

Sinus Surgery (Functional Endoscopic Sinus Surgery and Balloon Sinuplasty)

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Developed By: Medical Necessity Criteria Committee

I. Description

Functional endoscopic sinus surgery (FESS) is a minimally invasive technique in which sinus air cells and sinus ostia are opened using a rigid fiberoptic endoscope. Three factors are crucial in the normal physiologic functioning of the sinuses: a patent sinus ostia, normal mucociliary transport, and normal quantity and quality of secretions. Disruption of at least one of these factors can predispose a patient to inflammation and infection of the sinuses. FESS attempts to address the patency issue in patients with medically refractory chronic rhinosinusitis.

FESS is moderately effective for the treatment of recurrent acute or chronic infective sinusitis, chronic polyposis, mucocele, recurrent sinusitis aggravating pulmonary disease, sinus cysts and tumors, and uncomplicated rhinosinusitis. It has not been proven as effective treatment for allergic rhinitis. The goal of FESS is to return the mucociliary drainage of the sinuses to normal function. The paranasal sinuses are maintained in a healthy state by ventilation through the individual ostia and by a mucociliary transport mechanism that keeps a continuous protective layer of mucus flowing out of the sinuses (Slack&Bates).

Indications for balloon sinusplasty are somewhat similar to FESS. Balloon sinus ostial dilation (BSD) has been found to be most effective in the treatment of recurrent acute sinusitis (RARS) and chronic rhinosinusitis without nasal polyposis (CRSsNP) that has been refractory to medical therapy. Under direct vision or fluoroscopy, a thin catheter is inserted into the narrowed ostium, then a balloon is inflated under pressure to enlarge the opening by stretching the mucous membrane and creating a small bony fracture. Balloon sinuplasty has been developed as a less invasive alternative to functional endoscopic sinus surgery. Balloon sinuplasty is contraindicated in patients with polyps, eosinophilic mucosal membrane disease, sinonasal tumors, certain anatomical variants, and sinus disease with significant osteoneogenesis

For adults with recurrent acute sinusitis (RARS) or chronic sinusitis unresponsive to medical management, balloon sinuplasty or balloon ostial dilation is a procedure developed over the past decade in which the frontal, sphenoid, or maxillary sinus ostium is dilated using a balloon catheter. The procedure does not include surgical removal of tissue and can be performed in the office setting under local anesthesia. A registry of 1036 adult patients who received 3276 procedures had, at an average follow-up of 40 weeks, a revision rate of 1.3%. Although 95.2% of patients improved, the authors stated

that the study was not prospective or controlled, and it did not provide a comparative analysis of outcomes for sinus disease categorized by clinical staging. An observational study of 82 adults (with 313 ostial dilations) found that there was significant improvement in symptom scores and medication use at 1-year follow-up. The authors noted that the study had two structural limitations: symptom scores that were dependent upon patient recall and thus subject to bias, and lack of a control group to assess for placebo effect or other variables that could confound the outcomes. An observational study of 59 adults (with 107 ostial dilations) found, at 2-year follow-up, that there was significant improvement in symptom scores, although the authors noted the potential for a self-reporting bias to contribute to the improvement in symptom scores. A single-center study of 45 consecutive patients with chronic rhinosinusitis originally scheduled to undergo functional endoscopic sinus surgery who elected balloon sinuplasty of the frontal, maxillary, or sphenoid sinuses noted a failure rate of 65%, leading to the study's early cessation. A randomized double-blind study of 32 adult patients (50 sinuses) that compared sinuplasty with or without functional endoscopic sinus surgery to a Draf 1 procedure (complete removal of the anterior ethmoid cells and uncinate process surrounding the frontal recess to the frontal ostium) found, at 12-month follow-up, that both groups had significant improvement in symptom and radiologic extent of chronic rhinosinusitis scores. Additional larger, controlled studies were recommended. Cohort studies and randomized controlled trials have shown that balloon sinuplasty can result in long-term improvement in sinus symptoms and is not inferior to functional endoscopic sinus surgery.

For children with chronic sinusitis unresponsive to medical management, evidence for balloon sinuplasty is insufficient, and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. A prospective study of 30 children (56 sinuses) with chronic rhinosinusitis who failed medical therapy and underwent balloon sinuplasty reported that 51 of 56 sinuses were successfully dilated, as validated by nasal endoscopy and fluoroscopy. No short-term or long-term postoperative results were reported. The authors concluded that although the procedure is attractive in children because there is no bone or tissue removal, there are concerns about radiation exposure during fluoroscopy. A follow-up study of 32 children, of which 24 completed the 52-week follow-up, reported that 12 patients had significant improvement in Sino-Nasal-5 scores, 7 had moderate improvement, 2 had mild improvement, 1 had no improvement, and 2 had worsening. Additional studies comparing balloon sinuplasty with other treatment modalities were recommended. An observational study of 31 pediatric patients with chronic rhinosinusitis who failed medical therapy compared balloon sinuplasty and ethmoidectomy to functional endoscopic sinus surgery and reported that, at a mean follow-up of 9 months, there was no significant difference in overall improvement in sinus symptoms. Larger, long-term studies were recommended to more accurately identify patients who would benefit from the procedures as well as to determine if balloon sinuplasty alone would provide a better outcome as compared with functional endoscopic sinus surgery.

