# A PRESBYTERIAN

Subject: Balloon Dilation for ENT Procedures

Medical Policy #: 2.12

Status: Reviewed

Original Effective Date: 03/25/2015 Last Annual Review Date: 3-26-2025

## Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans, or the plan may have broader or more limited benefits than those listed in this Medical Policy.

## Description

Balloon Sinuplasty is a technique in which surgeons use balloons to dilate the sinus ostia. It is an alternative technique to the use of microdebriders and forceps. This procedure relies on a disposable catheter that has a thin guidewire at its tip. Guided by X-ray images or by a lighted fiberoptic tip, the catheter is threaded up to the opening of the blocked or poorly draining sinus and the guidewire is passed through the opening of the sinus. The narrow width of the guidewire enables it to pass into sinuses that are partially or fully closed due to tissue swelling. Once the guidewire is in place, a balloon is passed over the wire and gently inflated to compress the tissue that is blocking the sinus opening. The balloon is then deflated, and the catheter is removed. 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 or recurrent acute sinusitis in adult patients who have not responded adequately to conservative medical treatments such as decongestants and antibiotics. Balloon sinuplasty is generally limited to dilation of obstructed ostia in the frontal, sphenoid, and maxillary sinuses, but not in the ethmoid sinuses.

## **Coverage Determination**

Prior Authorization is required regardless of the setting. Logon to Pres Online to submit a request: <a href="https://ds.phs.org/preslogin/index.jsp">https://ds.phs.org/preslogin/index.jsp</a>

Benefit coverage is covered for Medicare, Medicaid and Commercial members based on the following.

- A. Balloon Sinuplasty may be covered when the following clinical indications and criteria are met:
  - 1. For a diagnosis of Chronic Rhinosinusitis when ALL the following criteria are met:
    - A. Absence of exclusion criteria as below and
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    - B. There is documentation of chronic rhinosinusitis that is present for greater than 12 continuous weeks and
    - C. There is documented failure of maximal medical therapy for combined total of at least 12 weeks, as demonstrated by persistent symptoms. Medical therapy must include:
      - 1. At least two completed courses of oral antibiotics from different classes given for the indication of sinusitis and
      - 2. A trial of steroid nasal spray for at least 30 days

### and

- D. Radiographic findings show **BOTH**:
  - 1. In the sinuses to be intervened upon, findings consistent with chronic sinusitis, including at least **one** of the following:
    - a. Air fluid levels
    - b. Mucosal thickening >2mm
    - c. Sinus opacification

and

2. If Ethmoid Sinus disease is present, the treatment plan for the Ethmoid Sinus <u>needs to be documented</u>, since the treatment of Balloon Dilation of the Ethmoid Sinus is not covered.

- 2. For a diagnosis of Recurrent Acute Sinusitis when ALL the following criteria are met:
  - A. Absence of exclusion criteria as below and
  - B. Member carries diagnosis of recurrent acute sinusitis and has documentation of 4 or more recurrent episodes of acute rhinosinusitis (ARS), with complete clearing of symptoms between episodes within a 6-month period; or 6 or more episodes with complete clearing of symptoms between episodes within a year.

and

- C. Each episode of acute rhinosinusitis meets the definition of ARS as follows with <u>ALL</u> of the following features:
  - 1. Inflammation of the mucosa of the nose and paranasal sinuses
    - a. Requires documentation of physical exam/endoscopy findings of each episode

### and

- 2. Sudden onset of <u>all</u> the following symptoms:
  - a. purulent nasal drainage
  - b. nasal obstruction,
  - c. facial pain/pressure/fullness
  - d. Symptom duration of up to 4 weeks duration.

