

## MEDICAL POLICY – 7.01.559

# Sinus Surgery in Adults

BCBSA Ref. Policies: 7.01.105 & 7.01.155

Effective Date: **Nov. 7, 2025\***  
 Last Revised: Jul. 8, 2025  
 Replaces: N/A

\*This policy has been revised.  
 Click here to view the current policy.

### RELATED MEDICAL POLICIES:

7.01.134 Steroid-Eluting Sinus Stents and Implants  
 7.01.158 Balloon Dilation of the Eustachian Tube  
 7.01.168 Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment of Chronic Rhinitis  
 11.01.525 Site of Service Ambulatory Service Center (ASC) Select Surgical Procedures

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## 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.

## Policy Coverage Criteria

We will review for medical necessity these elective surgical procedures.

We also will review the site of service for medical necessity. 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
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| <b>Medically necessary sites of service:</b> <ul style="list-style-type: none"> <li>• Ambulatory Surgical Center</li> </ul>                               | <b>Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. This is the preferred medically necessary site of service for certain elective surgical procedures.</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <ul style="list-style-type: none"> <li>• Off campus-outpatient hospital/medical center</li> <li>• On campus-outpatient hospital/medical center</li> </ul> | <ul style="list-style-type: none"> <li>• Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. An elective surgical procedure performed in a hospital outpatient department may be considered medically necessary if there is no access to an ambulatory surgical center due to one of the following criteria: There is no qualifying ASC within 30 miles that can provide the necessary care due to one of the following: <ul style="list-style-type: none"> <li>○ There is no geographically accessible ASC that has the necessary equipment to perform the procedure; or</li> <li>○ There is no geographically accessible ASC available at which the individual's physician has privileges; or</li> <li>○ An ASC's specific guideline prohibits the use of the ASC related to the individual's health condition or weight, or</li> </ul> </li> <li>• Individual is aged 18 or younger, or</li> <li>• The service being performed is in conjunction with an additional service that requires the use of a hospital outpatient</li> </ul> |

| Site of Service for Elective Surgical Procedures | Medical Necessity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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|                                                  | <p>department, and the procedures are being performed in the same operative session</p> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>• Individual has a clinical condition which puts them at increased risk for complications including any of the following (this list may not be all inclusive):             <ul style="list-style-type: none"> <li>○ <b>Anesthesia Risk</b> <ul style="list-style-type: none"> <li>▪ ASA classification III or higher (see <a href="#">definition</a>)</li> <li>▪ Personal history of complication of anesthesia</li> <li>▪ Documentation of alcohol dependence or history of cocaine use</li> <li>▪ Prolonged surgery (greater than 3 hours)</li> </ul> </li> <li>○ <b>Cardiovascular Risk</b> <ul style="list-style-type: none"> <li>▪ Uncompensated chronic heart failure (<a href="#">NYHA class</a> III or IV)</li> <li>▪ Recent history of myocardial infarction (MI) (less than 3 months)</li> <li>▪ Poorly controlled, resistant hypertension*</li> <li>▪ Recent history of cerebrovascular accident (less than 3 months)</li> <li>▪ Increased risk for cardiac ischemia (drug eluting stent placed less than 1 year or angioplasty less than 90 days)</li> <li>▪ Symptomatic cardiac arrhythmia despite medication</li> <li>▪ Significant valvular heart disease</li> </ul> </li> <li>○ <b>Liver Risk</b> <ul style="list-style-type: none"> <li>▪ Advanced liver disease (MELD Score greater than 8)**</li> </ul> </li> <li>○ <b>Pulmonary Risk</b> <ul style="list-style-type: none"> <li>▪ Chronic obstructive pulmonary disease (COPD) (FEV1 less than 50%)</li> <li>▪ Poorly controlled asthma (FEV1 less than 80% despite treatment)</li> <li>▪ Moderate to severe obstructive sleep apnea (OSA)***</li> </ul> </li> <li>○ <b>Renal Risk</b> <ul style="list-style-type: none"> <li>▪ End stage renal disease (on dialysis)</li> </ul> </li> <li>○ <b>Other</b></li> </ul> </li> </ul> |

| Site of Service for Elective Surgical Procedures                                                                                                          | Medical Necessity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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|                                                                                                                                                           | <ul style="list-style-type: none"> <li>▪ Morbid obesity (BMI greater than or equal to 50)</li> <li>▪ Pregnancy</li> <li>▪ Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP**** does not meet this criterion])</li> <li>▪ Anticipated need for transfusion(s)</li> </ul> <p><b>Note:</b> * 3 or more drugs to control blood pressure<br/> ** <a href="https://reference.medscape.com/calculator/meld-score-end-stage-liver-disease">https://reference.medscape.com/calculator/meld-score-end-stage-liver-disease</a><br/> *** Moderate-AHI greater than or equal to 15 and less than or equal to 30, Severe-AHI greater than or equal to 30<br/> ****DDAVP-Deamino-Delta-D-Arginine Vasopressin (Desmopressin)</p> |
| <ul style="list-style-type: none"> <li>• Off campus-outpatient hospital/medical center</li> <li>• On campus-outpatient hospital/medical center</li> </ul> | <b>These sites of service are considered not medically necessary for certain elective surgical procedures when the site of service criteria listed above are not met.</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <ul style="list-style-type: none"> <li>• Inpatient hospital/medical center</li> </ul>                                                                     | <b>This site of service is considered NOT medically necessary for these elective surgical procedures .</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

