Introduction

Sinusitis refers to infection or inflammation of the sinuses, which are small openings in the bones of the face. Sinusitis may develop after a respiratory illness. Symptoms include a stuffy nose, facial pain and discharge from the nose. Most sinus infections will get better without any specific treatment. For some people, sinus symptoms may last for months, and this is called chronic sinusitis. Standard therapy to treat chronic sinusitis may include decongestants, antibiotics, saline irrigation and the use of nasal spray containing steroids. When chronic sinusitis does not respond to standard medical treatments, then surgery may be the next step. Surgery can usually be done in an outpatient setting using a small scope that allows the doctor to see changes and treat them with tiny cutting tools. A new technology which includes a balloon to dilate blocked sinuses may also be helpful for some types of sinusitis.

This policy outlines the history and therapies that are recommended before proceeding to a sinus surgery for chronic sinusitis. There are other sinus conditions that may need surgery as a treatment, and those are listed in the policy as well. Sinus surgery that is not performed in a hospital operating room requires health plan pre-approval.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs providers about when a service may be covered.
Site of service is defined as the location where the surgical procedure is performed, such as an off campus-outpatient hospital or medical center, an on campus-outpatient hospital or medical center, an ambulatory surgical center, or an inpatient hospital or medical center.

### Site of Service for Elective Surgical Procedures

**Medical Necessity**

- Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. These are the preferred medically necessary sites of service for certain elective surgical procedures.

<table>
<thead>
<tr>
<th>Medically necessary sites of service:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Off campus-outpatient hospital/medical center</td>
</tr>
<tr>
<td>• On campus-outpatient hospital/medical center</td>
</tr>
<tr>
<td>• Ambulatory Surgical Center</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Inpatient hospital/medical center</th>
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</thead>
</table>

- Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. This site is considered medically necessary only when the patient has a clinical condition which puts him or her at increased risk for complications including any of the following (this list may not be all inclusive):

  - Anesthesia Risk
    - ASA classification III or higher (see definition)
    - Personal history of complication of anesthesia
    - Documentation of alcohol dependence or history of cocaine use
    - Prolonged surgery (>3 hours)
  - Cardiovascular Risk
    - Uncompensated chronic heart failure (NYHA class III or IV)
    - Recent history of myocardial infarction (MI) (<3 months)
    - Poorly controlled, resistant hypertension*
    - Recent history of cerebrovascular accident (<3 months)
    - Increased risk for cardiac ischemia (drug eluting stent placed <1 year or angioplasty <90 days)
    - Symptomatic cardiac arrhythmia despite medication
### Site of Service for Elective Surgical Procedures

<table>
<thead>
<tr>
<th>Medical Necessity</th>
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<tbody>
<tr>
<td>o Significant valvular heart disease</td>
</tr>
<tr>
<td>** Liver Risk **</td>
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<tr>
<td>o Advance liver disease (MELD Score &gt; 8)**</td>
</tr>
<tr>
<td>** Pulmonary Risk **</td>
</tr>
<tr>
<td>o Chronic obstructive pulmonary disease (COPD) (FEV1 &lt;50%)</td>
</tr>
<tr>
<td>o Poorly controlled asthma (FEV1 &lt;80% despite treatment)</td>
</tr>
<tr>
<td>o Moderate to severe obstructive sleep apnea (OSA)***</td>
</tr>
<tr>
<td>** Renal Risk **</td>
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<tr>
<td>o End stage renal disease (on dialysis)</td>
</tr>
<tr>
<td>** Other **</td>
</tr>
<tr>
<td>o Morbid obesity (BMI ≥ 50)</td>
</tr>
<tr>
<td>o Pregnancy</td>
</tr>
<tr>
<td>o Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP**** does not meet this criteria])</td>
</tr>
<tr>
<td>o Anticipated need for transfusion(s)</td>
</tr>
</tbody>
</table>

* 3 or more drugs to control blood pressure  
*** Moderate-AHI≥15 and ≤ 30, Severe-AHI ≥30  
****DDAVP-Deamino-Delta-D-Arginine Vasopressin (Desmopressin)

### Inpatient hospital/medical center

This site of service is considered NOT medically necessary for certain elective surgical procedures when the site of service criteria listed above are not met.

### Note:
The policy applies to individuals 19 years of age or older.

### Condition | Medical Necessity
---|---
**Functional Endoscopic Sinus Surgery (FESS)** | **Functional endoscopic sinus surgery (FESS) may be considered medically necessary when there have been:**
| Recurrent acute bacterial rhinosinusitis | - Four or more documented episodes of acute bacterial rhinosinusitis within 12 continuous months |