### and

- D. Each episode responded to a 1–3-week course of antibiotic therapy and
- E. Infections recur in spite of use of BOTH nasal steroid AND daily saline irrigations for at least 12 weeks' duration with at least two episodes of acute recurrent sinusitis as defined above while on this treatment.
- F. Imaging findings consistent with sinusitis or narrowing of drainage outflow tracts (osteomeatal complex) of the sinuses to be intervened upon, such as (at least one):
  - o Air fluid levels
  - Mucosal thickening >2mm
  - Sinus opacification
  - o concha bullosa
  - Infraorbital or supraorbital ethmoid cells that narrow the drainage pathway of the maxillary or frontal sinuses, respectively
  - o Mucosal thickening at the osteomeatal complex
  - and
  - 1. If present, treatment of concomitant allergic rhinitis, including avoidance measures, pharmacotherapy, and/or immunotherapy.
    - and
  - 2. Provider has given consideration to an immunological work up.

### Exclusion:

Balloon Sinuplasty will not be covered in the following circumstances:

- A. For requests for non-targeted 6-sinus procedures (bilateral maxillary, sphenoid, and frontal sinuses).
- B. For members 12 years and younger
- C. Absence of radiographic imaging support
- D. Requests for repeat procedures in members who have had prior balloon sinuplasty will require medical director review.

## B. Balloon Dilation for Eustachian Tube (BDET) Dysfunction may be covered when the following clinical indications and criteria are met.

A single treatment of unilateral or bilateral balloon dilation of the Eustachian tubes via nasal endoscopy is considered medically necessary when all the following criteria are met for the ear(s) to be treated (A, B, C, D, and E):

- A. The individual is 18 years of age or older; **and**
- B. The individual's history and physical exam include <u>ALL</u> the following (1, 2, 3, and 4):
  - 1. Eustachian tube dysfunction
    - i. Has been present for 3 months or more; and
    - ii. Persists despite medical therapy of any associated conditions (if present) such as allergic rhinitis, rhinosinusitis, or laryngopharyngeal reflux;
  - 2. Otoscopic examination shows either of the following (i or ii)
    - i. Persistent otitis media with effusion; or
    - ii. Tympanic membrane retraction; **and**
  - 3. Nasal endoscopic examination does not show physical obstruction of the Eustachian tube; and
  - 4. Either of the following (i or ii):
    - i. \*\*Abnormal tympanogram tracings (Type B or C); or
    - ii. Symptoms consistent with baro-challenge induced Eustachian tube dysfunction (that is: recurrent aural fullness, popping, or pain that reproducibly occurs with changes in pressure); **and**
- C. If history includes placement of tympanostomy tube(s), demonstrated improvement of obstructive Eustachian tube symptoms while the tube(s) were in place; **and**

Not every Presbyterian health plan contains the same benefits. Please refer to the member's specific benefit plan and Schedule of Benefits to determine coverage [MPMPPC051001].

- D. No history of previous balloon dilation of the Eustachian tubes; and
- E. No contraindication for balloon dilation, for example:
  - 1. Carotid abnormalities in the skull base; or
  - 2. Nasopharyngeal or skull base neoplasm; or
  - 3. \*\*\*Patulous Eustachian tube.

### **Exclusion**

Balloon dilation of the Eustachian tubes will not be covered in the following circumstances:

- A. Balloon dilation of the Eustachian tubes is considered not medically necessary when the criteria above are not met, and for all other indications.
- B. Repeat balloon dilation of the Eustachian tube is not medically necessary for all indications.
- C. Trans-tympanic balloon dilatation of the Eustachian tube is not medically necessary for all indications.

\*\* Tympanometry is a frequently used outcome measure in ETD. Tympanometry measures the mobility of the tympanic membrane and graphically displays results in tympanograms. Tympanograms are classified by the height and location of the tympanometric peak. They are classified into 3 general patterns: type A indicates normal middle ear and ET function; type B indicates poor tympanic membrane mobility ("flat" tympanogram), and type C indicates the presence of negative middle ear pressure.

\*\*\* The term patulous describes a condition in which the Eustachian tube is chronically patent. Symptoms suggesting patulous dysfunction include loudly hearing one's own voice or an echo of one's own voice (autophony), audible respirations, pulsatile tinnitus, and/or aural fullness (Tucci, 2019). BDET is contraindicated for patulous Eustachian tube dysfunction (Tucci, 2019). A diagnosis of patulous ETD is suggested by symptoms of autophony of voice, audible respirations, pulsatile tinnitus, and/or aural fullness.

## Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

Diagnostic endoscopy codes 31231-31235 may <u>not</u> be reported in conjunction with codes <b>31295-31298</b> (surgical endoscopy) when sinus endoscopy is performed on the same sinus as diagnostic endoscopy (31233 or 31235).	
CPT codes	Description
31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (e.g., balloon dilation), transnasal or via canine fossa
31296	Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (e.g., balloon dilation) (Do not report 31296 in conjunction with 31253, 31276, <u>31297</u> , <u>31298</u> , when performed on the ipsilateral side)
31297	Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus <i>ostium</i> (e.g., balloon dilation). (Do not report 31297 in conjunction with 31235, 31257, 31259, 31287, 31288, 31296, 31298, when performed on the ipsilateral side)
31298	Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (e.g., balloon dilation)(Do not report 31298 in conjunction with 31235, 31237, 31253, 31257, 31259, 31276, 31287, 31288, 31296, 31297, when performed on the ipsilateral side)
61782	Stereotactic computer-assisted navigation may be used to facilitate the performance of endoscopic sinus surgery.
69705	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); unilateral
69706	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); bilateral

## **Reviewed by / Approval Signatures**

Population Health & Clinical Quality Committee (PHCQC): <u>Clinton White MD</u> Senior Medical Director: <u>Jim Romero MD</u> Date Approved: 03-26-2025

### References

- 1. MCG, Ambulatory Care Guidelines, Sinuplasty 28th Edition. A-0478. Last Update 3/14/2024. Accessed 12/27/2024.
- 2. Hayes, Eustachian Tube Balloon Dilation for the Treatment of Chronic Eustachian Tube Dysfunction in Adults, Annual Review: 03-12-2024. [Accessed 12/27/2024]
- 3. Hayes, Balloon Sinuplasty for treatment of Chronic Rhinosinusitis, in Adult Patients, Published September 30, 2022, Annual review Jan 04, 2021. [Cited 12/27/2024].

Not every Presbyterian health plan contains the same benefits. Please refer to the member's specific benefit plan and Schedule of Benefits to determine coverage [MPMPPC051001].

- 4. Hayes, Balloon Sinuplasty for Chronic Sinusitis in Pediatric Patients. Annual review: Dec 09, 2022. [Cited 12/27/2024]
- 5. Up to Date, Eustachian tube dysfunction, Literature review current through: Nov 2024. This topic last updated: Nov 15, 2024 [Accessed 12/27/2024]
- 6. Aetna, Sinus Surgeries, # 0937, Last Review: 12/20/2024, Next review: 10/09/2025. [Cited 12/27/2024]
- 7. Aetna, Myringotomy and Tympanostomy Tube, #0418, Last review: 05/20/2024, Next review: 04/24/2025 [Cited 12-27-2024]
- 8. Cigna, Balloon Sinus Ostial Dilation for Chronic Sinusitis and Eustachian Tube Dilation, Coverage Policy # 0480, Next review Date 04/15/2025. [Cited 12/27/2024]
- Humana, Minimally Invasive Sinus and Eustachian Tube Procedures, Effective Date: 12/14/2023, Revision Date: 12/14/2023, Review Date: 04/27/2023 Policy Number: HUM-0309-026 [Cited 12/27/2024]
- 10. United Healthcare (Commercial), Sinus Surgeries and Interventions, Policy Number: 2024T0571P, Effective Date: Sept 1, 2024 [Cited 12/27/2024]
- 11. UnitedHealthcare® Omnibus Codes, Effective Dec 01, 2024. [Cited 12/27/2024]
- 12. U.S Food and Drug Administration (FDA), Dec 13, 2023, K230742 Trade/Device Name: ACCLARENT AERA Eustachian Tube Dilation System Regulation Number: 21 CFR 874.4180 Regulation Name: Eustachian tube balloon dilation system Regulatory Class: Class II Product Code: PNZ Dated: November 12, 2023 Received: November 13, 2023

