

# Balloon Dilation (Eustachian Tube and Sinus), Functional Endoscopic Sinus Surgery and RhinAer



INDEPENDENT CARE HEALTH PLAN

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## Medical Coverage Policy

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## Related Medical/Pharmacy Coverage Policies

Sinuva (mometasone furoate) sinus implant Pharmacy Coverage Policy

## Related Documents

Please refer to [CMS website](#) for the most current applicable National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

There are no NCD and/or LCDs for Balloon Dilation (Eustachian Tube and Sinus), Functional Endoscopic Sinus Surgery, and RhinAer.

## Description

Rhinosinusitis is an inflammatory condition of the cavities around the sinuses (nasal passages) which causes them to become swollen. It can be further classified as acute (isolated episode), recurrent acute (four or more occurrences in one year) or chronic (lasting longer than 12 weeks despite medical management). For an individual who experiences persistent symptoms despite medical management, surgical intervention of the sinus cavities may be necessary. Chronic rhinosinusitis is more difficult to accurately diagnose in children and adenoidectomy is primarily used as the first-line surgical treatment.<sup>29</sup>

**Balloon sinus ostial dilation, or balloon sinuplasty** is an outpatient treatment option for an individual diagnosed with recurrent acute or chronic rhinosinusitis. Endoscopic instruments are used to open the passages of the sinus ostia and paranasal spaces without cutting bone or removing tissue. Under local anesthesia, the surgeon inserts a small balloon through a tube placed in the nasal cavity where the blocked sinus is located. Using fluoroscopic guidance, the balloon is gradually inflated, deflated and then removed. The compression of soft bone and swollen tissue creates additional space and facilitates the drainage of mucus. The surgeon may assess the nasal passages with an endoscope following the procedure to confirm width.

Examples of these devices include, but may not be limited to:

- NuVent EM Dilation System
- VenSure Balloon
- Vent-Os Sinus Dilation System
- Ventera Sinus Dilation System

**Functional endoscopic sinus surgery (FESS)** is a minimally invasive surgical procedure intended to restore sinus ventilation and drainage by removal of diseased tissue and bone, which can facilitate the gradual resolution of mucosal disease. FESS is generally considered a standard of care for treating recurrent acute or chronic rhinosinusitis that has not responded to medical treatment. However, because FESS does not directly treat the underlying inflammatory disorder, sinus surgery must be followed by medical management to control inflammatory processes or symptoms will invariably return. Endoscopic sinus surgical procedures may occur in the ethmoid, frontal, maxillary and sphenoid sinuses.

**Drug-eluting sinus stents** are implantable devices placed to expand and prop open the sinus, support the bony structures inside the nose and are purported to prevent scar formation. Drug-eluting sinus stents (eg, mometasone furoate sinus implant), deliver a sustained, localized, controlled release of a corticosteroid which dissolves over time. Currently, the stents are being placed following surgery of the ethmoid, frontal and/or maxillary sinus cavities. Examples of these devices include, but may not be limited to, Propel, Propel Mini and Propel Contour.

For information regarding **Sinuva sinus implant** coverage determination/limitations, please refer to Sinuva (mometasone furoate) sinus implant Pharmacy Coverage Policy.

The Eustachian tube (ET) is a narrow passage that links the nasopharynx (back of the nose) to the middle ear. The functions of the ET include balancing middle ear pressure, protecting the middle ear from infection and nasal drainage, and allowing drainage of middle ear secretions. Eustachian tube dysfunction is

described as failure of the functional valve of the Eustachian tube to open and/or close properly, resulting in inadequate ventilation to the middle ear. This dysfunction may lead to either obstructive or patulous pathology.

