surgery when patients experience four annual episodes (with at least one episode confirmed via computed tomography or nasal endoscopy) and the patient has either failed a trial of topical nasal steroids or experienced RARS-related productivity loss. These findings are limited by the lack of studies with direct comparisons between treatment options, lack of randomization, and open-label design.

Authors Alekseenko and Karpischenko (2020) performed a prospective randomized control trial along with a comparative analysis of outcomes in pediatric patients (n = 64) who underwent external sinus surgery with an open approach versus a functional endoscopic sinus surgery (FESS) approach. Examinations of all patients were performed pre-operatively and at sixmonths post-operatively. The examinations performed were quality of life (QOL), Sino-Nasal Outcome Test-20 (SNOT-20) questionnaire, an endoscopic examination of nasal mucosa using Lund-Kennedy scoring and a computer tomography (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 chronic rhinosinusitis.

Singh et al. (2020) conducted a prospective, single institution study of 30 patients with chronic rhinosinusitis (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 \pm 4.5. Using the scoring the patients were divided into two groups. Group A had a Lund Mackay score \leq 13.1 and Group B \geq 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 chronic rhinosinusitis with nasal polyps (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 22-item Sinonasal Outcome Test (SNOT-22); 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 + Draf3 for patients with chronic rhinosinusitis with nasal polyps and asthma. Both RESS and RESS + Draf3 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 chronic rhinosinusitis with

nasal polyps 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 chronic rhinosinusitis (CRS) electing ESS. Long-term, disease-specific quality-of-life (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 10.9 years, on average. 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 CRS with polyposis. 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 Sinus and Nasal Quality of Life Survey (SN-5) which is a validated symptom questionnaire in pediatric chronic rhinosinusitis (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 FEES-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 a randomized, controlled trial. A total of 1,483 patients were identified: 353 (23.8%) received endoscopic and 1130 (76.2%) received open surgery. Age, gender, race, geographic region, tumor size, surgical margins, postoperative 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 (OS) (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 OS (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 (Kiliç 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 quality of life (QOL), ESS results in significant improvements. Continued medical therapy appears 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 quality of life (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 results 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 are 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 1301. Thirteen research groups reported that pediatric FESS is an effective treatment for CRS; the respective positive outcome ranged between 71 and 100% of operated children. Five studies concluded that this treatment modality is associated with significant improvement in the children's postoperative QOL. Systemic diseases and environmental factors may have unfavorable prognostic effects; cystic fibrosis is associated with at least 50% recurrence rate. The rate of major complications following pediatric FESS is 0.6%, and the respective rate of minor complications is 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 is associated with improvement in the children's QOL (grade B strength of recommendation). FESS also improves 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 are 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 overall 5-year survival rate 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 5-year overall survival 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 endoscopic sinus surgery in patients with chronic sinusitis without nasal polyps (CRS) 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 CRS with and without nasal polyps that underwent functional endoscopic sinus surgery with a 1-year postoperative follow up. Preoperative symptoms, CT scores, and endoscopic scores were recorded. Assessment of symptoms was performed subjectively using visual analogue scoring (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 preoperative CT, symptom, and endoscopic scores. Postoperative symptom and endoscopic scores also showed a significant correlation. Total CT scores of the CRS group were significantly lower than the scores of the NP group. Also, preoperative endoscopy and symptom scores were statistically lower in CRS group compared to NP group. Endoscopy total scores and symptom total scores of both groups were significantly decreased at postoperative 12th month. Statistically significant difference was observed between the preoperative and postoperative symptom and endoscopy scores. The patients with polyps had higher symptom scores and worse objective findings compared to the patients with CRS. In all patients' groups, objective and subjective scores seemed to correlate well preoperatively and postoperatively. These data suggest that endoscopic sinus surgery provides significant symptomatic relief and endoscopic healing in patients with CRS 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, functional endoscopic sinus surgery 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.

