Sinus Surgery
(Functional Endoscopic Sinus Surgery and Balloon Sinuplasty)

Date of Origin: 10/2015
Last Review Date: 06/28/2017
Effective Date: 07/01/2017

Dates Reviewed: 10/2015, 06/2017

Developed By: Medical Necessity Criteria Committee

I. Description

Chronic sinusitis is an inflammatory disorder of the sinonasal mucosa. Surgical treatment should only be attempted after failure of conservative treatment (i.e. analgesics, saline irrigation, intranasal glucocorticoids, oral decongestants, and antibiotics for bacterial infections).

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 ostiomeatal complex, 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 allergic fungal 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.

Balloon sinuplasty is used as a treatment for ostial narrowing of the paranasal sinuses. 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.

For adults with 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. While noninvasive dilation of sinus ostial obstruction may be an effective means of providing sinus drainage in some patients with recalcitrant chronic sinusitis, isolated frontal, maxillary, or sphenoid sinus disease that may be amenable to such therapy is probably uncommon. The goals of surgery for chronic sinusitis
extend beyond simply enlarging an ostial opening, and include removal of inflamed tissue and bone; surgical endoscopy and pathology are used to aid in diagnosis. 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 is insufficient, conflicting, or poor 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-0024
   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. Allergic fungal rhinitis with **1 or more** of the following:
      1. Chronic sinus polyposis that has not responded adequately to 1 or more months of medical treatment (e.g. nasal steroids, antibiotics)
      2. Mucocele
      3. Recurrent sinusitis that triggers or aggravates pulmonary disease (e.g. asthma, cystic fibrosis)
      4. Suppurative complication of sinusitis (e.g. subperiostial abscess, brain abscess)
      5. Symptomatic sinus osteoma, as seen on imaging
      6. Tumor, suspected or seen on imaging, physical examination, or endoscopy
   ii. Uncomplicated rhinosinusitis and **ALL of the following**:
      1. Abnormal findings from diagnostic evaluation, including **1 or more** of the following:
         a. Mucocele
         b. Negative CT scan but significant disease found on nasal endoscopy
         c. Obstruction or active infection on CT scan
         d. Obstructive symptoms due to polyposis
      2. Inadequate response to maximal therapy that included **ALL of the following**:
         a. Allergy assessment
         b. Nasal lavage
         c. Trial of 2 or more antibiotic courses
         d. Trial of nasal steroids
      3. Significant rhinosinusitis, as indicated by **ALL of the following**:
         a. Chronic rhinosinusitis that interferes with lifestyle
         b. Four or more documented episodes of acute rhinosinusitis in 1 year.

b. Sinus ostial dilation with a balloon (balloon sinuplasty) is indicated with **ALL of the following**:
   i. Chronic rhinosinusitis of the sinus to be dilated is confirmed on CT scan. The CT scan finding of chronic rhinosinusitis included **1 or more** of the following:
      1. Mucosal thickening
      2. Bony remodeling
      3. Bony thickening, or
      4. Obstruction of the ostiomeatal complex
   ii. Patient has **1 or more** of following symptoms:
      1. Anterior or posterior mucopurulent nasal discharge
      2. Nasal obstruction
      3. Facial pain, pressure, and fullness
      4. Decreased or lost sense of smell
   iii. Balloon sinuplasty is limited to the frontal, maxillary or sphenoid sinuses
   iv. Balloon sinuplasty is performed either as a stand-alone procedure or as part of functional endoscopic sinus surgery (FESS)
   v. Balloon sinuplasty is performed in patients older than 12 years of age whose symptoms persist longer than 12 weeks despite medical therapy with **1 or more** of the following:
      1. Nasal lavage
2. Antibiotic therapy for greater than or equal to 3 weeks
3. Intranasal corticosteroids for greater than or equal to 4 weeks
c. Balloon sinuplasty is NOT requested for the treatment of nasal polyps or tumors. There is insufficient evidence in the medical literature to support the safety and effectiveness for treatment of nasal polyps or tumors.
d. 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:

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<thead>
<tr>
<th>Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>31237</td>
<td>Nasal/sinus endoscopy, surgical; with biopsy, polypectomy or debridement separate procedure</td>
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<tr>
<td>31238</td>
<td>Nasal/sinus endoscopy, surgical; with control of nasal hemorrhage</td>
</tr>
<tr>
<td>31239</td>
<td>Nasal/sinus endoscopy, surgical; with dacryocystorhinostomy</td>
</tr>
<tr>
<td>31240</td>
<td>Nasal/sinus endoscopy, surgical; with concha bullosa resection</td>
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<tr>
<td>31254</td>
<td>Nasal/sinus endoscopy, surgical; with ethmoidectomy, partial (anterior)</td>
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<td>31255</td>
<td>Nasal/sinus endoscopy, surgical; with ethmoidectomy, total (anterior and posterior)</td>
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<td>31256</td>
<td>Nasal/sinus endoscopy, surgical, with maxillary antrostomy</td>
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<tr>
<td>31267</td>
<td>Nasal/sinus endoscopy, surgical, with maxillary antrostomy; with removal of tissue from maxillary sinus</td>
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<tr>
<td>31276</td>
<td>Nasal/sinus endoscopy, surgical with frontal sinus exploration, with or without removal of tissue from frontal sinus</td>
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<td>31287</td>
<td>Nasal/sinus endoscopy, surgical, with sphenoidotomy</td>
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<td>31288</td>
<td>Nasal/sinus endoscopy, surgical, with sphenoidotomy; with removal of tissue from the sphenoid sinus</td>
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<td>31290</td>
<td>Nasal/sinus endoscopy, surgical, with repair of cerebrospinal fluid leak; ethmoid region</td>
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<td>31291</td>
<td>Nasal/sinus endoscopy, surgical, with repair of cerebrospinal fluid leak; sphenoid region</td>
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<td>31292</td>
<td>Nasal/sinus endoscopy, surgical; with medial or inferior orbital wall decompression</td>
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<td>Code</td>
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<tr>
<td>31293</td>
<td>Nasal/sinus endoscopy, surgical; with medial orbital wall and inferior orbital wall decompression</td>
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<td>31295</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa</td>
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<td>31297</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation)</td>
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VI. Annual Review History

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<tr>
<th>Review Date</th>
<th>Revisions</th>
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<tr>
<td>10/28/2015</td>
<td>New Moda criteria adopted from MCG® guidelines for Functional Endoscopic Sinus Surgery and Sinuplasty</td>
<td>02/01/2016</td>
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<td>06/28/2017</td>
<td>Review: Upgraded to new template, changed policy and added criteria to approve balloon sinuplasty</td>
<td>07/01/2017</td>
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VII. References

• Sedaghat AR, Cunningham MJ. Does balloon catheter sinuplasty have a role in the surgical management of pediatric sinus disease? Laryngoscope 2011;121(10):2053-4. DOI: 10.1002/lary.21929.


• Browning GG. Updating a Cochrane review of endoscopic balloon dilation for chronic rhinosinusitis: A randomised controlled trial that is biased in its reporting. Clinical Otolaryngology 2012;37(3):222.


Appendix 1 – 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):

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<th>NCD/LCD Document(s):</th>
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NCD/LCD Document(s):

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Medicare Part B Administrative Contractor (MAC) Jurisdictions

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