**Note:** Depending on symptoms
<table>
<thead>
<tr>
<th>Condition</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chronic rhinosinusitis with or without polyposis</strong>&lt;br&gt;Note: Depending on symptoms and imaging findings, medically necessary surgery could be unilateral or bilateral.</td>
<td><strong>Functional endoscopic sinus surgery (FESS) may be considered medically necessary when:</strong>&lt;br&gt;• Chronic rhinosinusitis has been present for at least 12 continuous weeks&lt;br&gt;<strong>AND</strong>&lt;br&gt;• Medical therapy consisting of the following has been tried and failed:&lt;br&gt;  o At least one 5-7-day course of antibiotics within the last 6 months&lt;br&gt;<strong>AND</strong>&lt;br&gt;  o Topical intranasal steroids OR daily saline nasal irrigation for at least 6 consecutive weeks&lt;br&gt;<strong>AND</strong>&lt;br&gt;  o There is objective evidence of sinus disease as demonstrated by ONE of the following:&lt;br&gt;    ▪ Sinus computed tomography or magnetic resonance imaging showing significant mucosal thickening, or polyps, or opacification of the paranasal sinuses, or sinus ostial obstruction;&lt;br&gt;    <strong>OR</strong>&lt;br&gt;    ▪ Nasal endoscopy showing purulent mucus or edema in the middle meatus or ethmoid region, or polyps in the nasal cavity or middle meatus.</td>
</tr>
</tbody>
</table>
### Condition

**Medical Necessity**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Medical Necessity</th>
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<tbody>
<tr>
<td></td>
<td>sinus ostial obstruction</td>
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<tr>
<td></td>
<td><strong>OR</strong></td>
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<tr>
<td></td>
<td>▪ Nasal endoscopy showing purulent mucus or edema in the middle meatus or ethmoid region, or polyps in the nasal cavity or middle meatus.</td>
</tr>
<tr>
<td><strong>Revision surgery</strong></td>
<td><strong>Functional endoscopic sinus surgery (FESS) may be considered medically necessary for revision surgery when the following criteria are met:</strong></td>
</tr>
<tr>
<td></td>
<td>• At least 12 weeks have passed since previous surgery</td>
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<tr>
<td></td>
<td><strong>AND</strong></td>
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<tr>
<td></td>
<td>• Chronic rhinosinusitis has been present for at least 12 continuous weeks</td>
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<td></td>
<td><strong>AND</strong></td>
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<tr>
<td></td>
<td>• Medical therapy consisting of the following has been tried and failed:</td>
</tr>
<tr>
<td></td>
<td>o At least one 5-7 day course of antibiotics since the previous surgery</td>
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<td></td>
<td><strong>AND</strong></td>
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<td></td>
<td>o There is persistent objective evidence of sinus disease as demonstrated by one of the following:</td>
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<tr>
<td></td>
<td>▪ Sinus computed tomography or magnetic resonance imaging showing significant mucosal thickening, or polyps or opacification of the paranasal sinuses, or sinus ostial obstruction</td>
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<tr>
<td></td>
<td><strong>OR</strong></td>
</tr>
<tr>
<td></td>
<td>▪ Nasal endoscopy showing purulent mucus or edema in the middle meatus or ethmoid region, or polyps in the nasal cavity or middle meatus.</td>
</tr>
<tr>
<td><strong>Diagnoses considered medically necessary for FESS</strong></td>
<td><strong>Functional endoscopic sinus surgery (FESS) may be considered medically necessary when the following diagnoses are present.</strong></td>
</tr>
<tr>
<td></td>
<td>• Multiple nasal polyps (aka antrochoanal polyps)</td>
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<tr>
<td></td>
<td>• Cerebrospinal fluid (CSF) leak closure</td>
</tr>
<tr>
<td></td>
<td>• Choanal atresia repair</td>
</tr>
<tr>
<td></td>
<td>• Dacryocystorhinostomy (DCR)</td>
</tr>
<tr>
<td></td>
<td>• Epistaxis control</td>
</tr>
<tr>
<td></td>
<td>• Excision of selected tumors and nasal masses</td>
</tr>
<tr>
<td>Condition</td>
<td>Medical Necessity</td>
</tr>
<tr>
<td>-----------</td>
<td>------------------</td>
</tr>
</tbody>
</table>
|           | • Foreign body removal  
|           | • Optic nerve decompression  
|           | • Orbital decompression (eg, Graves ophthalmopathy)  
|           | • Recurrent sinusitis in people who have cystic fibrosis or severe asthma  
|           | • Sinus mucoceles  
|           | • Sinus disease has eroded into the bone  
|           | • Sinus disease in the immune compromised  
|           | • Sinus disease for invasive fungal disease  
|           | • Sinus disease for allergic fungal sinus disease  
|           | • Sinus disease related to Wegener’s granulomatosis  
|           | • Sinus disease related to hereditary hemorrhagic telangiectasia  
|           | • Sinus disease related to scarring or osteoneogenic changes  

### Balloon Sinus Ostial Dilation

**Chronic rhinosinusitis**

**Balloon sinus ostial dilation may be considered medically necessary when the following criteria are met:**

- Chronic rhinosinusitis symptoms have been present for at least 12 continuous weeks

**AND**

- Medical therapy consisting of the following has been tried and failed:
  - At least one 5-7 day course of antibiotics
  - Topical intranasal steroids or daily saline nasal irrigation for at least 6 consecutive weeks
  - There is objective evidence of sinus disease as demonstrated by one of the following:
    - Sinus computed tomography or magnetic resonance imaging showing significant mucosal thickening, or polyps, or opacification of the paranasal sinuses, or sinus ostial obstruction
  - Nasal endoscopy showing purulent mucus or edema in
Condition | Medical Necessity
--- | ---
 | the middle meatus or ethmoid region, or polyps in the nasal cavity or middle meatus.