**Note: This policy only applies to individuals aged 19 and older.**

| Condition                                         | Medical Necessity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|---------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Functional Endoscopic Sinus Surgery (FESS)</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Recurrent acute bacterial rhinosinusitis</b>   | <p><b>Functional endoscopic sinus surgery (FESS) may be considered medically necessary when there has been:</b></p> <ul style="list-style-type: none"> <li>• Four or more documented episodes of acute bacterial rhinosinusitis within 12 continuous months</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Medical therapy consisting of the following has been tried and failed: <ul style="list-style-type: none"> <li>○ At least <b>one</b> course of oral antibiotics of 5-7days within the last 6 months</li> </ul> </li> </ul> |

| Condition                                                      | Medical Necessity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
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|                                                                | <p><b>AND</b></p> <ul style="list-style-type: none"> <li>○ Topical intranasal steroids <b>OR</b> daily saline nasal irrigation for at least 4 consecutive weeks</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>○ There is objective evidence of sinus disease as demonstrated by one of the following: <ul style="list-style-type: none"> <li>▪ Sinus computed tomography or magnetic resonance imaging showing significant mucosal thickening, or polyps, or opacification of the paranasal sinuses, or sinus ostial obstruction, or air fluid levels,</li> </ul> </li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>▪ Nasal endoscopy shows purulent mucus or edema in the middle meatus, anterior ethmoid region, or sphenoethmoid region, or polyps in the nasal cavity or middle meatus.</li> </ul> <p><b>Note:</b> Depending on symptoms and imaging findings, medically necessary surgery could be unilateral or bilateral.</p>       |
| <p><b>Chronic rhinosinusitis with or without polyposis</b></p> | <p><b>Functional endoscopic sinus surgery (FESS) may be considered medically necessary when:</b></p> <ul style="list-style-type: none"> <li>• Chronic rhinosinusitis symptoms (e.g., mucopurulent drainage, nasal congestion/obstruction, facial pain/pressure, decreased sense of smell) have been present for at least 12 continuous weeks</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Medical therapy consisting of the following has been tried and failed: <ul style="list-style-type: none"> <li>○ At least <b>one</b> 5-7-day course of antibiotics within the last 6 months</li> </ul> </li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>○ Topical intranasal steroids <b>OR</b> daily saline nasal irrigation for at least 6 consecutive weeks</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>○ There is objective evidence of sinus disease as demonstrated by <b>ONE</b> of the following:</li> </ul> |

| Condition        | Medical Necessity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
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|                  | <ul style="list-style-type: none"> <li>▪ Sinus computed tomography or magnetic resonance imaging showing significant mucosal thickening, or polyps or opacification of the paranasal sinuses, or sinus ostial obstruction, or maxillary accessory ostium/ostia (ostiomeatal complex), or the presence of accessory ostia, or air fluid levels,</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>▪ Nasal endoscopy shows purulent mucus or edema in the middle meatus, or anterior ethmoid region, or sphenoethmoid region, or polyps in the nasal cavity or middle meatus.</li> </ul> <p><b>Note:</b> Depending on symptoms and imaging findings, medically necessary surgery could be unilateral or bilateral.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Revision surgery | <p><b>Functional endoscopic sinus surgery (FESS) may be considered medically necessary for revision surgery when the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• At least 12 weeks have passed since the previous surgery,</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Chronic rhinosinusitis symptoms (e.g., mucopurulent drainage, nasal congestion/obstruction, facial pain/pressure, decreased sense of smell) have been present for at least 12 continuous weeks,</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>• Medical therapy consisting of the following has been tried and failed:             <ul style="list-style-type: none"> <li>○ At least <b>one</b> 5-7-day course of antibiotics since the previous surgery</li> </ul> </li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>○ There is persistent objective evidence of sinus disease as demonstrated by one of the following:             <ul style="list-style-type: none"> <li>▪ Sinus computed tomography or magnetic resonance imaging showing significant mucosal thickening, or polyps, or opacification of the paranasal sinuses, or sinus ostial obstruction, or air fluid levels.</li> </ul> </li> </ul> <p><b>OR</b></p> |

| Condition                                                | Medical Necessity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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|                                                          | <ul style="list-style-type: none"> <li>Nasal endoscopy shows purulent mucus or edema in the middle meatus, or anterior ethmoid region, or sphenoethmoid region, or polyps in the nasal cavity or middle meatus.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Diagnoses considered medically necessary for FESS</b> | <p><b>Functional endoscopic sinus surgery (FESS) may be considered medically necessary when the following diagnoses are present.</b></p> <ul style="list-style-type: none"> <li>Multiple nasal polyps (aka antrochoanal polyps)</li> <li>Cerebrospinal fluid (CSF) leak closure</li> <li>Choanal atresia repair</li> <li>Dacryocystorhinostomy (DCR)</li> <li>Epistaxis control</li> <li>Excision of selected tumors and nasal masses</li> <li>Foreign body removal</li> <li>Optic nerve decompression</li> <li>Orbital decompression (e.g., Graves ophthalmopathy)</li> <li>Recurrent sinusitis in people who have cystic fibrosis or severe asthma</li> <li>Silent sinus syndrome (may also be noted as chronic maxillary atelectasis, Stage III) confirmed by paranasal sinus CT (computed tomography)</li> <li>Sinus mucocoeles</li> <li>Sinus disease has eroded into the bone</li> <li>Sinus disease in the immune compromised</li> <li>Sinus disease for invasive fungal disease</li> <li>Sinus disease for allergic fungal sinus disease</li> <li>Sinus disease related to Wegener's granulomatosis</li> <li>Sinus disease related to hereditary hemorrhagic telangiectasia</li> <li>Sinus disease related to scarring or osteoneogenetic changes</li> </ul> |

