INLAND EMPIRE HEALTH PLAN

IEHP UM Subcommittee Approved Authorization Guidelines
Balloon Catheter Dilation for the Treatment of Chronic Sinusitis or Balloon Sinuplasty

Policy:
IEHP considers the use of Balloon Sinus Ostial dilation for the treatment of any sinus condition including but not limited to sinusitis as investigational and experimental.

CPT-Code Number	Description
31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa
31296	Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation)
31297	Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation)
HCPCS	
S2344	Nasal/sinus endoscopy, surgical; with enlargement of sinus ostium opening using inflatable device (i.e., balloon sinuplasty

Medi-Cal Update Bulletin 449 November 2011 (1)
CPT codes 31295-31297 were added as new Medi-Cal Benefits. These codes are only Payable to the Primary Surgeon.

Code 31295 is not payable with codes 31233, 31256 or 31267 unless providers document the procedures were performed on different sinuses and use the appropriate National Correct Coding Initiative (NCCI)-associated modifier.

Code 31296 is not payable with 31276 unless providers document the procedures were performed on different sinuses and use the appropriate NCCI-associated modifier.

Code 31297 is not payable with 31235, 31287 or 31288 unless providers document the procedures were performed on different sinuses and use the appropriate NCCI-associated modifier.

Apollo
Balloon Sinuplasty™ is considered experimental/investigational. It is not a covered benefit by health plans or Medicare.

American Academy of Otolaryngology-Head and Neck Surgery, *Balloon Dilation*. 2010 (2)
The position statement notes that "sinus ostial dilation (e.g. balloon ostial dilation) is an appropriate therapeutic option in selected patients with sinusitis" and that an attending surgeon must make the final recommendation regarding use of techniques or instrumentation for sinus surgery.

American Rhinologic Society (ARS): *Revised Position Statement on Endoscopic Balloon Catheter Sinus Dilation Technology*. May 2007. (3)
Based on currently available scientific medical evidence, endoscopic balloon dilation technology is acceptable and safe for use in the management of sinus disease.

Endoscopic balloon dilation technology is a tool, not a procedure, available to the operating surgeon at his/her discretion for the surgical management of sinus disease.

Patients who are treated with this technology may require concurrent conventional endoscopic sinus surgery especially in the ethmoid sinuses much like any surgical instrument that may be used in some parts of the sinus and not others or in combination with other technologies. In a group of selected patients, the use of balloon catheter dilation technology alone may eliminate the need for other surgical techniques. Endoscopic balloon catheter dilation as a tool for dilating the opening of the maxillary sphenoid, and frontal sinuses is not investigational or experimental and should not be viewed as such

National Institute for Health and Clinical Excellence, *Balloon Catheter Dilation of Paranasal Sinus Ostia for Chronic Sinusitis*. 2008 (4)
The guidance states that the short-term "efficacy of balloon catheter dilation of paranasal sinus ostia for chronic sinusitis is adequate and raises no major safety concerns." Additionally, the guidance recommends the procedure be performed by experienced surgeons trained in both the procedure and imaging-assisted equipment.

European Position Paper on Rhinosinusitis and Nasal Polyps. 2012(5)
This evidence-based position paper states, "There is not enough data to support the use of balloon catheters as an alternative to standard endoscopic sinus surgery techniques."

ECRI Review- Hotline Response on Balloon Catheter Dilation for treating Chronic Sinusitis January 2014 (6)
A search was performed using PubMed, the Cochrane Library, and selected web-based resources for documents relevant to this topic and published between January 1, 2008, and December 23, 2013. The selected search results are listed in Table 1. Table 2 includes descriptions of systematic reviews and technology assessments. The reported results of the clinical studies

comparing treatments are summarized in Table 3. The information in these tables is based on a review of abstracts and not full articles. Several additional clinical studies, including two randomized controlled trials, have been published since the ECRI Institute report was published. The findings reported in the abstracts suggest that balloon catheter dilation may be as effective as

FESS in improving symptoms. However, the new clinical literature should be evaluated before making any conclusions on the efficacy of balloon catheter dilation for treating chronic sinusitis compared with FESS. In particular, the evidence should be examined to determine whether any of the devices listed above is more effective than the other. Abstracts often do not provide device names, and only a review of the full article can determine which devices were used in the studies listed below.

Table 1. Overview of the Clinical Literature (January 1, 2008, through December 23, 2013)

Publication Type	Number of Publications	References
Systematic reviews/Technology assessments	2	1 *see also section 3 of the* Search Summary
Cost-effectiveness analyses	0	---
Randomized controlled trials	2	2,3
Nonrandomized studies comparing treatments	6	4-9
Case series	32	10-41
Narrative reviews	13	42-54

Table 2. Systematic Reviews and Technology Assessments

Reference	Purpose of Systematic Review Technology Assessment	Resources Searched and Inclusion Criteria	Findings	Conclusions Reported in the Abstract
BlueCross BlueShield Association 2012 (7)	Determine whether balloon sinus ostial dilation improves health outcomes when used as a treatment for chronic rhinosinusitis compared to functional endoscopic sinus surgery (FESS).	MEDLINE was searched through December 2012 and limited to English-language articles. Bibliographies of identified articles supplemented the original search. Required case series, nonrandomized comparison trials, and randomized clinical trials involving at least 10 patients with chronic rhinosinusitis and reporting outcomes	1 randomized clinical trial, 3 nonrandomized comparative trials, and 9 case series studies met selection criteria. The randomized clinical trial compared balloon ostial dilation of the frontal sinus plus ethmoidectomy (using FESS) with FESS of the frontal sinus plus ethmoidectomy in 34 patients (see Plaza et al. 2011[3] in Table 3). The study was considered to be poor quality.	"Studies of balloon sinus ostial dilation do not allow conclusions regarding the comparative efficacy of balloon sinus ostial dilation to FESS."
Ahmed et al. 2011(8)	Evaluate the effectiveness of balloon sinus ostial dilation for treating patients with chronic rhinosinusitis (CRS) refractory to medical treatment.	Cochrane Ear, Nose and Throat Disorders Group Trials Register; Central; PubMed; EMBASE; CINAHL; Web of Science; BIOSIS Previews; Cambridge Scientific Abstracts; ISRCTN Register; and additional sources for published and unpublished trials. Last search date was December 20, 2010. Required randomized trials comparing functional endoscopic sinus surgery with either balloon dilation or a hybrid procedure.	1 study met inclusion criteria that have not yet undergone peer review. Reviewers stated that "the study as a whole suffers from a bias in the way its outcome measures were reported."	"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

Table 3. Clinical Studies

Reference	Number of Patients	Treatment	Results	Conclusions
Randomized Controlled Trials				
Cutler et al. 2013(9)	n = 92 adults with uncomplicated chronic rhinosinusitis (CRS) of the maxillary sinuses with or without anterior ethmoid disease who met criteria for medically necessary functional endoscopic sinus surgery (FESS)	Office balloon dilation (n = 50) vs. FESS (n = 42)	At 6 months, the mean 20-item Sino-Nasal Outcome Test (SNOT-20) showed clinically meaningful and statistically significant improvement: balloon = 1.67 +/- 1.10 and FESS = 1.60 +/- 0.96. The balloon arm was noninferior to FESS. The mean number of postprocedure debridements per patient was 0.1 +/-0.6 in the balloon arm vs. 1.2 +/-1.0 in the FESS arm, with the balloon group showing superiority.	"Balloon dilation is noninferior to FESS for symptom improvement and superior to FESS for postoperative debridements in patients with maxillary and anterior ethmoid disease. Balloon dilation is an effective treatment in patients with uncomplicated CRS who meet the criteria for medically necessary FESS."
Plaza et al. 2011(10)	n = 40 patients with CRS for whom medical therapy was not effective	Balloon dilation vs. Conventional frontal sinus drainage with a Draf I procedure	At 1-year assessment of 32 patients, both groups improved. Permeability of the frontal recess was more common after balloon dilation (73%) than after sinus drainage (62.5%).	"Balloon dilation of the frontal recess is a relatively safe and effective tool in the management of chronic frontal rhinosinusitis after intensive medical treatment has failed."
Nonrandomized Studies Comparing Treatments				
Tomazic et al. 2013(11)	n = 45 patients (112 sinuses) with CRS for whom medical therapy was not effective	Balloon-only (68 sinuses) vs. Hybrid (44 sinuses) (procedure not explained in the abstract)	Sinus failure rates were 65% in the balloon-only group vs. 66% in the hybrid group. Study discontinued due to the high failure rate.	No author conclusions presented in the abstract.
Koskinen et al. 2012(12)	n = 85 patients with CRS without nasal polyps and who also responded to a questionnaire	Balloon dilation (n = 40) vs. Surgery (n = 45)	Same response rates and symptom improvement in the 2 groups. In those with CRS-related morbidity and/or occupational exposure (subgroup analysis), symptom relief was better after surgery. More maxillary sinus punctures and antibiotic courses in the balloon group in the last 12 months.	Endoscopic sinus surgery might be superior to balloon sinuplasty, especially in patients with risk factors. There is a need to perform more controlled studies on the treatment choices of CRS."