Documentation Requirements

For recurrent acute bacterial rhinosinusitis (4 or more episodes within 12 continuous months of bacterial infection of the sinuses), chronic rhinosinusitis with or without polyposis (inflammation and swelling for at least 12 continuous weeks with or without the presence of polyps), and revision surgery (12 weeks since the previous surgery and chronic rhinosinusitis for at least 12 continuous weeks) written documentation in the medical record must include:

1. Onset and duration of symptoms
2. Maximal medical therapy tried and failed:
   - At least one course of oral antibiotics of 5-7 days within the last 6 months
   - Use of topical intranasal steroids OR daily saline nasal irrigation for a minimum of 4 consecutive weeks
3. Copy of the CT scan or MRI results, if done, or result of nasal endoscopy during the course of illness, that shows sinus pathology amenable to surgical treatment (a sinus condition that would likely benefit from surgery)

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>31253</td>
<td>Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including frontal sinus exploration, with removal of tissue from frontal sinus, when performed (new code effective 1/1/18)</td>
</tr>
<tr>
<td>31254</td>
<td>Nasal/sinus endoscopy, surgical; with ethmoidectomy, partial (anterior)</td>
</tr>
<tr>
<td>31255</td>
<td>Nasal/sinus endoscopy, surgical; with ethmoidectomy, total (anterior and posterior)</td>
</tr>
<tr>
<td>31256</td>
<td>Nasal/sinus endoscopy, surgical, with maxillary antrostomy;</td>
</tr>
<tr>
<td>31257</td>
<td>Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including sphenoidotomy (new code effective 1/1/18)</td>
</tr>
<tr>
<td>31259</td>
<td>Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including sphenoidotomy, with removal of tissue from the sphenoid sinus (new code</td>
</tr>
</tbody>
</table>
### Definition of Terms

**American Society of Anesthesiologists (ASA) Score:**

- **ASA 1** A normal healthy patient.
- **ASA 2** A patient with mild systemic disease.
- **ASA 3** A patient with severe systemic disease.
- **ASA 4** A patient with severe systemic disease that is a constant threat to life.
- **ASA 5** A moribund patient who is not expected to survive

**New York Heart Association (NYHA) Classification:**

- **Class I** No symptoms and no limitation in ordinary physical activity, eg, shortness of breath when walking, climbing stairs etc.
**Class II** Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.

**Class III** Marked limitation in activity due to symptoms, even during less-than-ordinary activity, eg, walking short distances (20–100 m). Comfortable only at rest.

**Class IV** Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients.

**Recurrent acute rhinosinusitis:** Four or more acute episodes per year of acute bacterial rhinosinusitis, without persistent symptoms between episodes.

**Rhinosinusitis:** Symptomatic inflammation of the paranasal sinuses and nasal cavity. The term rhinosinusitis is preferred because sinusitis is almost always accompanied by inflammation of the contiguous nasal mucosa. Rhinosinusitis may be further classified by duration.

- **Acute rhinosinusitis:** Symptoms lasting less than 4 weeks.
  - May be further classified into acute bacterial rhinosinusitis versus acute viral rhinosinusitis
  - Cardinal symptoms include nasal obstruction, facial pain-pressure, purulent nasal drainage

- **Chronic rhinosinusitis:** Symptoms lasting more than 12 weeks, with or without acute exacerbations. This is characterized by two or more symptoms, one of which is nasal blockage/obstruction/congestion or nasal discharge (anterior/posterior nasal drip), with or without facial pain/pressure and reduction or loss of smell with endoscopic evidence of mucopurulence, edema, and/or polyps and/or CT presence of mucosal thickening or air-fluid levels in the sinuses.

**Uncomplicated versus complicated rhinosinusitis:** Complicated indicates clinical extension of inflammation outside the paranasal sinuses and nasal cavity at the time of diagnosis.

**Consideration of Age**

A 2015 systematic review included 29 studies of the highest quality evidence which focused on therapies for adult chronic sinusitis (PMID 26325561). Much of the other current literature assesses adult patients, thus resulting in the focus of this policy.
Evidence Review

Description

**Functional Endoscopic Sinus Surgery**

Chronic rhinosinusitis (CRS) is a common chronic condition associated with significant morbidity. Functional endoscopic sinus surgery (FESS) involves the removal of varying amounts of tissue and the opening of sinus ostia to treat CRS in individuals who have failed medical therapy.

Functional endoscopic sinus surgery (FESS) is a minimally invasive, mucosal-sparing surgical technique used to treat medically refractory chronic rhinosinusitis with or without polyps or recurrent acute rhinosinusitis. Rigid endoscopes are employed to visualize the surgical field to achieve one or more of the following goals: (1) to open the paranasal sinuses to facilitate ventilation and drainage from the paranasal sinuses; (2) to remove polyps and/or osteitic bony fragments to reduce the inflammatory load; (3) to enlarge the sinus ostia to achieve optimal instillation of topical therapies; and (4) to obtain bacterial or fungal cultures and tissue for histopathology. In the majority of cases, the surgical procedure is performed entirely through the nostrils, leaving no external scars.

**Balloon Sinus Ostial Dilation**

Balloon ostial dilation (also known as balloon sinuplasty) is proposed as an alternative to traditional endoscopic sinus surgery for patients with chronic rhinosinusitis who fail medical management. The procedure involves placing a balloon in the sinus ostium and inflating the balloon to stretch the opening. It can be performed as a stand-alone procedure or as an adjunctive procedure to functional endoscopic sinus surgery (FESS).