II. Criteria: CWQI HCS-0158A

- A. Sinus surgery is requested for 1 or more of the following:
 - a. **Functional endoscopic sinus surgery (FESS)** is indicated for **1 or more** of the following:
 - i. Suspected allergic fungal sinusitis with evidence of disease by CT imaging that indicates but not limited to **ALL** of the following:
 1. Nasal polyposis
 2. Eosinophilic mucus

3. Computerized Tomographic (CT) scanning consistent with ARS (e.g. bony erosion or thinning, partial or complete opacification)
- ii. Antrochoanal polyp documented by CT imaging
- iii. Cerebrospinal fluid (CSF) rhinorrhea or conditions in which there is a skull base defect
- iv. Chronic rhino-sinusitis (with or without nasal polyps) with all of the following;
 1. Lasted longer than 12 weeks
 2. Persistent symptoms that have failed maximal medical treatment such as saline irrigations, antibiotics therapy, and intra-nasal corticosteroids
 3. Objective evidence of disease by CT imaging as evidenced by ostial obstruction or infection (e.g. but not limited to, air fluid levels, air bubbles, mucosal thickening, pansinusitis, or diffuse opacification)
- v. Complications of sinusitis, including abscess (brain and sub-periosteal) and extension to adjacent structures
- vi. Endonasal endoscopic hypophysectomy for pituitary adenoma
- vii. Endoscopic orbital decompression for Graves ophthalmopathy, with or without optic nerve decompression
- viii. Para-nasal sinus mucocele documented by CT imaging (excluding benign, asymptomatic mucus retention cysts)
- ix. Recurrent acute rhino-sinusitis (RARS) with all of the following;
 1. Two or more of the following symptoms
 - a. Nasal obstruction
 - b. Headache, pressure, facial pain (other causes have been ruled out) and/or fullness over the affected sinus
 - c. Decreased sense of smell
 - d. Anterior or posterior foul drainage
 2. Either of the following
 - a. 4 or more documented episodes within 12 continuous months
 - b. Chronic sinusitis (e.g. more than 12 weeks)
 3. Has failed maximal medical treatment as indicated by ALL of the following;
 - a. Saline irrigations at least 6 weeks
 - b. Antibiotics therapy, for a minimum of 2 weeks
 - c. Intranasal corticosteroids for at least 6 weeks
 - d. Allergy testing, if symptoms are consistent with allergic rhinitis and have not responded to appropriate environmental controls and pharmacotherapy [antihistamines, intranasal corticosteroids, leukotriene antagonists, etc].
 4. Objective evidence of disease by CT imaging as evidenced by ostial obstruction or infection (e.g. but not limited to, air fluid levels, air bubbles, mucosal thickening, pansinusitis or diffuse opacification)
- x. Sino-nasal polyposis with nasal airway obstruction or sub-optimal asthma control (forced expiratory volume in 1 second (FEV1) of less than 80% despite maximal medical treatment such as saline irrigations, antibiotics if bacterial infection is suspected, and intranasal corticosteroids
- xi. Unilateral para-nasal sinus opacification, symptomatic or asymptomatic, consistent with;

1. Chronic rhino-sinusitis (with or without nasal polyps) (see related indications in criteria above)
 2. Fungus ball
 3. Benign neoplasm e.g. sino-nasal inverted papilloma
- xii. Uncomplicated sinusitis (e.g. Sinusitis confined to paranasal sinuses without adjacent involvement of neurologic, soft tissue or bony structures)
- b. Moda Health considers FESS experimental or investigational for all other indications
- c. Moda Health considers revision FESS medically necessary when all the following are met:
- i. It has been at least 12 weeks since the previous FESS
 - ii. Chronic rhino-sinusitis has been present for at least 12 continuous weeks
 - iii. Failure of at least a minimum of 2 weeks course of antibiotics since the previous FESS
 - iv. Persistent objective evidence of sinus disease as documented by CT imaging
- d. Moda Health considers revision FESS experimental or investigational for all other indications
- e. **Sinus ostial dilation with a balloon (balloon sinuplasty)** is indicated for the treatment of uncomplicated sinusitis when ALL of the following requirements are met;
- i. Two or more of the following:
 1. Nasal obstruction
 2. Anterior/posterior mucopurulent (foul) drainage
 3. Facial pain, pressure, headache (when other causes have been ruled out), and/or fullness over the affected sinus
 4. Decreased sense of smell
 - ii. Either of the following:
 1. Four or more documented episodes of acute rhinosinusitis (less than 4 weeks duration) in 1 year
 2. Chronic rhinosinusitis (greater than 12 weeks in duration)
 - iii. Maximum medical therapy has been tried with all of the following:
 1. Antibiotics therapy for 2-3 weeks
 2. Nasal steroids for at least 6 weeks
 3. Saline nasal irrigation for at least 6 weeks
 4. Allergy testing (if symptoms are consistent with allergic rhinitis and have not responded to appropriate environmental controls and pharmacotherapy [e.g., anti-histamines or intranasal corticosteroids])
 - iv. Abnormal findings from diagnostic workup, as indicated by CT findings suggestive of evidence of inflammation with at least one of the following indications:
 1. Opacification of sinus cavity, or
 2. Air fluid levels, or
 3. Mucosal thickening of at least 2mm
 - v. Balloon sinuplasty is limited to the frontal, maxillary or sphenoid sinuses
 - vi. Balloon sinuplasty is performed either as a stand-alone procedure or as part of functional endoscopic sinus surgery (FESS)
- f. Moda Health considers balloon sinuplasty experimental or investigational for any of the following (not an all-inclusive list):

