

<b>Subject: Balloon Sinuplasty for Treatment of Chronic Sinusitis</b>		<b>Original Effective Date:</b> 11/16/15
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**DISCLAIMER**

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**DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL**

Balloon ostial dilation (also known as balloon sinuplasty™) is proposed as an alternative to traditional endoscopic sinus surgery for patients with chronic sinusitis who fail medical management. The procedure involves placing a balloon in the sinus ostium and inflating the balloon to stretch the opening. Balloon catheter sinusotomy is typically performed by an otolaryngologist on an outpatient basis, under general or local anesthesia. Balloon sinuplasty is intended for treatment of chronic sinusitis in adult patients who have not responded adequately to conservative medical treatments such as decongestants and antibiotics.

There are several balloon ostial dilation devices that have been FDA approved. The Relieva Sinus Balloon Catheter (Acclarent Inc.), XprESS (Entellus Medical Inc.) and the Sinus Dilatation System (ENTrigue Surgical Inc.) are classified by the Center for Devices and Radiological Health (CDRH) as an ENT (ear-nose-throat) manual surgical instrument and regulated as a Class I device.

**RECOMMENDATION**

Balloon ostial dilation and balloon sinuplasty are considered experimental, investigational and unproven due to insufficient evidence in the peer reviewed medical literature that that have not established safety, efficacy and effect on net health outcomes.

**SUMMARY OF MEDICAL EVIDENCE<sup>5-24</sup>**

There is insufficient published evidence to assess the role of balloon sinuplasty or the treatment of patients with chronic sinusitis, the safety and/or impact on health outcomes or patient management. Balloon sinuplasty is being investigated as a minimally invasive alternative to functional endoscopic sinus surgery, or as an adjunct to

endoscopic sinus surgery. There is some evidence that suggests when compared with FESS or adenoidectomy alone, balloon sinuplasty leads to improved health outcomes in selected patients and that this technique can be performed successfully and safely in patients with chronic rhinosinusitis. There is insufficient evidence on the impact of balloon sinuplasty on health outcomes. The quality of the evidence is low. Small randomized, controlled trials do not report significant improvements on clinically relevant outcome measures.<sup>8-24</sup>

A Cochrane review (2011) found one study (n=34) that randomised patients with chronic frontal sinusitis who had failed a prolonged course of medical treatment into two groups: balloon dilatation of the frontal recess (plus conventional FESS of other involved sinuses) versus conventional FESS (Draf type 1/2a procedures on the frontal sinuses). At 12 months follow up there was no statistically significant difference in radiological resolution of frontal sinuses between the two groups. The percentages of directly observed patent frontal recesses at 12 months were 75% in the balloon dilation group versus 63% in the FESS-only group. The authors state that this was statistically significant but details of the analysis were not presented. Indeed the study as a whole suffers from a bias in the way its outcome measures were reported. The review concluded that at present there is no convincing evidence supporting the use of endoscopic balloon sinus ostial dilation compared to conventional surgical modalities in the management of CRS refractory to medical treatment. With the escalating use of balloon sinuplasty, there is an urgent need for more randomised controlled trials to determine its efficacy over conventional surgical treatment modalities.<sup>9</sup>

A 2013 Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) report evaluated one randomized clinical trial, 3 nonrandomized comparative trials, and 9 case series studies that had a sample size of at least 10 in which clinical outcomes of patients with chronic rhinosinusitis were reported were included. The goal was to determine whether balloon sinus ostial dilation improves health outcomes when used as a treatment for chronic rhinosinusitis as compared to standard surgical treatment (FESS). The one randomized clinical trial compared balloon ostial dilation of the frontal sinus plus ethmoidectomy (using FESS) versus FESS of the frontal sinus plus ethmoidectomy. In this small poor quality trial of 34 patients, improvements in computed tomography images, symptom scores, and olfactory threshold were noted within each group. No statistical between-group comparisons were reported, but the magnitude of improvement in these outcomes appeared similar. One nonrandomized, retrospective, comparative trial evaluated balloon sinus ostial dilation and FESS in 70 adults. Compared to excluded patients, those enrolled had less-severe rhinosinusitis on imaging, and without systemic disease or excessive nasal polyps. Patients undergoing combined balloon sinus ostial dilation and FESS were excluded. The decrease in rhinosinusitis symptoms as measured by the SNOT-20 score was greater in the balloon sinus ostial dilation group than in the FESS group (1.99 versus 1.41,  $p=0.005$ ) at 3 months. Overall patient satisfaction favored balloon sinus ostial dilation and postoperative narcotic use was less in the balloon sinus ostial dilation group. The second nonrandomized, retrospective study compared balloon sinus ostial dilation to FESS in 31 pediatric patients. No specific rhinosinusitis symptom assessment was performed. Medical charts were reviewed for documentation of the presence and change in symptoms over time. Improvement was documented for 80% of balloon sinus ostial dilation patients and 62.5% of FESS patients ( $p$  not significant between the groups). A third nonrandomized study compared the results of 30 pediatric patients undergoing balloon sinus ostial dilation and adenoidectomy to 19 patients undergoing adenoidectomy. Eighty percent of balloon sinus ostial dilation patients improved at least 0.5 in the SN-5 score compared to 52.6% of adenoidectomy patients. However, the lack of comparison to FESS further limits study implications. Several case series studies of balloon sinus ostial dilation found improvements in symptom scores

after surgery. In the subsets of patients in the various studies followed at least 2 years, symptom improvement appeared durable. Few adverse events were reported. Revision rates after surgery varied from 3 to 9%. The review concluded that studies of balloon sinus ostial dilation do not allow conclusions regarding the comparative efficacy of balloon sinus ostial dilation to FESS.<sup>7</sup>

**CODING INFORMATION** THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa
31296	With dilation of frontal sinus ostium (eg, balloon dilation)
31297	With dilation of sphenoid sinus ostium (eg, balloon dilation)

HCPCS	Description
	N/A

ICD-9	Description [For dates of service prior to 10/01/2015]
473.0-473.9	Chronic sinusitis code range

ICD-10	Description [For dates of service on or after 10/01/2015]
J32.0-J32.8	Chronic sinusitis code range

**REFERENCES**

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- Food and Drug Administration [website]. 510K Summary. ENTrigue Surgical's Sinus Dilation System. Accessed at: [http://www.accessdata.fda.gov/cdrh\\_docs/pdf12/K121351.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf12/K121351.pdf)
- Food and Drug Administration [website]. 510K Summary. XprESS Multi-Sinus Dilation Tool. Accessed at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K142252>

**Hayes and TEC**

- Hayes Health Technology Brief. Relieva Balloon Sinuplasty (Acclarent Inc.) for Chronic Sinusitis in Adults. Winifred Hayes Inc. Lansdale, Pa. August 2014.

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### Peer Reviewed Publications

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### **Other Resources and Professional Guidelines**

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