| Condition                            | Medical Necessity                                                                                                                                                                                                                                                                                    |
|--------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Balloon Sinus Ostial Dilation</b> |                                                                                                                                                                                                                                                                                                      |
| <b>Chronic rhinosinusitis</b>        | <p><b>Balloon sinus ostial dilation may be considered medically necessary when the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>Chronic rhinosinusitis symptoms (e.g., mucopurulent drainage, nasal congestion/obstruction, facial pain/pressure, decreased</li> </ul> |

| Condition | Medical Necessity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
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|           | <p>sense of smell) have been present for at least 12 continuous weeks</p> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>Medical therapy consisting of the following has been tried and failed: <ul style="list-style-type: none"> <li>At least <b>one</b> 5-7-day course of antibiotics</li> </ul> </li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>Topical intranasal steroids or daily saline nasal irrigation for at least 6 consecutive weeks</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>There is objective evidence of sinus disease as demonstrated by one of the following: <ul style="list-style-type: none"> <li>Sinus computed tomography or magnetic resonance imaging showing significant mucosal thickening, or polyps, or opacification of the paranasal sinuses, or sinus ostial obstruction, maxillary accessory ostium/ostia (ostiomeatal complex), or the presence of accessory ostia, or air fluid levels,</li> </ul> </li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>Nasal endoscopy shows purulent mucus or edema in the middle meatus, or anterior ethmoid region, or sphenoid region, or polyps in the nasal cavity or middle meatus.</li> </ul> |

## Documentation Requirements

**For recurrent acute bacterial rhinosinusitis (4 or more episodes within 12 continuous months of bacterial infection of the sinuses), written documentation in the medical record must include:**

- Onset and duration of symptoms
- Maximal medical therapy tried and failed:
  - At least **one** course of oral antibiotics of 5-7 days within the last 6 months

**AND**

- Use of topical intranasal steroids **OR** daily saline nasal irrigation for a minimum of 4 consecutive weeks

## Documentation Requirements

3. Copy of the sinus 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)

**For chronic rhinosinusitis with or without polyposis ([e.g., mucopurulent drainage, nasal congestion/obstruction, facial pain/pressure, decreased sense of smell] for at least 12 continuous weeks with or without the presence of polyps), 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**AND**
  - Use of topical intranasal steroids **OR** daily saline nasal irrigation for a minimum of 6 consecutive weeks
3. Copy of the sinus 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)

**For revision surgery (12 weeks since the previous surgery and chronic rhinosinusitis symptoms for at least 12 continuous weeks have been present), 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**AND**
3. Copy of the sinus CT scan or MRI results, if done, or result of nasal endoscopy during the course of illness, that shows persistent evidence of sinus pathology amenable to surgical treatment (a sinus condition that would likely benefit from surgery)

**For balloon sinus ostial dilation chronic rhinosinusitis (e.g., mucopurulent drainage, nasal congestion/obstruction, facial pain/pressure, decreased sense of smell) has been present 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

## Documentation Requirements

### AND

- Use of topical intranasal steroids **OR** daily saline nasal irrigation for at least 6 consecutive weeks
- 3. Copy of the sinus 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

| Code       | Description                                                                                                                                                                        |
|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>CPT</b> |                                                                                                                                                                                    |
| 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, 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                                                                                |
| 31295      | Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); maxillary sinus ostium, transnasal or via canine fossa                                                    |
| 31296      | Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); frontal sinus ostium                                                                                      |

| Code         | Description                                                                                               |
|--------------|-----------------------------------------------------------------------------------------------------------|
| 31297        | Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); sphenoid sinus ostium            |
| 31298        | Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); frontal and sphenoid sinus ostia |
| <b>HCPCS</b> |                                                                                                           |
| C1726        | Catheter, balloon dilatation, nonvascular                                                                 |

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Related Information

### 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, e.g., 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, e.g., 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 cavities. 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 that last 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.

**Silent sinus syndrome:** Is a rare condition seen as a spontaneous, asymptomatic collapse of an air sinus associated with negative sinus pressures. The condition is characterized by sunken eyes (enophthalmos), double vision (diplopia), and the downward displacement of the eyeball in the eye socket (hypoglobus). It generally affects the maxillary sinuses. A diagnosis is made by a confirmatory computed tomography (CT) scan. Treatment is generally endoscopic surgery which makes an outlet for the mucous drainage, and reconstruction of the orbital floor may at times be necessary. Silent sinus syndrome is considered a subtype of stage III chronic maxillary atelectasis.

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

Criteria for “maximal medical therapy” used before endoscopic sinus surgery is attempted have been reported in a minority (21%) of published studies of endoscopic sinus surgery (Dautremont & Rudmik, 2015). The criteria used vary across studies, but studies that have reported specific criteria most often report using topical steroids (91.4%; mean duration, 8.4 weeks) and oral antibiotics (87.7%; mean duration, 23 days) (Dautremont & Rudmik, 2015). Systematic reviews of randomized controlled trials (RCTs) have consistently demonstrated improved symptoms of chronic rhinosinusitis with topical steroids. In contrast, weak evidence supports the use of systemic antibiotics in chronic rhinosinusitis.

## Balloon Ostial Dilation (BOD) used in combination with Functional Endoscopic Sinus Surgery (FESS)

- BOD when used as a tool during functional endoscopic sinus surgery (FESS) in the same sinus cavity is considered to be an integral part of the FESS procedure.
- When BOD is used as an adjunct to FESS (defined as FESS on 1 sinus and BOD on another sinus in the same individual during the same operation) medical necessity criteria for BOD apply to the sinus being considered for BOD.

## 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 individuals, thus resulting in the focus of this policy.

## Evidence Review

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### 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.

#### Balloon Sinus Ostial Dilation

Balloon ostial dilation (BOD, also known as balloon sinuplasty) is proposed as an alternative to functional traditional endoscopic sinus surgery (FESS) for individuals with chronic rhinosinusitis (CRS) or recurrent acute rhinosinusitis (RARS) 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 FESS.

## Background

### Functional Endoscopic Sinus Surgery

#### 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.<sup>1</sup> 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 polyps; CRS with nasal polyps; and allergic fungal sinusitis. The latter is a less common subtype thought to result from chronic allergic inflammation to colonizing nasal fungi. This policy focuses on the more common subtypes: CRS with and without nasal polyps. Both subtypes present with similar symptoms. However, CRS with nasal polyps is, by definition, associated with nasal polyps that are visible on rhinoscopy or nasal endoscopy. Further, CRS with nasal polyps 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 individuals, 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.<sup>2,3</sup> On the other hand, a study that used bacterial ribosomal RNA sequencing to evaluate the sinus microbiome in individuals with and without CRS found a quantitative increase in bacterial and fungal RNA



expression in individuals with CRS, but no major differences in the types of microorganisms detected.<sup>4</sup> Bacterial biofilms have been identified in cases of CRS.<sup>5</sup>

### ***Medical Therapy***

Medical therapy for CRS, with or without polyps, is often multimodal, including nasal irrigation, topical and/or systemic corticosteroids, monoclonal antibodies, and/or antibiotic therapy.<sup>6</sup> Guidelines from the American Academy of Otolaryngology-Head and Neck Surgery (2015; affirmed in 2020 by the American Academy of Family Physicians) 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 RCTs.<sup>7,8</sup> 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.<sup>1</sup> 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 symptoms scores. There was some evidence that two systemic therapies (oral corticosteroids, doxycycline), both for three weeks, improved polyp scores in individuals 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.<sup>9</sup> 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 non-macrolide oral antibiotics.



A 2016 Cochrane review of studies evaluating systemic and topical antibiotics for CRS included five RCTs (N=293), all of which compared systemic antibiotics with placebo or another pharmacological intervention.<sup>10</sup> Reviewers found "very little evidence that systemic antibiotics are effective in individuals with chronic rhinosinusitis" and that "more research in this area, particularly evaluating longer-term outcomes and adverse effects, is required."

In 2019, the US Food and Drug Administration (FDA) approved the first treatment for CRS with nasal polyps - dupilumab (Dupixent). Results from clinical trials revealed that individuals who received dupilumab "had statistically significant reductions in their nasal polyp size and nasal congestion compared to the placebo group" and also "reported an increased ability to smell and required less nasal polyp surgery and oral steroids."<sup>11</sup> This was followed by the approval of omalizumab (Xolair) in 2020 as add-on maintenance treatment for adults with nasal polyps with an inadequate response to nasal corticosteroids.<sup>12</sup> In 2021, mepolizumab (Nucala) was also approved as an add-on maintenance treatment in adults with CRS with nasal polyps.<sup>13</sup>

## ***Surgery***

FESS involves the insertion of an endoscope into the nose for a direct visual examination of the openings into the sinuses. Using the endoscope and a combination of surgical tools (e.g., curettes, forceps, powered micro-debriders, powered shavers, and/or sinus balloon catheters), surgeons enlarge the patient's sinus openings to clear passageways in order to restore normal sinus ventilation and drainage. The goal of surgery is to improve sinus ventilation and drainage by enlarging the openings of the sinuses, removing any polyps and correcting significant structural problems that may be hindering drainage.

The maxillary sinus creates a unique challenge. The maxillary ostia, located within the ethmoid infundibulum, often cannot be accessed transnasally without excising a portion of the uncinate process. An alternative approach to the maxillary ostia is through the sinus, via the canine fossa. A guidewire can be advanced from within the maxillary sinus to the nasal fossa. The dilating balloon can enlarge the ostia while deflecting the uncinate process.

Approximately 350,000 FESS procedures are done each year in the United States for CRS.

The goals of surgery for CRS include removing polyps and debris that may be sources of inflammatory mediators and preventing 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 (e.g., Caldwell-Luc procedure), although open procedures may have a role in complicated sinus pathologies (e.g., 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 1](#)).

**Table 1. The Draf Classification for Endoscopic Frontal Sinusotomy**

| Type                  | Description                                                                                              |
|-----------------------|----------------------------------------------------------------------------------------------------------|
| Draf I                | Anterior ethmoidectomy without altering frontal sinus ostium                                             |
| Draf IIA              | Removal of ethmoid cells that extend into frontal sinus                                                  |
| Draf IIB              | Removal of frontal sinus floor between the middle turbinate and the lamina papyracea                     |
| Draf III <sup>a</sup> | Removal of frontal sinus floor from orbit to orbit with contiguous portions of the superior nasal septum |

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

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

## Balloon Sinus Ostial Dilation

Balloon ostial dilatation (BOD) can be used as an alternative or as an adjunct to FESS for those with CRS or recurrent acute rhinosinusitis (RARS). The goal of this technique, when used as an alternative to FESS, is to improve sinus drainage using a less invasive approach. The procedure involves placing a guidewire in the sinus ostium, advancing a balloon over the guidewire, and then stretching the opening by inflating the balloon. The guidewire location is confirmed with fluoroscopy or with direct transillumination of the targeted sinus cavity. General anesthesia may be needed for this procedure to minimize an individual's movement.

According to the manufacturer, the RELIEVA SPINPLUS Balloon Sinuplasty System is intended to: provide a means to access the sinus space and illuminate within and transilluminate across nasal

and sinus structures; dilate the sinus ostia and spaces associated with the paranasal sinus cavities for diagnostic and therapeutic procedures; and irrigate from within a target sinus for therapeutic procedures and to facilitate diagnostic procedures.

<https://www.jnjmedicaldevices.com/en-US/product/relieva-spinplus-balloon-sinuplasty-system> (Accessed March 13, 2024).