**Balloon dilation of the Eustachian tube (BDET)** is a procedure intended to dilate (widen) the cartilaginous portion of the Eustachian tube to treat persistent obstruction. Along with the procedure, a nasopharyngoscopy may be performed to evaluate whether there are any anatomic challenges that may complicate the procedure or require additional surgical intervention. The guide catheter is used to access the ET through the nose. The clinician then threads the balloon catheter through the guide catheter and inflates the balloon (via injection of saline or sterile water), which purportedly opens a pathway for mucus and air to flow through the ET. Once the ET is dilated, the balloon is deflated and removed. Examples of these devices include, but may not be limited to, AERA Eustachian Balloon Dilation System and NuVent Eustachian Tube Dilation Balloon.

**RhinAer** is a noninvasive procedure that purportedly treats chronic rhinitis by destroying inflamed soft tissue and disrupting the posterior nasal nerve signals that are thought to cause excess mucus production and congestion. A probe is inserted intranasally that administers low-temperature radiofrequency energy to ablate the posterior nasal nerve and reduce inflamed soft tissue.

### Coverage Determination

*iCare follows the CMS requirement that only allows coverage and payment for services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.*

*In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:*

#### **Balloon Dilation of the Eustachian Tube (BDET)**

**BDET** will be considered medically reasonable and necessary when the following requirements are met:

- Documentation indicates failure of conservative therapy (eg, over-the-counter oral medications, nasal sprays); **AND**
- Documentation shows signs and symptoms of Eustachian tube dysfunction (eg, changes in hearing, ear pain, ringing in the ear)

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

**Balloon sinus ostial dilation** will be considered medically reasonable and necessary when all of the following requirements are met:

- Balloon dilation is limited to the frontal, maxillary and/or sphenoid sinuses; **AND**
- The system is used according to the FDA-approved indications for age and sinus cavities; **AND**

- Documentation of rhinosinusitis as **EITHER**:
  - Chronic rhinosinusitis (greater than 12 consecutive weeks); **OR**
  - Recurrent acute rhinosinusitis (4 or more occurrences in 1 year);

**AND ALL** of the following:

- Documented failure of medical therapy demonstrated by persistent upper respiratory symptoms despite treatment consisting of the following:
  - Antibiotic therapy if bacterial infection is suspected; **AND**
  - Appropriate environmental controls, antihistamine nasal spray (eg, Astepro, Patanase) and/or allergen immunotherapy (eg, injections); **AND**
  - Intranasal or oral corticosteroids; **AND**
- Radiographic confirmation following the treatments noted above which demonstrate **one or more** of the following:
  - Infection/sinusitis of the affected sinus(es); **OR**
  - Obstruction within the affected sinus(es); **OR**
  - Surrounding anatomy contributing to obstruction of the affected sinus(es)

**Balloon sinus ostial dilation used adjunctively during functional endoscopic sinus surgery (FESS) in the *same* sinus cavity is considered integral to the primary procedure and not separately reimbursable.**

**Functional Endoscopic Sinus Surgery (FESS)**

**FESS** will be considered medically reasonable and necessary when the following requirements are met:

- Acute complications of rhinosinusitis confirmed by computerized tomography (CT) scan or diagnostic endoscopic exam, consisting of **one or more** of the following:
  - Abscess (epidural, intracerebral, orbital, subdural, subperiosteal); **OR**
  - Cavernous sinus thrombosis; **OR**
  - Cellulitis (orbital, preseptal); **OR**
  - Frontal bone osteomyelitis; **OR**
  - Meningitis; **OR**
- Allergic fungal sinusitis and **ALL** of the following:
  - Nasal airway obstruction; **AND**
  - Positive findings on CT scan (eg, fungal ball); **OR**

- Cerebrospinal fluid rhinorrhea; **OR**
- Chronic sinus polyposis creating nasal obstruction which is unresponsive to medical treatment for at least 4 consecutive weeks (eg, antibiotics, nasal steroids); **OR**
- Documentation of rhinosinusitis as **EITHER**:
  - Chronic rhinosinusitis (greater than 12 consecutive weeks); **OR**
  - Recurrent acute rhinosinusitis (4 or more occurrences in 1 year);