Background

**Functional Endoscopic Sinus Surgery**

**Chronic Rhinosinusitis**

Chronic rhinosinusitis (CRS) is a highly prevalent inflammatory disorder of the paranasal sinuses and the mucosa of the nasal passages that affects 3% to 7% of adults.¹ In adults, CRS is
characterized by symptoms related to nasal and sinus obstruction and inflammation, including mucopurulent nasal drainage, nasal congestion, facial pain or pressure, and anosmia or hyposmia, that persist for at least 12 weeks.

Three CRS subtypes exist, and may have somewhat different treatment strategies: CRS without nasal polyposis; CRS with nasal polyposis; and allergic fungal sinusitis. The latter is a less common subtype thought to result from chronic allergic inflammation to colonizing nasal fungi. This evidence review focuses on the more common subtypes: CRS with and without nasal polyposis. Both subtypes present with similar symptoms. However, CRS with nasal polyposis is, by definition, associated with nasal polyps that are visible on rhinoscopy or nasal endoscopy. Further, CRS with nasal polyposis is more likely to be associated with asthma and aspirin intolerance; this triad is referred to as Samter syndrome or aspirin-exacerbated respiratory disease.

CRS is associated with impaired quality of life (QOL) for affected patients, and with high direct and indirect costs for medical treatments and lost productivity. Most often, the negative health effects of CRS are related to the unpleasant symptoms associated with CRS, including nasal congestion, nasal drainage, and facial pain or pressure. In rare cases CRS can be associated with serious complications, including orbital cellulitis, osteomyelitis, or intracranial extension of infection.

While acute sinusitis is considered a more traditional infectious process, CRS is a chronic inflammatory disease of the upper airways, with multiple underlying causes. Risk factors for CRS with or without nasal polyps include anatomic variations and gastroesophageal reflux. There are conflicting reports about the association between allergy and CRS without nasal polyps, although weak evidence has suggested that allergy may be associated with CRS with nasal polyps. In addition, aspirin sensitivity may be associated with CRS with nasal polyps. The role of bacterial, viral, and fungal microorganisms in CRS has been actively investigated. There is some evidence that CRS is associated with a predominance of anaerobic bacteria. On the other hand, a study that used bacterial ribosomal RNA sequencing to evaluate the sinus microbiome in patients with and without CRS found a quantitative increase in bacterial and fungal RNA expression in patients with CRS, but no major differences in the types of microorganisms detected. Bacterial biofilms have been identified in cases of CRS.

**Diagnostic Criteria**

Several medical organizations have developed criteria for the diagnosis of CRS, which are summarized in Table 1. Most diagnostic schema require the presence of the major symptoms of
CRS for more than 12 weeks, combined with objective evidence of mucosal inflammation on sinus imaging, endoscopy or rhinoscopy, or both.

**Table 1. CRS Diagnostic Criteria**

<table>
<thead>
<tr>
<th>Organization</th>
<th>Chronic Rhinosinusitis Definition</th>
</tr>
</thead>
</table>
| International Consensus Statement on Allergy and Rhinology: Rhinosinusitis (2016) | “Sinonasal inflammation persisting for more than 12 weeks. Symptoms must include at least 2 of the following:  
- Nasal blockage/obstruction/congestion  
- Nasal discharge (anterior/posterior)  
- Facial pain/pressure  
- Reduction/loss of smell”  
“Additionally, the diagnosis must be confirmed by:  
- Evidence of inflammation on paranasal sinus examination or computed tomography (CT)  
- Evidence of purulence coming from paranasal sinuses or ostiomeatal complex.”  
“CRS is divided into CRSwNP or CRSsNP based on the presence or absence of nasal polyps” |
| American Academy of Allergy, Asthma, and Immunology et al (2005) | “Symptoms for 8 weeks or longer of varying severity consisting of the same symptoms as seen in acute sinusitis. In chronic sinusitis there should be abnormal findings on CT or MRI. Some patients with chronic sinusitis might present with vague or insidious symptoms.” |
| European Academy of Allergology and Clinical Immunology and the European Rhinologic Society (2012) | “Rhinosinusitis in adults is defined as:  
- Inflammation of the nose and the paranasal sinuses characterized by two or more symptoms, one of which should be either nasal blockage/obstruction/congestion or nasal discharge (anterior/posterior nasal drip):  
  - ± facial pain/pressure  
  - ± reduction or loss of smell  
and either  
- endoscopic signs of:  
  - nasal polyps, and/or  
  - mucopurulent discharge primarily from middle meatus, and/or oedema/mucosal obstruction primarily in middle meatus  
and/or  
- CT changes: ” |
<table>
<thead>
<tr>
<th>Organization</th>
<th>Chronic Rhinosinusitis Definition</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>o mucosal changes within the osiomeatal complex and/or sinuses”</td>
</tr>
<tr>
<td></td>
<td>“Chronic rhinosinusitis with nasal polyps (CRSwNP): Chronic rhinosinusitis as defined above and bilateral, endoscopically visualized polyps in middle meatus.”</td>
</tr>
<tr>
<td></td>
<td>“Chronic rhinosinusitis without nasal polyps (CRSsNP): Chronic rhinosinusitis as defined above and no visible polyps in middle meatus, if necessary following decongestant.”</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>British Society for Allergy and Clinical Immunology (2008)</th>
<th>Diagnostic criteria for rhinosinusitis:</th>
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<tbody>
<tr>
<td></td>
<td>“Major symptoms – two of the following, one to be:</td>
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<tr>
<td></td>
<td>• Nasal congestion or obstruction</td>
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<tr>
<td></td>
<td>• Nasal discharge (anterior or posterior)</td>
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<td></td>
<td>o ± Facial pain or pressure</td>
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<td>o ± Olfactory disturbance</td>
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<td></td>
<td>AND either</td>
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<td></td>
<td>Endoscopic signs (one or more of):</td>
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<tr>
<td></td>
<td>• Polyps</td>
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<tr>
<td></td>
<td>• Mucopurulent discharge from middle meatus</td>
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<tr>
<td></td>
<td>• Oedema/obstruction at middle meatus</td>
</tr>
<tr>
<td></td>
<td>OR</td>
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<tr>
<td></td>
<td>Computerized Tomography (CT) signs”</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>American Academy of Otolaryngology – Head and Neck Surgery Foundation (2015)</th>
<th>“12 weeks or longer of [2] or more of the following signs and symptoms:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Mucopurulent drainage (anterior, posterior, or both)</td>
</tr>
<tr>
<td></td>
<td>• Nasal obstruction (congestion)</td>
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<tr>
<td></td>
<td>• Facial pain-pressure-fullness, or</td>
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<tr>
<td></td>
<td>• Decreased sense of smell</td>
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<td></td>
<td>AND</td>
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<tr>
<td></td>
<td>Inflammation is documented by one or more of the following findings:</td>
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<td></td>
<td>• Purulent (not clear) mucus or edema in the middle meatus or anterior ethmoid region</td>
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<tr>
<td></td>
<td>• Polyps in nasal cavity or the middle meatus, and/or radiographic imaging showing inflammation of the paranasal sinuses”</td>
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</tbody>
</table>

