FUNCTIONAL ENDOSCOPIC SINUS SURGERY (FESS)

Policy Number: CS144.F

Effective Date: September 1, 2018

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced. The terms of the federal, state or contractual requirements for benefit plan coverage may differ greatly from the standard benefit plan upon which this Medical Policy is based. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage supersede this Medical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the contractual requirements for benefit plan coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines 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.

BENEFIT CONSIDERATIONS

Before using this policy, please check the federal, state or contractual requirements for benefit coverage.

COVERAGE RATIONALE

Functional endoscopic sinus surgery (FESS) is proven and medically necessary for one or more of the following:

- Individuals with chronic rhinosinusitis (defined as rhinosinusitis lasting longer than 12 weeks) with both of the following:
  - Chronic rhinosinusitis of the sinus to be operated on is confirmed on computed tomography (CT) scan by one or more of the following:
    - Mucosal thickening
    - Bony remodeling
    - Bony thickening or
    - Obstruction of the ostiomeatal complex
    - Opacified sinus
  - Symptoms persist despite medical therapy with one or more of the following:
    - Nasal lavage
    - Antibiotic therapy, if bacterial infection is suspected
    - Intranasal corticosteroids
- Mucocele documented on CT scan
- Concha bullosa documented on CT scan
Rhinosinusitis, also referred to as sinusitis, is inflammation of the mucosal membrane lining the nasal cavities and the paranasal sinuses. Rhinosinusitis lasting more than 12 weeks is classified as chronic rhinosinusitis (CRS) (Rosenfeld et al. 2015; Peters et al. 2014).

The goals of treating CRS are to eliminate underlying causes, reduce sinus inflammation, and drain nasal passages. Medical therapy is the first-line treatment for CRS. Treatments recommended may include nasal saline sprays, nasal lavage, antibiotic therapy, nasal corticosteroids, oral or injected corticosteroids, decongestants, over-the-counter pain relievers, and antihistamines.
relievers, leukotriene modifiers, and antihistamines. Patients who do not respond to medical therapy are candidates for sinus surgery (Marple et al. 2011).

Functional endoscopic sinus surgery (FESS) is a set of minimally invasive surgical techniques which allow direct visual examination and opening of the sinuses for the treatment of chronic rhinosinusitis which has not responded to medical treatment. 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**

**Functional Endoscopic Sinus Surgery (FESS)**

Sethi and Chakravarti (2016) conducted a single center, prospective interventional study to evaluate the role of FESS in refractory pediatric CRS and to assess the change in postoperative quality of life (QOL). Study included 35 children (aged between 6 and 12 years) with refractory CRS, not responding to 4 weeks of maximal medical therapy. Outcomes were evaluated via global assessment of Rhinosinusitis Symptom severity score and SN-5 QOL life score both preoperatively and 1 year post-surgery. Results demonstrated that 91.4% children showed an improvement in the total symptom severity score and in their QOL at 12 months. No major complications were encountered in any of the cases. The authors concluded that ESS is a safe and effective surgical management for children with CRS refractory to maximal medical therapy leading to an improvement in their QOL.

Koch et al. (2016) performed a prospective comparative study to assess benefit of FESS with septorhinoplasty (SRP) vs SRP alone in individuals with CRS with or without polyps and combined with a deformity of the outer nose. Participants (n=110) were equally divided into the 2 surgical groups. Prophylactic antibiotics and anesthesia were the same for both groups. The only difference between the 2 groups was actual operative time. There were no differences in postoperative inflammation or any other significant complication (e.g., bleeding, edema.) The authors concluded that the combined FESS and SRP is a safe and effective method without an increased risk of complications compared with SRP alone.

Wang et al. (2016) performed a single center comparative study to explore the effect of FESS on the treatment of bronchiectasis combined with CRS. 161 cases were divided into medication and operation groups according to their selected therapeutic method. For CRS, the operative group underwent FESS versus pharmacological therapy. The score of clinical symptoms for bronchiectasis, forced expiratory volume in one second (FEV1), sinusonal outcome test (SNOT-22 score), and Lund-Mackay score were evaluated for all cases before and after treatment, respectively, and then the value changes in the score of clinical symptoms, FEV1, SNOT-22 score, and Lund-Mackay score between both time points were calculated. The frequency of acute exacerbation for bronchiectasis was also recorded within the 6-month follow-up. This study revealed nearly 59% of cases with bronchiectasis also had CRS. Compared with pre-therapy, post-therapy symptoms and scores in both groups were all significantly decreased. At 6 months, the operation group experienced less frequent acute exacerbations and continued to exhibit improved clinical symptoms and assessment scores than the medication group. FEV1 did not improve in either group when compared with pre-therapy.