## **Publication History**

- 03/25/15 New Policy. Original effective date. Use of a catheter-based inflatable device (balloon ostial dilatation) in the treatment of sinusitis
- 01/27/16 Annual review. Change of ICD-9 to ICD-10
- 07/24/18 Annual review. Medical policy name changed from Balloon Sinuplasty to Balloon Dilation for ENT Procedures
- 11/20/19 Annual review. Policy updated with literature review; reference 5, 7 & 8 added and updated 1-5. No Medicare national coverage determination found, using term Sinuplasty. Hayes' new report on PCRS was reviewed by Dr. Romero. No change to policy statement but changed "age under 18 are excluded" to members 12 years or younger are excluded.
- 01/27/21 Annual review. Reviewed by PHP (Presbyterian Health Plan) Medical Policy Committee on 12/18/2020. No change. The criteria will remain for all LOB, since it is still compatible with other payers and Hayes rating remains in good rating. Exclusion added: The use of eustachian tube balloon dilation (ETBD) for the treatment of adult and pediatric eustachian tube dysfunction (CPT 69705 & 69706) are non-covered. Error correction: Effective date is 03-25-2015 not 05-22-06. Will Continue PA (Policy Articles) for CPT code: 31295,31296, 31297, 31298.
- 01/26/22 Annual review. Reviewed by Reviewed by PHP Medical Policy Committee on 11/19/2021. No change. Continue coverage for chronic rhinosinusitis and recurrent acute sinusitis for all LOB. The criteria are still in line with other payers and professional society such as AAO-HNS. Will Continue PA for CPT code: 31295,31296, 31297, 31298 for all product lines. The use of eustachian tube balloon dilation (ETBD) for the treatment of adult and pediatric eustachian tube dysfunction (CPT 69705 & 69706) will continue as noncovered and will be configured as investigational for all product lines.
- 01-25-23 Annual review. Reviewed by PHP Medical Policy Committee on 11/11/2022. Continue coverage for balloon sinuplasty for the two diagnoses: Chronic Rhinosinusitis and Recurrent Acute sinusitis for all LOB. Continuing non-coverage for eustachian tube balloon dilation (69705 & 69706), still considered investigational and will resume configuration as such. Continue PA for 31295,31296, 31297, 31298. Updated on 10/24/2023: Reviewed by PHP Medical Policy Committee on 10/18/2023. Coverage for Eustachian Tube Balloon Dilation (CPT codes 69705 and 69706) has been determined medically necessary for patients with refractory Eustachian Tube Dysfunction (ETD) for ALOB, effective July 01, 2023. ICD-10 Table was also removed. Removed current configuration and allow payment of 69705 and 69706 with a prior authorization effective 7/1/23 for all LOB.
- 02-07-24 Annual review. Reviewed by PHP Medical Policy Committee on 11/28/2023. No change. Continue coverage for balloon sinuplasty for the two diagnoses: Chronic Rhinosinusitis and Recurrent Acute sinusitis; Eustachian Tube Balloon Dilation for refractory Eustachian Tube Dysfunction for all LOB. Continue PA requirement for CPT codes: 31295,31296, 31297, 31298, 69705 & 69706.
- 03-26-25 Annual review. Reviewed by PHP Medical Policy Committee on 01-03-2025. Continue coverage without change. There is only one payer that updated criteria for age for BDET based off of FDA K230742, Dec-2023. PHP will wait to consider changing age until more scientific evidence are produced for BDET for individuals 8 to 17 years of age. Continue PA requirement for CPT code to control misuse: 31295, 31296, 31297, 31298, 69705 & 69706.

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.

For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: <u>Click here for Medical Policies</u>

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### Web links:

At any time during your visit to this policy and find the source material web links has been updated, retired, or superseded, PHP is not responsible for the continued viability of websites listed in this policy.

When PHP follows a particular guideline such as LCDs (Local Coverage Determinations), NCDs (National Coverage Determination), MCG, NCCN (National Comprehensive Cancer Network) (National Comprehensive Cancer Network) etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.