CRS: chronic rhinosinusitis; CRSsNP: chronic rhinosinusitis without nasal polyps; CRSwNP: chronic rhinosinusitis with nasal polyps; CT: computed tomography; MRI: magnetic resonance imaging.
Evaluation of patients for allergic disorders, immunodeficiencies, or both, may be indicated depending on the presence of associated symptoms.

**Medical Treatment**

Medical therapy for CRS, with or without polyps, is often multimodal, including nasal irrigation, topical and/or systemic corticosteroids, and/or antibiotic therapy. Guidelines from the American Academy of Otolaryngology-Head and Neck Surgery (2015) have recommended the use of saline nasal irrigation, topical intranasal corticosteroids, or both, for symptom relief of CRS, on the basis of systematic reviews of randomized controlled trials (RCTs). There is a specific recommendation against the use of topical and systematic antifungal therapies. The guidelines do not include a statement specifically addressing the use of systemic antibiotics for CRS; however, in the list of future research needs, the authors included: “Perform additional RCTs to clarify the impact of antibiotic therapy on CRS outcomes.”

A systematic review by Rudmik and Soler (2015) evaluated the evidence for various medical therapies for chronic sinusitis, excluding allergic fungal sinusitis. Reviewers included 29 studies, with 12 meta-analyses (with a total of >60 RCTs), 13 systematic reviews, and 4 individual RCTs not included in any meta-analyses. Topical corticosteroids were associated, in multiple studies, with improved symptom scores, reduced polyp size, and decreased polyp recurrence after surgery. Saline nasal irrigation was associated, in multiple studies, with significant improvements in symptom scores. There was some evidence that 2 systemic therapies (oral corticosteroids, doxycycline), both for 3 weeks, improved polyp scores in patients with CRS with nasal polyps. Long-term (>3 months) macrolide therapy was associated in an RCT with improved symptoms and QOL in individuals with CRS without nasal polyps, although other studies did not find a benefit with chronic macrolide use.

In 2014, an evidence-based review summarized a series of earlier evidence-based reviews with recommendations related to CRS. This review concluded that both saline irrigation and topical corticosteroids are well-supported by the available published literature for treatment of CRS, with and without nasal polyps. For CRS with polyps, the evidence demonstrated short-term improvement in symptoms after short-term oral corticosteroid treatment. For CRS with or without nasal polyps, a small number of RCTs have shown improvement in nasal endoscopy scores and some symptoms with oral macrolide therapy. However, for CRS with or without nasal polyps, there was very limited evidence on the use of nonmacrolide oral antibiotics.

A 2011 Cochrane review of studies comparing systemic antibiotics with placebo for CRS in adults identified a study (N=64 patients) judged to be at high risk of bias. Reviewers
concluded: “Further good quality trials, with large sample sizes, are needed to evaluate the use of antibiotics in chronic rhinosinusitis.”

**Surgical Treatment**

The goals of surgery for CRS include removing polyps and debris that may be sources of inflammatory mediators and prevent the effective delivery of local medical therapies. In addition, to varying degrees, surgical techniques involve the creation of open sinus cavities, usually via dilation of the sinus ostia, to permit better drainage from the sinus cavities and more effective delivery of local therapies.

