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Reviewed: 08/26/21

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## Subject: Balloon Ostial Dilation (Balloon Sinuplasty) and Implantable Devices

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

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### DESCRIPTION:

Balloon sinuplasty is proposed as an alternative to endoscopic sinus surgery for individuals with chronic sinusitis who fail medical management (e.g., mucolytic, decongestant (oral and topical), antibiotic therapy). Balloon sinuplasty involves placing a balloon in the sinus ostium and inflating the balloon to stretch the opening.

The U.S. Food and Drug Administration (FDA) have cleared through the 510(k) process several devices (e.g., Relieva™ and Relieva Acella™ Sinus Balloon Catheter [Acclarent, Inc.] and Entellus Medical FinESS Sinus Treatment [Entellus Medical, Inc.], Xpress™ Balloon Device [Entellus Medical, Inc.], MESIRE™) for the catheterization and dilation of the sinus. Balloon sinuplasty can be performed as a stand-alone procedure or as an adjunctive procedure to endoscopic sinus surgery.

The U.S. Food and Drug Administration (FDA) have cleared through the 510(k) process the Vent-OS™ Sinus System, an instrument intended to provide a means to access the sinus space and to dilate the axillary sinus ostia and associated spaces in adults for diagnostic and therapeutic procedures.

Sinus stents (steroid-eluting), spacers and implants are devices that are used postoperatively following endoscopic sinus surgery (ESS) for treatment of recurrent sinonasal polyposis following ESS. These devices maintain patency of the sinus openings in the postoperative period, and/or serve as a local drug delivery vehicle. The intent of these devices is to maintain patency of the sinus openings in the postoperative period, and/or to serve as a local drug delivery vehicle. The U.S. Food and Drug Administration (FDA) have cleared through the 510(k) process several devices (e.g., Propel™, Propel™ mini, PROPEL Contour [Intersect ENT], SINUVA™ [Intersect ENT]).

The Propel™ device is indicated for use following ethmoid sinus surgery to maintain patency. The device is a self-expanding, bioabsorbable steroid-eluting stent.

The MicroFlow Spacer is indicated for use as a postoperative spacer to maintain an opening to the frontal sinuses within the first 14 days following surgery. The device is temporary and requires manual removal.

The SINUVA™ Sinus Implant is a corticosteroid-eluting (mometasone furoate) implant indicated for the treatment of nasal polyps in patients ≥ 18 years of age who have had ethmoid sinus surgery.

### **POSITION STATEMENT:**

The use of a FDA approved catheter-based inflatable device (e.g., balloon sinuplasty, balloon sinus dilation) in the treatment of sinusitis is **considered integral** to the traditional nasal/sinus endoscopic surgery or functional endoscopic sinus surgery (FESS) and is not separately reimbursable

The use of implantable sinus devices(e.g., Propel™, MicroFlow Spacer, ) for postoperative treatment following endoscopic sinus surgery, for the treatment or recurrent sinonasal polyposis and for all other conditions is considered **experimental or investigational** for all indications. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Note:** For Sinuva (mometasone furoate) sinus implant, refer to Drugs and Biologics without a Medical Coverage Guideline (Orphan Drugs and Off-Label and Labeled Use of FDA Approved Drugs), 09-J0000-38.

### **BILLING/CODING INFORMATION:**

#### **CPT Coding:**

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
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

#### **LOINC Codes:**

The following information may be required documentation to support medical necessity: physician history and physical, physician progress notes, plan of treatment and reason for catheter-based inflatable device (e.g., balloon sinuplasty, balloon sinus dilation).

<b>Documentation Table</b>	<b>LOINC Codes</b>	<b>LOINC Time Frame Modifier Code</b>	<b>LOINC Time Frame Modifier Codes Narrative</b>
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim

Attending physician progress note	18741-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Plan of treatment	18776-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim

### **REIMBURSEMENT INFORMATION:**

Refer to section entitled [POSITION STATEMENT](#).

### **PROGRAM EXCEPTIONS:**

**Federal Employee Program (FEP):** Follow FEP guidelines.

**State Account Organization (SAO):** Follow SAO guidelines.

#### **Medicare Advantage products:**

No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

### **DEFINITIONS:**

No guideline specific definitions apply.

### **RELATED GUIDELINES:**

None applicable.

### **OTHER:**

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Other names used to report balloon sinuplasty:

Balloon catheter sinuplasty

Balloon sinus dilation (BSD)

Catheter-based inflatable device

Functional Endoscopic Dilation of the Sinuses (FEDS)

Functional Endoscopic Sinus Surgery (FESS)

Hybrid procedure (balloon sinuplasty performed in conjunction with functional endoscopic sinus surgery (FESS))

Sinus balloon dilation

Sinus ostial dilation

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### **COMMITTEE APPROVAL:**

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 08/26/21.

### **GUIDELINE UPDATE INFORMATION:**

03/15/07	New Medical Coverage Guideline.
06/15/07	Reformatted guideline; updated references.
03/15/08	Scheduled review; no change in position statement. Updated description section, updated references.
03/15/09	Scheduled review. No change in position statement (experimental or investigational). Updated references.
03/15/10	Scheduled review. No change in position statement (experimental or investigational). Updated references.
01/01/11	Annual HCPCS coding update: added 31295, 31296, and 31297. Added program exception for Medicare Advantage products.
02/15/11	Guideline reviewed; added position statement for catheter-based inflatable device (e.g. balloon sinuplasty). Revised experimental or investigational position statement for catheter-based inflatable device (e.g. balloon sinuplasty).
04/01/11	First quarter HCPCS update; deleted S2344.
10/01/11	Revision; formatting changes.
12/15/11	Guideline reviewed; revised description and experimental and investigational statement for clarity. Updated references.
10/15/12	Scheduled reviewed; Deleted experimental or investigational position statement for catheter-based inflatable device (e.g., balloon sinuplasty, balloon sinus dilation) as a stand-alone procedure.
12/15/13	Scheduled review. No change in position statement. Added FDA cleared devices (Relieva Acella™ and Xpress™ Balloon Device [Entellus Medical, Inc.]). Added Medicare Advantage products program exception. Updated references.
09/15/14	Added position statement for implantable sinus stents and spacers. Added S1090. Updated references.
09/15/15	Guideline reviewed; no change in position statements. Revised name of guideline; added "balloon ostial dilation. Updated references.



01/01/16	Annual HCPCS code update. Added 0406T and 0407T.
07/15/17	Guideline reviewed. Revised position statement (added long-term and health).
01/01/18	Annual HCPCS code update. Added 31298.
05/15/18	Review; no change to position statement. Updated description, reimbursement information section and references.
01/01/19	Annual HCPCS code update. Deleted 0406T and 0407T.
03/15/19	Review; revised implantable devices statement. Updated references.
10/01/19	Quarterly CPT/HCPCS update. Deleted code S1090. Added note to position statement for Sinuva.
01/01/20	Annual HCPCS code update. Revised code descriptor (31295, 31296, 31297, 31298).
08/15/20	Review; no change to position statement. Deleted J7401 from reimbursement information. Updated references.
09/15/21	Review; no change to position statement. Updated references.