**AND ALL** of the following:

- Documented failure of medical therapy demonstrated by persistent upper respiratory symptoms despite treatment consisting of **ALL** of the following:
  - Antibiotic therapy if bacterial infection is suspected; **AND**
  - Appropriate environmental controls, antihistamine nasal spray (eg, Astepro, Patanase) and/or allergen immunotherapy (eg, injections); **AND**
  - Intranasal or oral corticosteroids; **AND**
- Radiographic confirmation following the treatments noted above which demonstrate **one or more** of the following:
  - Infection/sinusitis of the affected sinus(es); **OR**
  - Obstruction within the affected sinus(es); **OR**
  - Surrounding anatomy contributing to obstruction of the affected sinus(es); **OR**
- Foreign body removal; **OR**
- Mucoceles; **OR**
- Posterior epistaxis, uncontrolled; **OR**
- Recurrent sinusitis (4 or more occurrences in 1 year) that triggers or aggravates pulmonary disease (eg, asthma, cystic fibrosis); **OR**
- Tumors suspected via CT scan, diagnostic endoscopy or physical examination

**Nasal sinus debridement after FESS** will be considered medically reasonable and necessary.

**Repeat FESS** following failure of a previous sinus surgical procedure will be considered medically reasonable and necessary.

*The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.*

## Coverage Limitations

[US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage](#)

### SINUS TREATMENTS

The following **sinus treatments** will not be considered medically reasonable and necessary:

- Balloon sinus ostial dilation for the ethmoid sinuses; **OR**
- Drug-eluting sinus stents (eg, Propel, Propel Mini, Propel Contour); **OR**
- RhinAer procedure

A review of the current medical literature shows that the evidence is insufficient to determine that these services are standard medical treatments. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

### Summary of Evidence

Randomized control trials (RCTs) show the effectiveness of balloon sinus ostial dilation in single-cell sinus cavities (eg, frontal, maxillary, sphenoid); however, available study results do not support the use in the **ethmoid sinus** which has multiple cells with an intricate structure through which the paranasal sinuses drain.<sup>23</sup> Clinical study results are limited to efficacy data regarding balloon sinus ostial dilation of the frontal, maxillary and sphenoid sinuses. Although improvement in chronic rhinosinusitis has been demonstrated, available study results are limited and are at risk for bias due to sponsorship by manufacturers of the balloon catheters.<sup>43</sup>

A recent systematic review showed improved Sino-Nasal Outcome Test (SNOT-22) scores for patients treated with **drug-eluting sinus stents** as compared to topical medication treatment for chronic rhinosinusitis. However, scores did not differ statistically at 3-month follow-up studies. Two RCTs showed risk for bias and small study size that included too few individuals to be conclusive.<sup>24</sup> There remains a lack of longer-term unbiased RCTs with comparative data between drug-eluting sinus stents and medication therapy demonstrating the safety and efficacy of drug-eluting sinus stents for the treatment of chronic rhinosinusitis.<sup>28</sup>

Available evidence from one RCT and two case studies suggest that **RhinAer** may be safe and effective in treating chronic rhinosinusitis symptoms in most individuals after treatment. However, the difference in symptom improvement between RhinAer and sham treatment at three-month follow-up is not statistically

significant enough to arrive at a definitive conclusion.<sup>25</sup> There remains a lack of longer-term unbiased RCTs with comparative data for RhinAer versus conventional or alternative procedures.<sup>29</sup>

### Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
30117	Excision or destruction (eg, laser), intranasal lesion; internal approach	
30999	Unlisted procedure, nose	
31237	Nasal/sinus endoscopy, surgical; with biopsy, polypectomy or debridement (separate procedure)	
31238	Nasal/sinus endoscopy, surgical; with control of nasal hemorrhage	
31239	Nasal/sinus endoscopy, surgical; with dacryocystorhinostomy	
31240	Nasal/sinus endoscopy, surgical; with concha bullosa resection	
31241	Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery	
31253	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including frontal sinus exploration, with removal of tissue from frontal sinus, when performed	
31254	Nasal/sinus endoscopy, surgical with ethmoidectomy; partial (anterior)	
31255	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior)	
31256	Nasal/sinus endoscopy, surgical, with maxillary antrostomy;	
31257	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including sphenoidotomy	
31259	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including sphenoidotomy, with removal of tissue from the sphenoid sinus	
31267	Nasal/sinus endoscopy, surgical, with maxillary antrostomy; with removal of tissue from maxillary sinus	
31276	Nasal/sinus endoscopy, surgical, with frontal sinus exploration, including removal of tissue from frontal sinus, when performed	
31287	Nasal/sinus endoscopy, surgical, with sphenoidotomy;	

31288	Nasal/sinus endoscopy, surgical, with sphenoidotomy; with removal of tissue from the sphenoid sinus	
31290	Nasal/sinus endoscopy, surgical, with repair of cerebrospinal fluid leak; ethmoid region	
31291	Nasal/sinus endoscopy, surgical, with repair of cerebrospinal fluid leak; sphenoid region	
31292	Nasal/sinus endoscopy, surgical, with orbital decompression; medial or inferior wall	
31293	Nasal/sinus endoscopy, surgical, with orbital decompression; medial and inferior wall	
31294	Nasal/sinus endoscopy, surgical, with optic nerve decompression	
31295	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); maxillary sinus ostium, transnasal or via canine fossa	
31296	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); frontal sinus ostium	
31297	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); sphenoid sinus ostium	
31298	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); frontal and sphenoid sinus ostia	
31299	Unlisted procedure, accessory sinuses	
69705	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); unilateral	
69706	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); bilateral	
69799	Unlisted procedure, middle ear	
<b>CPT® Category III Code(s)</b>	<b>Description</b>	<b>Comments</b>
No code(s) identified		
<b>HCPCS Code(s)</b>	<b>Description</b>	<b>Comments</b>
No code(s) identified		

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## Appendix

### Appendix A

#### Balloon Sinus Dilation Systems

Balloon Sinus Dilation Systems for Adults	FDA Indications
<ul style="list-style-type: none"> <li>• NuVent EM Sinus Dilation System</li> </ul>	<ul style="list-style-type: none"> <li>• Locate and move tissue, bone or cartilaginous tissue surrounding the drainage pathways of frontal, maxillary, and sphenoid sinuses to facilitate dilation of the sinus ostia<sup>47</sup></li> </ul>
<ul style="list-style-type: none"> <li>• RELIEVA SCOUT Multi-Sinus Dilation System</li> </ul>	<ul style="list-style-type: none"> <li>• Access and dilate the sinus ostia and spaces associated with the sphenoid, frontal and maxillary sinus cavities<sup>48</sup></li> </ul>
<ul style="list-style-type: none"> <li>• Vent-Os Sinus Dilation System</li> </ul>	<ul style="list-style-type: none"> <li>• Access and dilate the maxillary sinus ostia<sup>53</sup></li> </ul>
<ul style="list-style-type: none"> <li>• Mesire Sinus Balloon Dilation System</li> <li>• RELIEVA SPINPLUS Balloon Sinuplasty System</li> <li>• RELIEVA SPINPLUS NAV Balloon Sinuplasty System</li> <li>• RELIEVA ULTIRRA Sinus Balloon Catheter</li> </ul>	<ul style="list-style-type: none"> <li>• Access and dilate the sinus ostia and spaces associated with the paranasal sinus cavities<sup>46,49,50,51</sup></li> </ul>
<ul style="list-style-type: none"> <li>• VenSure Balloon Device</li> <li>• Ventera Sinus Dilation System</li> <li>• XprESS ENT Dilation System</li> </ul>	<ul style="list-style-type: none"> <li>• Access and treat the frontal ostia/recesses, sphenoid sinus ostia and maxillary ostia<sup>45,52,54</sup></li> </ul>

## Change Summary

- 01/01/2024 New Policy.
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