This policy is limited to BOD when used as a standalone procedure. BOD may also be used in combination with FESS.<sup>39,40</sup> When used as an adjunct to FESS, it is intended to facilitate and/or increase access to the sinuses. BOD may also be used on one sinus and FESS on another sinus in the same individual during the same operation.

## Summary of Evidence

### Functional Endoscopic Sinus Surgery

For individuals with uncomplicated CRS with or without nasal polyposis who receive FESS, the evidence includes randomized controlled trials (RCTs) and systematic reviews. The relevant outcomes are symptoms, functional outcomes, 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. 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 that the technology results in an improvement in the net health outcome.

For individuals with uncomplicated CRS refractory to medical therapy who receive FESS, the evidence includes an RCT, a systematic review of non-randomized comparative studies, and additional non-randomized studies published since the systematic review. Relevant outcomes are symptoms, functional outcomes, changes in disease status, quality of life, and treatment-related morbidity. One RCT was identified in individuals who have failed therapy with nasal irrigation and corticosteroids. This RCT found that FESS was not superior to maximal medical therapy that includes antibiotics along with nasal irrigation and topical or systemic corticosteroids. Although no RCTs have been identified that evaluated FESS in individuals with CRS who failed a regimen that included antibiotic therapy, a systematic review of non-randomized comparative cohorts and pre-post studies is available. This meta-analysis suggests that in individuals who have failed maximal medical therapy (nasal irrigation, corticosteroids, and antibiotics), FESS can improve symptoms compared to continued medical management.



Individuals most likely to select and benefit from FESS are those with lower disease-specific quality of life. Multiple additional non-randomized studies further support improvements in quality of life and functional outcomes after FESS in this setting. Surgical treatment of CRS with FESS may thus be appropriate for individuals who meet diagnostic criteria for CRS and have failed maximal medical management. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

## Balloon Sinus Ostial Dilation

For individuals with chronic rhinosinusitis who receive balloon ostial dilation (BOD) as a stand-alone procedure, the evidence includes a systematic review, RCTs, and observational studies.. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. A meta-analysis of three studies indicated a statistically significant yet not clinically significant preference for BOD over FESS in terms of patient-related quality of life. The REMODEL RCT confirmed that BOD was not inferior to FESS for treating chronic rhinosinusitis, with the effect's durability observed over 24 months. In a retrospective cohort study that used data from a large commercial insurance database to examine adverse events in individuals who underwent BOD (n=2851) or FESS (n=11,955), the overall complication rate was 5% with BOD and 7% with FESS. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with RARS who receive BOD as a stand-alone procedure, the evidence includes a systematic review and RCTs. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. A systematic review on RARS management identified two (of 10) studies focused on BOD as a treatment modality. Although an improvement in quality of life was observed across both studies, the small sample sizes, diverse outcome measures, and study heterogeneity prevented the authors from conducting a meta-analysis. In the REMODEL RCT, 32% of participants (N=29) with RARS were diagnosed. BOD was found to be non-inferior to FESS in terms of quality of life at both six and twelve months post-procedure. Another RCT, CABERNET, comparing BOD plus medical care to medical care alone in individuals with RARS (N=59), demonstrated significantly improved quality of life and fewer sinus infections after six months in the balloon dilation group. The current body of evidence is limited by small sample sizes, unblinded outcome assessment, lack of appropriate comparators, and heterogeneity in outcome measures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.



## Ongoing and Unpublished Clinical Trials

### Functional Endoscopic Sinus Surgery

A currently ongoing trial that might influence this review is listed in [Table 2](#).

**Table 2. Summary of Key Trials**

| NCT No.                     | Trial Name                                                                                                                                                                         | Planned Enrollment | Completion Date |
|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-----------------|
| <b>Ongoing</b>              |                                                                                                                                                                                    |                    |                 |
| <a href="#">NCT05598814</a> | Optimisation of Treatment in Patients with CRSwNP. An RCT of Mepolizumab and Surgical Treatment With FESS and Mepolizumab Versus Only Mepolizumab Over a 6- and 12-month Follow-up | 52                 | Aug 2025        |

### Balloon Sinus Ostial Dilation

Some currently ongoing trials that might influence this review are listed in [Table 3](#).

**Table 3. Summary of Key Trials**

| NCT No.                     | Trial Name                                                                                                                  | Planned Enrollment | Completion Date                         |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------|--------------------|-----------------------------------------|
| <b>Ongoing</b>              |                                                                                                                             |                    |                                         |
| <a href="#">NCT04645511</a> | A Placebo Controlled Randomised Study of the Balloon Sinuplasty Efficiency in Chronic or Recurrent Maxillary Rhinosinusitis | 120                | Dec 2027 (last update posted: Oct 2022) |

NCT: national clinical trial.

## Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or the National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Guidelines on the diagnosis and management of CRS are described in [Table 4](#) and [Table 5](#).