Techniques for functional endoscopic sinus surgery (FESS), in which an endoscope is used to access the sinus cavities and varying degrees of tissue are removed and the sinus ostia are opened, have evolved since the development of the nasal endoscope in the 1960s. FESS has largely replaced various open techniques for CRS (eg, Caldwell-Luc procedure), although open procedures may have a role in complicated sinus pathologies (eg, endonasal tumors).

FESS encompasses a variety of degrees of sinus access and tissue removal, and is described based on the sinuses accessed. The Draf classification is used to describe degrees of endoscopic frontal sinusotomy (see Table 2).

### Table 2. Draf Classification for Endoscopic Frontal Sinusotomy

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draf I</td>
<td>Anterior ethmoidectomy without altering frontal sinus ostium</td>
</tr>
<tr>
<td>Draf IIA</td>
<td>Removal of ethmoid cells that extend into frontal sinus</td>
</tr>
<tr>
<td>Draf IIB</td>
<td>Removal of frontal sinus floor between the middle turbinate and the lamina papyracea</td>
</tr>
<tr>
<td>Draf III&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Removal of frontal sinus floor from orbit to orbit with contiguous portions of the superior nasal septum</td>
</tr>
</tbody>
</table>

<sup>a</sup> Modified Lothrop procedure.

FESS can also be used to access the ethmoid sinuses, which may involve creation drainage into the maxillary sinuses (maxillary antrostomy).
Outcomes

To quantify the severity of CRS and to assess treatment response, various outcomes measures can be used, including patient-reported QOL measures, radiologic scores, and endoscopic grading.

The Lund-McKay scoring system uses radiologist-rated information derived from computed tomography scans regarding opacification of the sinus cavities, generating a score ranging from 0 to 12.\textsuperscript{31,32}

Several disease-specific patient-reported QOL scores have been used. Commonly used is the Sino-Nasal Outcome Test-20 (SNOT-20), a validated questionnaire, in which patients complete 20 symptom questions on a categorical scale (0 [no bother] to 5 [worst symptoms can be]). Average rankings can be reported over all 20 symptoms, as well as by 4 subclassified symptom domains. The SNOT-22 is a variation of the SNOT-20 that includes 2 additional questions ("nasal obstruction" and "loss of smell and taste"). The minimal clinically important difference for the SNOT-22 has been estimated to be 8.9 points.\textsuperscript{33}

Additionally, QOL may be reported based on overall health-related QOL scores, such as the 36-Item Short-Form Health Survey. The Survey consists of 8 scales on various health domains, which are transformed into a scale ranging from 0 to 100 (100 corresponding to best health).

Summary of Evidence

Functional Endoscopic Sinus Surgery

For individuals with CRS with or without nasal polyposis who receive FESS, the evidence includes randomized controlled trials and systematic reviews. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. A small number of trials, with methodologic limitations, generally have not reported clinically significant differences in symptom improvement with FESS compared with medical therapy. Two Cochrane reviews evaluating FESS for CRS with and without nasal polyposis have reported that FESS can be accomplished safely, but clinical trials have not demonstrated significant improvements with FESS compared with standard medical therapy. The evidence is insufficient to determine the effects of the technology on health outcomes.
**Balloon Sinus Ostial Dilation**

For individuals with chronic rhinosinusitis who receive balloon ostial dilation as a stand-alone procedure, the evidence includes systematic reviews and RCTs. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The available systematic reviews (including a Cochrane review and a TEC Assessment) have concluded that, although nonrandomized evidence has suggested balloon ostial dilation has similar outcomes to FESS, evidence from randomized trials is needed to demonstrate an improvement in outcomes for patients treated with balloon ostial dilation. Since the publication of those systematic reviews, an additional RCT (REMODEL) has been published. It assessed 105 patients, reporting short-term improvement in symptoms similar to those seen with FESS and potential advantages for balloon ostial dilation on postoperative recovery time and pain medication use. Limitations of the REMODEL trial included its unblinded outcomes assessment and differential dropout between groups. Other trials have provided limited additional evidence. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with chronic rhinosinusitis who receive balloon ostial dilation as an adjunct to FESS, the evidence includes 2 RCTs and single-arm series. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Neither available RCT reported significant clinically meaningful benefits associated with the addition of balloon ostial dilation to FESS. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Clinical Input From Physician Specialty Societies And Academic Medical Centers**

**Functional Endoscopic Sinus Surgery**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 specialty societies and 3 academic medical centers (4 responses), for a total of 6 responses, while this policy was under review in 2016. Input was consistent that the use of functional endoscopic sinus surgery is medically necessary for the treatment of chronic rhinosinusitis. Opinions about specific criteria for the diagnosis of chronic
rhinosinusitis differed, although most reviewers provided some for diagnosis of chronic rhinosinusitis and failure of medical management.

**Balloon Sinus Ostial Dilation**

**2013 Input**

In response to requests, input was received from 2 specialty societies and 6 academic medical centers while this policy was under review in 2013. Input was mixed on whether balloon ostial dilation should be medically necessary, either as a stand-alone procedure or as an adjunct to functional endoscopic sinus surgery (FESS). There was no consensus on subpopulations of patients with chronic rhinosinusitis who might benefit from balloon ostial dilation. There was a consensus that randomized controlled trials should compare balloon ostial dilation with standard care in order to determine efficacy.

