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.]) 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:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>31295</td>
<td>Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); maxillary sinus ostium, transnasal or via canine fossa</td>
</tr>
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<td>31296</td>
<td>Nasal/sinus endoscopy, surgical; with dilation (e.g., balloon dilation); frontal sinus ostium</td>
</tr>
<tr>
<td>31297</td>
<td>Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); sphenoid sinus ostium</td>
</tr>
<tr>
<td>31298</td>
<td>Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); frontal and sphenoid sinus ostia</td>
</tr>
</tbody>
</table>

**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).

<table>
<thead>
<tr>
<th>Documentation Table</th>
<th>LOINC Codes</th>
<th>LOINC Time Frame Modifier Code</th>
<th>LOINC Time Frame Modifier Codes Narrative</th>
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</thead>
<tbody>
<tr>
<td>Physician history and physical</td>
<td>28626-0</td>
<td>18805-2</td>
<td>Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim</td>
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### Attending physician progress note

<table>
<thead>
<tr>
<th>Code</th>
<th>Start Date</th>
<th>End Date</th>
<th>Notes</th>
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</thead>
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<td>18805-2</td>
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### Plan of treatment

<table>
<thead>
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<th>Code</th>
<th>Start Date</th>
<th>End Date</th>
<th>Notes</th>
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<td>18776-5</td>
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### Physician history and physical

<table>
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<tr>
<th>Code</th>
<th>Start Date</th>
<th>End Date</th>
<th>Notes</th>
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<td>18805-2</td>
<td>Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim</td>
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</tr>
</tbody>
</table>

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**REIMBURSEMENT INFORMATION:**

Refer to section entitled **POSITION STATEMENT**.

If J7401 is reported for Propel, considered investigational.

**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)
- 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
REFERENCES:
1. American Academy of Otolaryngology Head and Neck Surgery (ASO-HNS) Position Statement: Dilation of Sinuses, Any Method (e.g., balloon, etc.), 03/12/17.
6. Blue Cross Blue Shield Association Balloon Ostial Dilation for Treatment of Chronic Sinusitis Medical Policy 7.01.105, 02/19.
7. Blue Cross Blue Shield Association Steroid-Eluting Sinus Stents Medical Policy 7.01.134, 02/19.


47. National Institute for Health and Clinical Excellence-Balloon catheter dilation of paranasal sinus ostia for chronic sinusitis, 09/08.


COMMITTEE APPROVAL:
This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 02/28/19.

GUIDELINE UPDATE INFORMATION:
<table>
<thead>
<tr>
<th>Date</th>
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<tr>
<td>03/15/07</td>
<td>New Medical Coverage Guideline.</td>
</tr>
<tr>
<td>06/15/07</td>
<td>Reformatted guideline; updated references.</td>
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<tr>
<td>03/15/08</td>
<td>Scheduled review; no change in position statement. Updated description section, updated references.</td>
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<tr>
<td>03/15/09</td>
<td>Scheduled review. No change in position statement (experimental or investigational).</td>
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<td>Date</td>
<td>Event</td>
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<tr>
<td>03/15/10</td>
<td>Updated references.</td>
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<tr>
<td>01/01/11</td>
<td>Annual HCPCS coding update: added 31295, 31296, and 31297. Added program exception for Medicare Advantage products.</td>
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<td>02/15/11</td>
<td>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).</td>
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<tr>
<td>04/01/11</td>
<td>First quarter HCPCS update; deleted S2344.</td>
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<tr>
<td>10/01/11</td>
<td>Revision; formatting changes.</td>
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<tr>
<td>12/15/11</td>
<td>Guideline reviewed; revised description and experimental and investigational statement for clarity. Updated references.</td>
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<tr>
<td>10/15/12</td>
<td>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.</td>
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<td>12/15/13</td>
<td>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.</td>
</tr>
<tr>
<td>09/15/14</td>
<td>Added position statement for implantable sinus stents and spacers. Added S1090. Updated references.</td>
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<tr>
<td>09/15/15</td>
<td>Guideline reviewed; no change in position statements. Revised name of guideline; added &quot;balloon ostial dilation. Updated references.</td>
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<td>01/01/16</td>
<td>Annual HCPCS code update. Added 0406T and 0407T.</td>
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<tr>
<td>07/15/17</td>
<td>Guideline reviewed. Revised position statement (added long-term and health).</td>
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<td>01/01/18</td>
<td>Annual HCPCS code update. Added 31298.</td>
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<tr>
<td>05/15/18</td>
<td>Review; no change to position statement. Updated description, reimbursement information section and references.</td>
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<td>03/15/19</td>
<td>Review; revised implantable devices statement. Updated references.</td>
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<td>Annual HCPCS code update. Revised code descriptor (31295, 31296, 31297, 31298).</td>
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