**Table 4. CRS Diagnostic Criteria**

| Organization                                                                                    | Chronic Rhinosinusitis Definition                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| International Consensus Statement on Allergy and Rhinology: Rhinosinusitis (2021) <sup>34</sup> | <p>"Greater than or equal to 12 weeks of:</p> <p>Two or more of the following symptoms:</p> <ul style="list-style-type: none"><li>• Nasal discharge (rhinorrhea or post-nasal drip)</li><li>• Nasal obstruction or congestion</li><li>• Hyposmia</li><li>• Facial pain/pressure</li><li>• Cough</li></ul> <p>AND</p> <p>One or more of the following objective findings:</p> <ul style="list-style-type: none"><li>• Evidence of inflammation on nasal endoscopy or computed tomography</li><li>• Evidence of purulence coming from paranasal sinuses or ostiomeatal complex."<p>AND</p><p>"CRS is divided into CRSwNP or CRSsNP based on the presence or absence of nasal polyps"</p></li></ul> |
| American Academy of Otolaryngology – Head and Neck Surgery Foundation (2015) <sup>7, 8</sup>    | <p>"12 weeks or longer of [2] or more of the following signs and symptoms:</p> <ul style="list-style-type: none"><li>• Mucopurulent drainage (anterior, posterior, or both)</li><li>• Nasal obstruction (congestion)</li><li>• Facial pain-pressure-fullness, or</li><li>• Decreased sense of smell</li></ul>                                                                                                                                                                                                                                                                                                                                                                                    |

| Organization | Chronic Rhinosinusitis Definition                                                                                                                                                                                                                                                                                                                                             |
|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|              | <p>AND</p> <p>Inflammation is documented by one or more of the following findings:</p> <ul style="list-style-type: none"> <li>• Purulent (not clear) mucus or edema in the middle meatus or anterior ethmoid region</li> <li>• Polyps in nasal cavity or the middle meatus, and/or</li> <li>• Radiographic imaging showing inflammation of the paranasal sinuses.”</li> </ul> |

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.

**Table 5. American Academy of Otolaryngology-Head and Neck Surgery Guidelines on Management of CRS in Adults\***

| Guideline                                                                                                                                                                                                                                           | Type of Recommendation | Aggregate Evidence Quality                              | Confidence in Evidence |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|---------------------------------------------------------|------------------------|
| “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.”                                    | Strong recommendation  | B (cross-sectional studies)                             | Medium                 |
| “Clinicians should assess the patient with chronic rhinosinusitis or recurrent acute rhinosinusitis for multiple chronic conditions that would modify management such as asthma, cystic fibrosis, immunocompromised state, and ciliary dyskinesia.” | Recommendation         | B (1 systematic review, multiple observational studies) | Medium                 |
| “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                 |

| Guideline                                                                                                                   | Type of Recommendation           | Aggregate Evidence Quality     | Confidence in Evidence |
|-----------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------------------------|------------------------|
| "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                   |

\*Adapted from Rosenfeld et al (2015)<sup>8</sup> CRS: chronic rhinosinusitis; RCT: randomized controlled trial.

**Table 6. Joint Task Force on Practice Parameters Guidelines for the Medical Management of CRS with Nasal Polyposis\***

| Recommendation                                                                         | Strength of Recommendation | Certainty of Evidence |
|----------------------------------------------------------------------------------------|----------------------------|-----------------------|
| Treatment with INCS is suggested (rather than no INCS) in people with CRSwNP           | Conditional                | Low                   |
| Treatment with biologics is suggested (rather than no biologics) in people with CRSwNP | Conditional                | Moderate              |
| Treatment with ATAD is suggested (rather than no ATAD) in people with AERD             | Conditional                | Moderate              |

\*Adapted from Rank et al (2023)<sup>35</sup> AERD: aspirin (or nonsteroidal anti-inflammatory drug)-exacerbated respiratory disease; ATAD: aspirin therapy after desensitization; CRSwNP: chronic rhinosinusitis with nasal polyposis; INCS: intranasal corticosteroids.

## Balloon Sinus Ostial Dilation

### American Academy of Otolaryngology – Head and Neck Surgery et al

In 2018, the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) published a clinical consensus statement on balloon dilation of the sinuses.<sup>60</sup> Participating subgroups included the Triologic Society, the American Rhinologic Society, the American Academy of Otolaryngic Allergy, and the American Academy of Allergy, Asthma & Immunology. The expert panel used Delphi method surveys to assess consensus on proposed statements.

Statements achieving a mean score of 7.00 or higher and having no more than 1 outlier (2 or more Likert points from the mean in either direction) met criteria for consensus. Strong consensus was defined as a mean Likert score of 8.00 or higher with no outliers. The following statements met consensus; statements reaching strong consensus are noted as such: (The updated information to guideline statement can be found on the AAO-HNS website dated April 2021).

#### Patient Criteria:

- Balloon dilation is not appropriate for patients who are without both sinonasal symptoms and positive findings on CT. (Strong consensus)
- Balloon dilation is not appropriate for the management of headache in patients who do not otherwise meet the criteria for chronic sinusitis or recurrent acute sinusitis. (Strong consensus)
- Balloon dilation is not appropriate for the management of sleep apnea in patients who do not otherwise meet the criteria for chronic sinusitis or recurrent acute sinusitis. (Strong consensus)
- CT scanning of the sinuses is a requirement before balloon dilation can be performed. (Strong consensus)
- Balloon dilation is not appropriate for patients with sinonasal symptoms and a CT that does not show evidence of sinonasal disease.
- Balloon dilation can be appropriate as an adjunct procedure to FESS in patients with chronic sinusitis without nasal polyps.
- There can be a role for balloon dilation in patients with persistent sinus disease who have had previous sinus surgery.
- There is a role for balloon sinus dilation in managing patients with recurrent acute sinusitis as defined in the AAO-HNSF guideline based on symptoms and CT evidence of ostial occlusion and mucosal thickening.

#### Perioperative Considerations:

- Surgeons who consider reusing devices intended for dilation of the sinuses should understand the regulations set forth by the FDA for reprocessing such devices and ensure that they are followed. (Strong consensus)
- Balloon dilation can be performed under any setting as long as proper precautions are taken, and appropriate monitoring is performed.
- Balloon dilation can be performed under local anesthesia with or without sedation.



Outcome:

- Balloon dilation can improve short-term quality-of-life outcomes in patients with limited CRS without polyposis.
- Balloon dilation can be effective in frontal sinusitis.