Dalziel et al. (2006) performed a systematic review of safety and effectiveness of FESS for the removal of nasal polyps. All randomized controlled trials (RCTs), nonrandomized comparative studies, and case series studies that described outcomes associated with FESS for the excision of nasal polyps were included. Forty-two publications comprised of 3 RCTs, 4 nonrandomized comparative studies, and 35 case series studies were included in the review. FESS was compared with endoscopic polypectomy, Caldwell-Luc, radical nasalization, and intranasal ethmoidectomy. In general, studies were of poor quality and lacked description of important variables influencing surgical outcome. Overall complications for FESS from case series studies ranged from 0.3 to 22.4%. Major complications ranged from 0 to 1.5% and minor complications ranged from 1.1 to 20.8% (median, 7.5%). The potentially most serious complications were cerebrospinal fluid leaks, injury to the internal carotid artery, dural exposure, meningitis, bleeding requiring transfusion, periorbital/orbital fat exposure, and orbital penetration. Symptomatic improvement ranged from 78 to 88% for FESS compared with 43 to 84% for comparative procedures. From case series, symptomatic improvement ranged from 40 to 98% (median, 88%). The authors concluded that FESS may offer some advantages in safety and effectiveness over comparative techniques, but wide variation in reported results and methodological shortcomings of studies limit the certainty of these conclusions.

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.

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 quality-of-life (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 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.

Regab et al. (2004) conducted a prospective, RCT evaluating and comparing the medical and surgical treatment of polypoid and nonpolypoid CRS. Ninety patients with CRS were equally randomized either to medical or surgical therapy. All patients underwent pre- and posttreatment assessments before starting the treatment, after 6 months, and after 1 year. Both the medical and surgical treatment of CRS significantly improved almost all the subjective and objective parameters of CRS, with no significant difference being found between the medical and surgical groups, except for the total nasal volume in CRS and CRS without polyposis groups, in which the surgical treatment demonstrated greater changes. The authors concluded that CRS should be initially targeted with maximal medical therapy (e.g., a 3 month course of a macrolide antibiotic, douche, and topical steroid), with surgical treatment being reserved for cases refractory to medical therapy. The authors indicated that the presence of nasal polyps is not a poor prognostic factor for the efficacy of CRS therapy, either surgical or medical.

Wood et al. (2017) performed a prospective study to prospectively 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 to medical treatment and prolonged medical therapy is recommended after FESS.

A number of nonrandomized, uncontrolled studies reported that FESS may be safe and effective for treating sinusitis (Damm et al. 2002; Khalid et al. 2004; Toros et al. 2007), mucocele (Scangas et al. 2013), and tumors (Pagella et al. 2012) including polyposis (Humayun et al. 2013; Djukic et al. 2015; Ehnhage et al. 2009).

**Professional Societies**

**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. 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 state that the indications for endoscopic sinus surgery include a history of one of more of the following (AAO-HNS, 2015):

- 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
American Academy of Allergy Asthma and Immunology (AAAA), the American College of Allergy Asthma and Immunology (ACAAI), and the Joint Council of Allergy Asthma and Immunology (JCAAI)

In a practice parameter for the diagnosis and management of rhinosinusitis, the AAAA, ACAAI, and JCAAI recommend 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 (Peters et al. 2014):

- 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 (Peters et al. 2014).

American College of Radiology (ACR)
The ACR Appropriateness Criteria for Sinonasal Disease states:

- 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. (ACR, 2013, reaffirmed 2017).

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

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.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for functional endoscopic sinus surgery (FESS). Local coverage determinations (LCDs) do not exist at this time.
(Accessed June 21, 2018)

REFERENCES


### POLICY HISTORY/REVISION INFORMATION

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/01/2018</td>
<td>Updated coverage rationale:</td>
</tr>
<tr>
<td></td>
<td>o Modified language to clarify [the listed service is] proven <strong>and</strong> medically</td>
</tr>
<tr>
<td></td>
<td>necessary</td>
</tr>
<tr>
<td></td>
<td>o Replaced reference to &quot;patients&quot; with &quot;individuals&quot;</td>
</tr>
<tr>
<td></td>
<td>Updated supporting information to reflect the most current description of</td>
</tr>
<tr>
<td></td>
<td>services, clinical evidence, and references</td>
</tr>
<tr>
<td></td>
<td>Archived previous policy version CS144.E</td>
</tr>
</tbody>
</table>