**Practice Guidelines and Position Statements**

**Functional Endoscopic Sinus Surgery**

**American Academy of Otolaryngology-Head and Neck**

In 2015, the American Academy of Otolaryngology-Head and Neck Surgery updated its clinical practice guidelines on the management of sinusitis in adults, which recommended the following on the diagnosis and treatment of chronic rhinosinusitis (see Table 3).^{11}

**Table 3. Guidelines on Management of CRS in Adults**

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Type of Recommendation</th>
<th>Aggregate Evidence Quality</th>
<th>Confidence in Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;The clinician should confirm a clinical diagnosis of CRS with objective documentation of sinonasal inflammation, which may be accomplished using anterior rhinoscopy, nasal endoscopy, or computed tomography.&quot;</td>
<td>Strong recommendation</td>
<td>B (cross-sectional studies)</td>
<td>Medium</td>
</tr>
<tr>
<td>&quot;Clinicians should assess the patient with chronic</td>
<td>Recommendation</td>
<td>B (1 systematic)</td>
<td>Medium</td>
</tr>
</tbody>
</table>
Guideline | Type of Recommendation | Aggregate Evidence Quality | Confidence in Evidence
--- | --- | --- | ---
rhinosinusitis or recurrent acute rhinosinusitis for multiple chronic conditions that would modify management such as asthma, cystic fibrosis, immunocompromised state, and ciliary dyskinesia.* | | 
"The clinician may obtain testing for allergy and immune function in evaluating a patient with chronic rhinosinusitis or recurrent acute rhinosinusitis." | Option | C (systematic review of observational studies) | Medium
"The clinician should confirm the presence or absence of nasal polyps in a patient with CRS." | Recommendation | A (systematic review of RCTs) | Medium
"Clinicians should recommend saline nasal irrigation, topical intranasal corticosteroids, or both for symptom relief of CRS | Recommendation | A (systematic reviews of RCTs) | High
"Clinicians should not prescribe topical or systemic antifungal therapy for patients with CRS." | Recommendation (against therapy) | A (systematic reviews of RCTs) | High

CRS: chronic rhinosinusitis; RCT: randomized controlled trial.

**Balloon Sinus Ostial Dilation**

**American Academy of Otolaryngology – Head and Neck Surgery**

In 2017, the American Academy of Otolaryngology – Head and Neck Surgery updated its statement on balloon ostial dilation, reaffirming its 2010 position statement: “Sinus ostial dilation … is a therapeutic option for selected patient with chronic rhinosinusitis…. This approach may be used alone … or in conjunction with other instruments…."\(^{65}\)

**American Rhinologic Society**

A position statement, revised in 2017, from the American Rhinologic Society, stated that sinus ostial dilation is "a therapeutic option for selected patients with chronic rhinosinusitis (CRS) … who have failed appropriate medical therapy."\(^{67}\)
National Institute for Health and Clinical Evidence

In 2016, the Institute published a recommendation on the use of the XprESS Multi-Sinus Dilation System for the treatment of chronic rhinosinusitis:

1.1 “The case for adopting the XprESS multi-sinus dilation system for treating uncomplicated chronic sinusitis after medical treatment has failed is supported by the evidence. Treatment with XprESS leads to a rapid and sustained improvement in chronic symptoms, fewer acute episodes and improved quality of life which is comparable to functional endoscopic sinus surgery (FESS).

1.2 XprESS should be considered in patients with uncomplicated chronic sinusitis who do not have severe nasal polyposis. In these patients, XprESS works as well as FESS, is associated with faster recovery times, and can more often be done under local anaesthesia.”

Ongoing and Unpublished Clinical Trials

Functional Endoscopic Sinus Surgery

A search of ClinicalTrials.gov in December 2017 did not identify any ongoing or unpublished trials that would likely influence this review.

Balloon Sinus Ostial Dilation

Some currently unpublished trials that might influence this review are listed in Table 4.

Table 4. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unpublished</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01990820</td>
<td>Study for the Management of Pediatric Chronic Rhinosinusitis With or Without Balloon Sinuplasty</td>
<td>48</td>
<td>Mar 2016 (unknown)</td>
</tr>
<tr>
<td>NCT01714687†</td>
<td>Comparison of Balloon Sinuplasty In-Office Versus Medical Management for Recurrent Acute Sinusitis Patients (CABERNET)</td>
<td>59</td>
<td>Apr 2016 (completed)</td>
</tr>
</tbody>
</table>
**Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**Regulatory Status**

*Functional Endoscopic Sinus Surgery*

Functional endoscopic sinus surgery is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

*Balloon Sinus Ostial Dilation*

In 2008, the Relieva™ Sinus Balloon Catheter (Acclarent, Menlo Park, CA) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA determined that this device was substantially equivalent to existing devices for use in dilating the sinus ostia and paranasal spaces in adults and maxillary sinus spaces in children. Subsequent devices developed by Acclarent have also been cleared by FDA through the 510(k) process. They include the Relieva Spin Sinus Dilation System® (cleared in 2011) and the Relieva Seeker Balloon Sinuplasty System® (cleared in 2012).

In 2008, the FinESS™ Sinus Treatment (Entellus Medical, Maple Grove, MN) was cleared for marketing by FDA through the 510(k) process. The indication noted is to access and treat the maxillary ostia/ethmoid infundibulum in adults using a transantral approach (FDA product code: EOB). The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures. Two other balloon sinus ostial dilation devices, the ENTrigue® Sinus Dilation System (ENTrigue Surgical, acquired by more recently by Smith & Nephew), and the XprESS™ Multi-Sinus Dilation Tool, also received 510(k) clearance in 2012.

In 2013, a sinus dilation system (Medtronic Xomed, Jacksonville, FL), later named the NuVent™ EM Balloon Sinus Dilation System, was cleared for marketing by FDA through the 510(k) process for use in conjunction with a Medtronic computer-assisted surgery system when surgical
navigation or image-guided surgery may be necessary to locate and move tissue, bone, or cartilaginous tissue surrounding the drainage pathways of the frontal, maxillary, or sphenoid sinuses.

Also in 2013, a sinus dilation system (Smith & Nephew), later named the Ventera™ Sinus Dilation System, was cleared for marketing through the 510(k) process to access and treat the frontal recesses, sphenoid sinus ostia, and maxillary ostia/ethmoid infundibula in adults using a transnasal approach.

FDA product code: LRC.

References

1. Rudmik L, Soler ZM. Medical therapies for adult chronic sinusitis: a systematic review. JAMA. Sep 1 2015;314(9):926-939. PMID 26325561


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/08/14</td>
<td>New policy, add to Surgery section. Considered medically necessary as addressed in this policy. Policy held for provider notification and will be effective April 15, 2015.</td>
</tr>
<tr>
<td>03/20/15</td>
<td>Implementation delayed until July 1, 2015.</td>
</tr>
<tr>
<td>04/05/15</td>
<td>Implementation delayed until August 15, 2015.</td>
</tr>
<tr>
<td>04/13/15</td>
<td>Implementation delayed until August 18, 2015, to align with provider notification.</td>
</tr>
<tr>
<td>05/14/15</td>
<td>Implementation delayed until October 15, 2015 to facilitate appropriate provider notification.</td>
</tr>
<tr>
<td>06/17/15</td>
<td>Implementation delayed until December 30, 2015.</td>
</tr>
<tr>
<td>09/08/15</td>
<td>Interim review. Added references 8, 9. Expanded definitions for acute rhinosinusitis, subacute rhinosinusitis and chronic rhinosinusitis. Clarified maximal medical therapy in policy statements. Policy statements further defined from previous uncomplicated rhinosinusitis to recurrent acute bacterial rhinosinusitis and chronic rhinosinusitis with or without polyposis. Policy effective Jan. 1, 2016.</td>
</tr>
<tr>
<td>12/16/15</td>
<td>Implementation delayed until May 1, 2016.</td>
</tr>
<tr>
<td>05/01/16</td>
<td>Annual review, changes approved April 18, 2016. Policy updated with the removal of “without medical review” for list of medically necessary indications other than recurrent acute bacterial rhinosinusitis and chronic rhinosinusitis; revision surgery was added to this list. No other changes.</td>
</tr>
<tr>
<td>05/24/16</td>
<td>Update Related Policies. Remove 7.01.134 as it is archived.</td>
</tr>
<tr>
<td>07/01/16</td>
<td>Policy moved to new format. No change in content or coverage.</td>
</tr>
<tr>
<td>01/01/17</td>
<td>Interim review, changes approved December 13, 2016. Added clarification statement: Depending on symptoms and imaging findings, medically necessary surgery could be unilateral or bilateral. Revised need for antibiotic therapy from two courses to one course 10 – 14 days. Revised objective evidence requirements in policy statements. Clarified topical intranasal steroid use in consecutive weeks. Added policy statement with criteria for revision surgery. Added references 5, 6, 27. Removed CPT code 31237.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>02/17/17</td>
<td>Updated title of Related Policy.</td>
</tr>
<tr>
<td>05/05/17</td>
<td>Revised Prior Authorization Requirements section.</td>
</tr>
<tr>
<td>01/16/18</td>
<td>Minor edit, added Documentation Requirements table to the Policy Coverage Criteria section.</td>
</tr>
<tr>
<td>01/23/18</td>
<td>Coding update, added new CPT codes 31241, 31253, 31257, 31259, and 31298 (new codes effective 1/1/18).</td>
</tr>
<tr>
<td>03/01/18</td>
<td>Interim Review, approved February 27, 2018. Note added that this policy has been revised. Added Surgery Site of Service criteria, which becomes effective June 1, 2018.</td>
</tr>
<tr>
<td>05/01/18</td>
<td>Annual Review, approved April 10, 2018. Oral antibiotic course changed to 5-7 days. Modified topical intranasal steroids OR saline nasal irrigation for at least 6 consecutive weeks statement. Deleted use of topical intranasal steroids as a requirement for revision surgery. Added additional diagnoses for which functional endoscopic sinus surgery is considered medically necessary, per medical community input. Updated references 1-30, added references 31-68. Removed CPT code 31241.</td>
</tr>
<tr>
<td>06/01/18</td>
<td>Minor update; removed note and link to updated policy. Surgery Site of Service criteria becomes effective.</td>
</tr>
<tr>
<td>09/21/18</td>
<td>Minor updated. Added Consideration of Age statement.</td>
</tr>
</tbody>
</table>

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S909, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
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Premera Blue Cross tiin qabaachuu danda’a. Dawa guuyaa fi deeggarsa argachuu minga ni qabaattu.}

Italiano (Italian):

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