The AAO-HNS updated its statement on balloon ostial dilation, reaffirming its 2010 position statement: "Sinus ostial dilation ... is a therapeutic option for selected patients with chronic rhinosinusitis.... This approach may be used alone ... or in conjunction with other instruments...." (Most recent revision with references added, 4/13/2021)<sup>61</sup>

In 2015, the Academy's Foundation updated its 2007 clinical practice guidelines on adult sinusitis, which do not discuss surgical therapy or use of balloon sinuplasty.<sup>7</sup>

### **National Institute for Health and Clinical Evidence**

In 2008 (reaffirmed in 2012), a guidance on balloon catheter dilation of paranasal sinus ostia from the National Institute for Health and Care Excellence (NICE) stated:

- "Current evidence on the short-term efficacy of balloon catheter dilation of paranasal sinus ostia for chronic sinusitis is adequate and raises no major safety concerns.
- This procedure should only be carried out by surgeons with experience of complex sinus surgery, and specific training in both the procedure and the use of fluoroscopy.
- Publication of long-term outcomes will be helpful in guiding the future use of this technique. NICE may review the procedure upon publication of further evidence."<sup>62</sup>

In 2016, NICE published a recommendation on the use of the XprESS Multi-Sinus Dilation System for the treatment of chronic rhinosinusitis<sup>63</sup>:

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."



The recommendation was based on the results of the REMODEL study: the committee "considered that the evidence from REMODEL demonstrated that balloon dilation (with either XprESS or FinESS) is clinically non-inferior to FESS in terms of alleviating symptoms in patients with uncomplicated chronic sinusitis." Single-arm observational studies were of lower quality but were consistent with the findings of the REMODEL study. This guidance was reaffirmed in July 2020.

### **American Rhinologic Society**

A position statement, revised in 2023, from the American Rhinologic Society, stated that sinus ostial dilation is "a therapeutic option for selected patients with chronic rhinosinusitis (CRS) and recurrent acute rhinosinusitis (RARS) who have failed appropriate medical therapy."<sup>64</sup>

### **Medicare National Coverage**

There is no national coverage determination.

### **Regulatory Status**

#### **Functional Endoscopic Sinus Surgery**

Functional endoscopic sinus surgery is a surgical procedure and, as such, is not subject to regulation by the US Food and Drug Administration (FDA).

#### **Balloon Sinus Ostial Dilation**

In 2008, the Relieva Sinus Balloon Catheter (Integra LifeSciences, formerly Acclarent) was cleared for marketing by the US 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 (see Table 7 below).



In 2008, the FinESS Sinus Treatment (Entellus Medical, Maple Grove, MN) was cleared for marketing by the 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 (Smith & Nephew, formerly ENTrigue Surgical), and the XprESS Multi-Sinus Dilation Tool (Stryker, formerly Entellus Medical), 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 the 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. Ventera Sinus Dilation System does not require a guide wire or an illumination system as it is intended for use as a tool in combination with endoscopic sinus surgery.<sup>39</sup>

**Table 7** summarizes the currently FDA cleared balloon sinus dilation devices.

FDA product code: LRC.

**Table 7. Balloon Ostial Dilation Devices Cleared by the US Food and Drug Administration**

| Device                                   | Manufacturer        | 510(k) No. | Date Cleared | Indication           |
|------------------------------------------|---------------------|------------|--------------|----------------------|
| Relieva Ultirra Sinus Balloon Catheter   | Acclarent, Inc.     | K190525    | 05/03/2019   | Sinus Ostia Dilation |
| Sinusway Dilation System                 | 3NT Medical Ltd.    | K181838    | 12/20/2018   | Sinus Ostia Dilation |
| MESIRE - Balloon Sinus Dilatation System | Meril Life Sciences | K172737    | 12/12/2017   | Sinus Ostia Dilation |



| Device                                         | Manufacturer                | 510(k)<br>No. | Date<br>Cleared | Indication           |
|------------------------------------------------|-----------------------------|---------------|-----------------|----------------------|
| Relieva SpinPlus Nav Balloon Sinuplasty System | Acclarent, Inc.             | K171687       | 10/13/2017      | Sinus Ostia Dilation |
| Relieva UltirraNav Sinus Balloon Catheter      | Acclarent Inc.              | K161698       | 10/24/2016      | Sinus Ostia Dilation |
| Vent-Os Sinus Dilation Family                  | Sinusys Corp.               | K160770       | 6/29/2016       | Sinus Ostia Dilation |
| Relieva Scout Multi-Sinus Dilation System      | Acclarent Inc.              | K153341       | 2/12/2016       | Sinus Ostia Dilation |
| XprESS Multi-Sinus Dilation System             | Entellus Medical Inc.       | K152434       | 11/20/2015      | Sinus Ostia Dilation |
| DSS Sinusplasty Balloon Catheter               | Intuit Medical Products LLC | K143738       | 8/27/2015       | Sinus Ostia Dilation |
| Relieva SpinPlus Balloon Sinuplasty System     | Acclarent Inc.              | K143541       | 4/22/2015       | Sinus Ostia Dilation |
| XprESS Multi-Sinus Dilation Tool               | Entellus Medical Inc.       | K142252       | 10/17/2014      | Sinus Ostia Dilation |
| Relieva Scout Multi-Sinus Dilation System      | Acclarent Inc.              | K140160       | 2/20/2014       | Sinus Ostia Dilation |