- i. Bony dysplasia (including but not limited to fibrous dysplasia, Paget’s disease)
 - ii. Allergic fungal rhinosinusitis
 - iii. History of failed balloon procedure to be treated
 - iv. Isolated ethmoid sinus disease
 - v. Mucocele causing sinusitis
 - vi. Nasal polyposis (grade 2 or greater)
 - vii. Repeat balloon procedure in any of the sinuses
 - viii. Samter’s triad (aspirin sensitivity)
 - ix. Sinusitis secondary to autoimmune or connective tissue disorders (i.e., including, but not limited to, sarcoidosis, granulomatosis with polyangiitis [PGA])
 - x. Sinusitis secondary to ciliary dysfunction, (i.e., including but not limited to, cystic fibrosis, Kartagener’s syndrome)
 - xi. Suppurative or non-suppurative complications of sinusitis including extension to adjacent structures such as the orbit or central nervous system
 - xii. Suspected or known sino-nasal benign or malignant tumor (including but not limited to squamous cell, adenoid cystic or adenocarcinoma, inverted papilloma)
- g. Balloon sinuplasty is **NOT** requested for children 12 years of age or younger. There is insufficient evidence in the medical literature to support the safety and effectiveness of balloon sinuplasty in the treatment of rhinosinusitis in children.

III. Information Submitted with the Prior Authorization Request:

1. Chart notes documenting symptoms and previous conservative treatment failures
2. Imaging studies
3. Laboratory reports

IV. CPT or HCPC codes covered:

Codes	Description
31237	Nasal/sinus endoscopy, surgical; with biopsy, polypectomy or debridement (separate procedure)
31238	Nasal/sinus endoscopy, surgical; with control of nasal hemorrhage
31239	Nasal/sinus endoscopy, surgical; with dacryocystorhinostomy
31240	Nasal/sinus endoscopy, surgical; with concha bullosa resection
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 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, with or without removal of tissue from frontal sinus
31287	Nasal/sinus endoscopy, surgical, with sphenoidotomy
31288	Nasal/sinus endoscopy, surgical, with sphenoidotomy; with removal of tissue from the sphenoid sinus
31290	Nasal/sinus endoscopy, surgical, with repair of cerebrospinal fluid leak; ethmoid region
31291	Nasal/sinus endoscopy, surgical, with repair of cerebrospinal fluid leak; sphenoid region
31292	Nasal/sinus endoscopy, surgical; with medial or inferior orbital wall decompression
31293	Nasal/sinus endoscopy, surgical; with medial orbital wall and inferior orbital wall decompression
31294	Nasal/sinus endoscopy, surgical; with optic nerve decompression
31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa
31296	Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation)
31297	Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation)
31298	Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (eg, balloon dilation)

V. Annual Review History

Review Date	Revisions	Effective Date
10/28/2015	New Moda criteria adopted from MCG® guidelines for Functional Endoscopic Sinus Surgery and Sinuplasty	02/01/2016
06/28/2017	Review: Upgraded to new template, changed policy and added criteria to approve balloon sinuplasty	07/01/2017
8/2018	Annual Review- updated from MCG™ 22 nd Edition guidelines for FESS; added new CPT codes- added ICD-10 codes; added additional indication for balloon sinuplasty	08/22/2018
10/2019	Annual Review: No changes	11/01/2019
01/27/2021	Annual Review: AllMed and HCS review. Rewording and grammar updates for the Description. Rewording and adding missing requirements for FESS, Recurrent acute rhino-sinusitis and Balloon sinuplasty sections.	02/01/2021
01/26/2021	Annual Review: no changes	02/01/2022
02/22/2023	Annual Review: no changes	03/01/2023

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Appendix 1 – Applicable ICD-10 diagnosis codes:

Codes	Description
J32.0	Chronic maxillary sinusitis
J32.1	Chronic frontal sinusitis
J32.3	Chronic sphenoidal sinusitis
J32.4	Chronic pansinusitis
J32.8	Other chronic sinusitis
J32.9	Chronic sinusitis, unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s):

NCD/LCD Document (s):

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC