

FUNCTIONAL ENDOSCOPIC SINUS SURGERY (FESS)

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Related Policy
<ul style="list-style-type: none"> Balloon Sinus Ostial Dilation

INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify its policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

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.

CONDITIONS OF COVERAGE

Applicable Lines of Business/ Products	This policy applies to Oxford Commercial plan membership.
Benefit Type	General Benefits Package
Referral Required (Does not apply to non-gatekeeper products)	No
Authorization Required (Precertification always required for inpatient admission)	Yes ^{1,2}
Precertification with Medical Director Review Required	Yes ^{1,2}
Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)	Inpatient, Outpatient, Office
Special Considerations	<p>¹Precertification with review by a Medical Director or their designee is required.</p> <p>²Participating providers in the office setting: Precertification is required for services performed in the office of a participating provider. Non-participating/ out-of-network providers in the office setting:</p>

Special Considerations
(continued)

Precertification is not required, but is encouraged for out-of-network services performed in the office. If precertification is not obtained, Oxford will review for out-of-network benefits and medical necessity after the service is rendered.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine 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
- Complications of sinusitis such as abscess
- Tumor documented on CT scan (such as polyposis or malignancy)
- Recurrent Acute Rhinosinusitis (RARS)

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).

Chronic Rhinosinusitis (CRS): Chronic Rhinosinusitis 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.

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.

Recurrent Acute Rhinosinusitis (RARS): RARS has been defined as four episodes per year of Acute Rhinosinusitis with distinct symptom free intervals between episodes.

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 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

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DESCRIPTION OF SERVICES

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, 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 pharmacologics alone for the medication group. The score of clinical symptoms for bronchiectasis, forced expiratory volume in one second (FEV1), sinonasal 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 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.

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 refractory 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 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: (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.

REFERENCES

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2018T0578F]

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
10/01/2018	<ul style="list-style-type: none"> • Updated conditions of coverage/special considerations; modified notation to clarify: <ul style="list-style-type: none"> ○ For participating providers in the office setting: Precertification is required for services performed in the office of a participating provider ○ For non-participating/out-of-network providers in the office setting: Precertification is not required, but is encouraged for out-of-network services performed in the office; if precertification is not obtained, Oxford will review <i>for out-of-network benefits and</i> medical necessity after the service is rendered • Updated coverage rationale: <ul style="list-style-type: none"> ○ Modified language to clarify [the listed service is] proven and medically necessary ○ Replaced reference to “patients” with “individuals” • Updated supporting information to reflect the most current description of services, clinical evidence, and references • Archived previous version ENT 022.5 T2