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**Original Effective Date: 03/15/17**

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**Revised: 08/15/24**

# 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.**



## 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.

**Summary and Analysis of Evidence:** In an evaluation study, Castro et al (2021) evaluated the 4-year outcomes and effectiveness of balloon sinuplasty in the treatment of chronic rhinosinusitis (CRS) of 110 patients with CRS for balloon sinuplasty. Sinus symptoms were determined by the Sino-Nasal Outcome Test (SNOT-22), endoscopic examination determined by Modified Lund Kennedy score (MLK) and computerized tomography scan of paranasal sinuses (CT-PNS) was evaluated through Lund Mackay scores (LM). Data was collected from 82 patients with chronic rhinosinusitis without nasal polyps (CRSsNP) and from 28 patients with nasal polyps (CRSwNP). The authors concluded that balloon sinuplasty appears to be safe and effective for the treatment of CRS with great long-term outcome.

Kutluhan et al (2020) Chronic rhinosinusitis is a broad clinical syndrome characterized by mucosal inflammation of the nose and paranasal sinuses. In order for the paranasal sinuses to maintain their physiological functions; the ostiomeatal complex drainage pathways must be open. Surgical procedures are an important treatment option in patients who do not respond adequately to medical treatment. Although the methods and instruments used in functional endoscopic sinus surgery have continued to improve in recent years, the scar tissue formed during operation disrupts the drainage of the sinuses and reduces postoperative success. The natural ostiodilatation method, which is performed by balloon sinoplasty method, has become more and more popular in recent years. The technique of balloon sinuplasty was compared with the classical functional endoscopic sinus surgery method by considering the severity of chronic sinusitis on the same patient. Total of 61 chronic sinusitis patients was included in the study. Paranasal sinus tomography of the patients was taken and according to the Lund-Mackay scoring, chronic sinusitis levels were determined. Cases were divided into two groups: Group 1 (severe chronic sinusitis group) and Group 2 (mild chronic sinusitis). The authors found that there was no statistically significant difference in the results of comparison of sinuses which underwent balloon sinoplasty and classical functional endoscopic sinus surgery in Group 2 after Lund-Mackay scores. However in Group 1, the results of the comparison of postoperative Lund-Mackay scores of the balloon sinoplasty and the classical endoscopic operation were statistically significantly lower than those of the face half operated with the classical functional endoscopic sinus surgery. The authors concluded that the success of balloon sinoplasty in patients with mild sinusitis is the same as in classic functional endoscopic sinus surgery. However, as the severity of sinusitis increases, the efficacy of balloon sinoplasty decreases.

In a review by Han and Kern (2019) Chronic rhinosinusitis (CRS) causes severe symptoms that lead to poor quality of life. When optimal medical therapy does not improve CRS symptoms, then endoscopic sinus surgery (ESS) can be used in patients with persistent symptoms and radiographic evidence of CRS to improve patients' symptoms and quality of life. Despite appropriate and complete sinus surgery, there can be issues after sinus surgery such as synechiae formation and recurrence of polyps in certain CRS patients that can decrease long-term outcomes. Corticosteroids are used to decrease postoperative scarring and edema as well as prevent recurrence of nasal polyp formation after sinus surgery. However, the use of oral or systemic steroid can lead to serious short-term and long-term complications.

Therefore, a safer alternative would be the topical delivery of steroid via steroid-eluting sinus implants. A literature review was performed to identify clinical studies evaluating steroid-eluting implants. Two forms of steroid-eluting implants were identified, Propel family products and Sinuva. Four prospective randomized clinical studies were identified for the Propel family products. Two prospective randomized clinical studies were identified for Sinuva. The results from the clinical studies showed that the use of the various steroid-eluting sinus implants can improve postoperative results after ESS as well as treat the recurrence of nasal polyps after sinus surgery without the need for additional sinus surgery. The authors concluded that novel steroid-eluting implants appear to be beneficial for CRS patients immediately post-operatively as well as for nasal polyps patients. Interestingly, these implants could be used as a substitute for the beneficial effect of systemic steroid use for CRS patients

## 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:

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| 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).

| Documentation Table | LOINC Codes | LOINC Time Frame Modifier Code | LOINC Time Frame Modifier Codes Narrative |
|---|---|---|---|

| | | | |
|---|---|---|---|
| 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 and Coverage Committee on 07/25/24.

## GUIDELINE UPDATE INFORMATION:

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| 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. |

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| 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. |
| 08/15/23 | Review; no change to position statement. Updated references. |
| 08/15/24 | Review; no change to position statement. Updated references. |