Thottam et al. 012(13)	n = 31 pediatric patients with CRS	Balloon catheter sinuplasty (BCS) with ethmoidectomy (n = 15) vs. FESS (n = 16)	Both groups improved. Fewer antibiotics used in the balloon group.	"Both BCS and FESS are suitable treatments for CRS in children. Both treatments significantly reduced CRS complaints post-operatively and had similar overall results. BCS patients required significantly fewer antibiotics post-operatively for CRS related disease when compared to FESS.

Table 4. Payer Policies

Payer	Policy Name	Date of Last Review	Coverage Policy
Anthem (14)	Balloon Sinus Ostial Dilation	11/14/2013	"The use of balloon sinus ostial dilation for the treatment of any sinus condition, including, but not limited to sinusitis, is considered investigational and not medically necessary."
BC/BS North Caroloina (15)	Balloon Ostial Dilation for Treatment of Chronic Sinusitis	08/2013	The use of a catheter-based inflatable device (balloon sinuplasty) is considered investigational in the treatment of sinusitis. BCBSNC does not provide coverage for investigational services or procedures.
United Healthcare-Health Plan of Nevada (16)	Balloon Sinuplasty	05/6/2013	"Balloon sinuplasty during endoscopic sinus surgery is not medically necessary for the treatment of chronic sinusitis."
Health Net (17)	Balloon Sinuplasty for Treatment of Chronic Sinusitis.	08/2013	"Health Net considers balloon sinuplasty medically necessary to relieve obstruction of the maxillary, sphenoid, and frontal sinus ostia, either alone or in combination with standard endoscopic sinus surgery techniques, for patients with chronic rhinosinusitis (CRS) when **all** of the following are met: 1. Documentation that the inflammation of the paranasal sinuses has persisted for 12 weeks or longer 2. Patient has **at least one** of the following symptoms/signs: Anterior or posterior mucopurulent nasal discharge. Nasal obstruction. Facial-pain-pressure-fullness. Headache 3. Patient has **at least one** finding of chronic sinusitis by CT scan: Air fluid levels ☐ Mucosal thickening > 2 mm. Opacification 4. Continued symptoms/findings after antibiotic therapy for ≥ 3 wks, meeting **either one** of the following: ☐ Antibiotic therapy guided by C & S ☐ Beta-lactamase resistant antibiotic (e.g., trimethoprim-sulfisoxazole, amoxicillin clavulanate, cefuroxime)

Background:

Balloon dilation is a minimally invasive surgical technique used during sinus surgery to relieve blocked sinuses and restore normal mucus flow; it may also be promoted as an alternative to traditional functional endoscopic sinus surgery (FESS) for some patients. Surgeons performing FESS use standard cutting tools (e.g., microdebriders, forceps, curettes) to dissect and remove tissue and bone. Purported benefits of using balloon catheters instead of cutting tools to

restructure and widen the sinuses are less bleeding, less postoperative pain, and a shorter recovery period.

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Revised:

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