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 osteomeatal 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. Recruitment lasted 21 months. Scans were evaluated with all 4 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). Posttreatment 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.

Clinical Practice Guidelines

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

The AAO-HNS developed an expert consensus statement on the use of sinus ostial dilation (SOD) of the paranasal sinuses (AAO-HNS, 2018). An expert panel of otolaryngologists was assembled to represent general otolaryngology and relevant subspecialty societies. A modified Delphi method was used to distill expert opinion into clinical statements that met a standardized definition of consensus. Consensus was reached that there is a role for treating patients with recurrent acute sinusitis as defined in the AAO-HNSF guideline based on symptoms and the CT evidence of ostial occlusion and mucosal thickening.

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 chronic rhinosinusitis (CRS). Computed tomography (CT) of the paranasal sinuses should be obtained when endoscopic sinus surgery is considered or planned in patients with CRS or recurrent acute rhinosinusitis (ARS). 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 endoscopic sinus surgery for adults states that the indications for endoscopic sinus surgery 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
- Recurrent acute rhinosinusitis

The AAO-HNS clinical indicators for endoscopic sinus surgery 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 chronic rhinosinusitis expert consensus statement concluded that the effectiveness of balloon sinuplasty compared to traditional endoscopic sinus surgery for pediatric CRS cannot be determined based on current evidence. It also states that adenoidectomy is an effective first-line surgical procedure for children aged 13 years and older with CRS (AAO-HNS, 2014).

In the 2021 clinical indicators for pediatric endoscopic sinus surgery, 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 recurrent ARS.

American Academy of Allergy Asthma and Immunology (AAAAI), the American College of Allergy Asthma and Immunology (ACAAI), and the 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 recurrent acute sinusitis or chronic sinusitis, 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 EUOFOREA 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 CRS without nasal polyps 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 antiinflammatory antibiotic with a post-treatment total SNOT-22 score >/= 20

The 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 chronic rhinosinusitis (CRS), chronic rhinosinusitis with nasal polyps (CRSwNP) acute rhinosinusitis (ARS) and recurrent acute rhinosinusitis (RARS) (Orlandi et al. 2021). The summary states that endoscopic sinus surgery (ESS) is recommended for rhinonologic 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
- Sino-Nasal Outcome Test 22 (SNOT-22) preoperative score ≥ 20
- Sinus inflammation and/or purulence on nasal endoscopy
- Sinus inflammation on Computed Tomography (CT)

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.

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.

References

Alekseenko S, Karpischenko S. Comparative analysis of the outcome of external and endoscopic frontal sinus surgery in children. Acta Otolaryngol. 2020 Aug;140(8):687-692.

American Academy of Allergy Asthma and Immunology (AAAAI)/ American College of Allergy Asthma and Immunology (ACAAI). Joint Task Force Practice Parameter. Diagnosis and management of rhinosinusitis. 2014.

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) Clinical indicators: Endoscopic sinus surgery, pediatric. April 23, 2021. Available at: https://www.entnet.org/resource/clinical-indicators-endoscopic-sinus-surgery-pediatric/. Accessed April 18, 2023.

American Academy of Otolaryngology Head and Neck Surgery (AAO-HNS). Expert consensus statement. Balloon Dilation of the Sinuses. 2018.

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) Clinical indicators: Endoscopic sinus surgery, adult. 2012, Updated April 23, 2021.

American College of Radiology (ACR). [Website] ACR Appropriateness Criteria. Sinonasal Disease. 2012.Revised 2021.

Djukic V, Dudvarski Z, Arsovic N, et al. Clinical outcomes and quality of life in patients with nasal polyposis after functional endoscopic sinus surgery. Eur Arch Otorhinolaryngol. 2015 Jan;272(1):83-9.

European Forum for Research and Education in Allergy and Airway Diseases (EUFOREA). European Position Paper on Rhinosinusitis and Nasal Polyps. 2020.