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## History

| Date     | Comments                                                                                                                                                                                                                                                                                                                                                                                                        |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 12/08/14 | 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.                                                                                                                                                                                                                                     |
| 03/20/15 | Implementation delayed until July 1, 2015.                                                                                                                                                                                                                                                                                                                                                                      |
| 04/05/15 | Implementation delayed until August 15, 2015.                                                                                                                                                                                                                                                                                                                                                                   |
| 04/13/15 | Implementation delayed until August 18, 2015, to align with provider notification.                                                                                                                                                                                                                                                                                                                              |
| 05/14/15 | Implementation delayed until October 15, 2015 to facilitate appropriate provider notification.                                                                                                                                                                                                                                                                                                                  |
| 06/17/15 | Implementation delayed until December 30, 2015.                                                                                                                                                                                                                                                                                                                                                                 |
| 09/08/15 | 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. |
| 12/16/15 | Implementation delayed until May 1, 2016.                                                                                                                                                                                                                                                                                                                                                                       |
| 05/01/16 | 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.                                                                                                              |
| 05/24/16 | Update Related Policies. Remove 7.01.134 as it is archived.                                                                                                                                                                                                                                                                                                                                                     |



| Date     | Comments                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 07/01/16 | Policy moved to new format. No change in content or coverage.                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 08/01/16 | Interim Update, changes approved July 12, 2016. Note added that policy addresses age 19 and older. Added term: multiple nasal polyps. Added medically necessary indication, rationale and references for balloon sinus ostial dilation. Added references 5-19, 24. Policy title changed to Sinus Surgery.                                                                                                                                                                                                                |
| 01/01/17 | 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. |
| 02/17/17 | Updated title of Related Policy.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 05/01/17 | Annual review, changes approved April 11, 2017. Added references 13, 23, 24, 25. Policy statement unchanged.                                                                                                                                                                                                                                                                                                                                                                                                             |
| 05/05/17 | Revised Prior Authorization Requirements section.                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 01/16/18 | Minor edit, added Documentation Requirements table to the Policy Coverage Criteria section.                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 01/23/18 | Coding update, added new CPT codes 31241, 31253, 31257, 31259, and 31298 (new codes effective 1/1/18).                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 03/01/18 | 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.                                                                                                                                                                                                                                                                                                                                                  |
| 05/01/18 | 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.                      |
| 06/01/18 | Minor update; removed note and link to updated policy. Surgery Site of Service criteria becomes effective.                                                                                                                                                                                                                                                                                                                                                                                                               |
| 09/21/18 | Minor updated. Added Consideration of Age statement.                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 05/01/19 | Annual Review, approved April 2, 2019. Policy updated with literature review through January 2019; reference 44 added, references 53-57 removed. Policy statement unchanged. Removed CPT code 31299.                                                                                                                                                                                                                                                                                                                     |
| 12/10/19 | Minor update, added 7.01.134 to related policies as it was reinstated effective December 5, 2019.                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 01/01/20 | Coding update, revised descriptors for CPT codes 31295, 31296, 31297, and 31298.                                                                                                                                                                                                                                                                                                                                                                                                                                         |



| Date     | Comments                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 08/01/20 | Annual Review, approved July 2, 2020. Policy updated with literature review through January 7, 2020; references added.                                                                                                                                                                                                                                                                                                                                            |
| 11/01/20 | Coding update. Added HCPCS code C1726.                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 05/01/21 | Annual Review, approved April 1, 2021. Policy updated with literature review through January 12, 2021; references added. Policy statements unchanged.                                                                                                                                                                                                                                                                                                             |
| 09/01/21 | Interim Review, title changed from "Sinus Surgery" to "Sinus Surgery in Adults"                                                                                                                                                                                                                                                                                                                                                                                   |
| 05/01/22 | Annual Review, approved April 25, 2022. Policy updated with literature review through December 28, 2021; references added. Policy statements unchanged.                                                                                                                                                                                                                                                                                                           |
| 05/04/22 | Minor update to related policy title 7.01.134 – changed from "Steroid-Eluting Sinus Stents" to "Steroid-Eluting Sinus Stents and Implants". Added related policy 7.01.168 Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment of Chronic Rhinitis.                                                                                                                                                                                            |
| 05/01/23 | Annual Review, approved April 10, 2023. Policy updated with literature review through December 27, 2022; references added. Added clarifying language to chronic rhinosinusitis symptoms and to imaging criteria for clarity only, policy intent unchanged. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.                                      |
| 05/18/23 | Minor correction. Documentation guidelines corrected to appropriately align with medical policy statements.                                                                                                                                                                                                                                                                                                                                                       |
| 12/01/23 | Interim Review, approved November 14, 2023. References added. Silent sinus syndrome (aka chronic maxillary atelectasis) added to list of conditions for which FESS may be considered medically necessary.                                                                                                                                                                                                                                                         |
| 01/01/24 | Interim Review, approved December 11, 2023. Reference added. Added maxillary accessory ostium/ostia (ostiomeatal complex), or the presence of accessory ostia to imaging findings associated with chronic rhinosinusitis.                                                                                                                                                                                                                                         |
| 05/01/24 | Annual Review, approved April 8, 2024. Policy updated with literature review through January 22, 2024; reference added. Policy statements unchanged.                                                                                                                                                                                                                                                                                                              |
| 05/01/25 | Annual Review, approved April 7, 2025. Policy updated with literature review through January 7, 2025; references added. Policy statements unchanged. Added CPT codes 31233, 31235 and 31240 to policy to match policy criteria.                                                                                                                                                                                                                                   |
| 08/01/25 | Interim Review, approved July 8, 2025. Removed CPT 31233, 31235 & 31240. Removed Related Policy 11.01.524 Site of Service: Select Surgical Procedures. The following policy changes are effective November 7, 2025, following 90-day provider notification. Added related policy 11.01.525 Site of Service Ambulatory Service Center (ASC) Select Surgical Procedures. Added Site of Service Ambulatory Service Center (ASC) Select Surgical Procedures criteria. |



**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2025 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