Higgins TS, Thorp B, Rawlings BA, et al. Outcome results of endoscopic vs craniofacial resection of sinonasal malignancies: a systematic review and pooled-data analysis. Int Forum Allergy Rhinol. 2011 Jul-Aug;1(4):255-61.

Kılıç S, Kılıç SS, Baredes S, et al. Comparison of endoscopic and open resection of sinonasal squamous cell carcinoma: a propensity score-matched analysis of 652 patients. Int Forum Allergy Rhinol. 2018 Mar;8(3):421-434.

Kim JS, Kwon SH. Recurrence of sinonasal inverted papilloma following surgical approach: A meta-analysis. Laryngoscope 2017;127(1):52-58.

Likness MM, Pallanch JF, Sherris DA, et al. Computed tomography scans as an objective measure of disease severity in chronic rhinosinusitis. Otolaryngol Head Neck Surg. 2014 Feb;150(2):305-11.

Lourijsen ES, Reitsma S, Vleming M, et al. Endoscopic sinus surgery with medical therapy versus medical therapy for chronic rhinosinusitis with nasal polyps: a multicentre, randomised, controlled trial. Lancet Respir Med. 2022 Apr;10(4):337-346.

Maru YK, Gupta Y. Concha bullosa: Frequency and appearances on sinonasal CT. Indian J Otolaryngol Head Neck Surg. 1999 Dec;52(1):40-4.

Ni JS, Kompelli AR, Nguyen SA, et al. The Sinus and Nasal Quality of Life Survey (SN-5) in the management of pediatric chronic rhinosinusitis: a systematic review and meta-analysis. Int J Pediatr Otorhinolaryngol. 2018;111:162-169.

Orlandi RR, Kingdom TT, Smith TL, et al. International consensus statement on allergy and rhinology: rhinosinusitis 2021. Int Forum Allergy Rhinol. 2021 Mar;11(3):213-739.

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. 2017 Feb;7(2):119-127.

Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (update): adult sinusitis. Otolaryngol Head Neck Surg. 2015;152(2 Suppl):S1-S39.

Saltagi MZ, Comer BT, Hughes S, et al. Management of recurrent acute rhinosinusitis: A systematic review. Am J Rhinol Allergy. 2021 Feb 23:1945892421994999.

Scangas GA, Gudis DA, Kennedy DW. The natural history and clinical characteristics of paranasal sinus mucoceles: a clinical review. Int Forum Allergy Rhinol. 2013 Sep;3(9):712-7.

Singh GB, Arora N, Tomar S, et al. The role of sinus CT in surgical treatment decisions for chronic rhinosinusitis. Am J Otolaryngol. 2020 Nov-Dec;41(6):102729.

Smith TL, Schlosser RJ, Mace JC, et al. Long-term outcomes of endoscopic sinus surgery in the management of adult chronic rhinosinusitis. Int Forum Allergy Rhinol. 2019 Aug;9(8):831-841.

Toros SZ, Bölükbasi S, Naiboğlu B, et al. Comparative outcomes of endoscopic sinus surgery in patients with chronic sinusitis and nasal polyps. Eur Arch Otorhinolaryngol. 2007 Sep;264(9):1003-8.

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). 2013 Dec;52(12):1091-7.

Wood AJ, Zhou L, Wilkinson S, et al. Effectiveness of extensive sinus surgery with post-operative medical management for chronic rhinosinusitis. J Laryngol Otol. 2017 Feb 20:1-6.

Zhang L, Zhang Y, Gao Y, et al. Long-term outcomes of different endoscopic sinus surgery in recurrent chronic rhinosinusitis with nasal polyps and asthma. Rhinology. 2020 Apr 1;58(2):126-135.

Policy History/Revision Information

Date	Summary of Changes
10/01/2023	Application
	Individual Exchange Plans
	Removed language indicating this Medical Policy does not apply to Individual Exchange benefit
	plans in the states of Massachusetts, Nevada, and New York
	Supporting Information
	Archived previous policy version 2023T0578N

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. 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.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. 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.