I. POLICY/Criteria

A. The use of balloon sinus ostial dilation, e.g. Balloon Sinuplasty™, for the treatment of chronic sinusitis is considered medically necessary when all of the following criteria are met:

1. Documentation of persistent rhinosinusitis for greater than three months; AND
2. Documented failure of medical therapy greater than three months in duration demonstrated by persistent upper respiratory symptoms despite therapy consisting of a minimum of two different antibiotics with a trial of steroid spray, antihistamine spray and/or decongestant; AND
3. Radiological evidence of at least ONE of the following:
   i. Air fluid levels; OR
   ii. Mucosal thickening > 2mm; OR
   iii. Opacification; OR
   iv. Nasal polyposis

B. The use of devices (e.g., the Propel™ sinus implant, the Relieva Stratus™ MicroFlow spacer, and the Sinu-Foam™ spacer) for maintaining sinus ostial patency following balloon sinus ostial dilation and / or endoscopic sinus surgery is experimental and investigational because their effectiveness has not been established.

Balloon sinus ostial dilation used as an adjunct during endoscopic sinus surgery (FESS) is considered integral to the primary FESS procedure and not separately reimbursable.

II. MEDICAL NECESSITY REVIEW

☐ Required ☒ Not Required ☐ Not Applicable
III. APPLICATION TO PRODUCTS

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** This policy applies to insured HMO/EPO plans.
- **POS:** This policy applies to insured POS plans.
- **PPO:** This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO:** For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL:** For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE:** Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN:** For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: [http://www.michigan.gov/mdch/0,1607,7-132-2945-42542-42543-42546-42551-159815--00.html](http://www.michigan.gov/mdch/0,1607,7-132-2945-42542-42543-42546-42551-159815--00.html). If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: [http://www.michigan.gov/mdch/0,1607,7-132-2945-5100-87572--00.html](http://www.michigan.gov/mdch/0,1607,7-132-2945-5100-87572--00.html), the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.
IV. DESCRIPTION

Chronic sinusitis is defined as a prolonged or recurrent infection and inflammation of the nasal sinuses. Chronic, long term sinusitis may develop in people with chronic allergies, deviated nasal septum or other obstruction of the nose. Additionally, dental infections such as tooth abscesses may also spread into the sinus and infect it directly.

A technique referred to as balloon sinus ostial dilation or Balloon Sinuplasty™ has been proposed as an alternative or in addition to standard endoscopic surgery. This procedure proposes the use of a small balloon-like device instead of the other devices usually used. There are two different devices available on the market that dilate the sinuses. With the first type of device, the balloon is placed in the blocked sinus passage under endoscopic guidance through the nostril. The second is placed in the sinus through an incision made in the gums and maxillary bone under the front lip of the individual. In both cases, once the balloon is in place in the ostia of the targeted sinus, the balloon is inflated to push the sinus tissue and bone out of the way, creating a larger airway passage and allowing drainage of nasal secretions.

Results of the available studies provide preliminary evidence that balloon sinus ostial dilation is relatively safe and efficacious for the treatment of chronic sinusitis that is refractory to medical therapy. Despite these promising early findings, the overall quality of the evidence is low since the majority of the available studies lack controls and adequate follow-up of the majority of the enrolled patients. The patient selection criteria for this therapy have not been well defined. Furthermore, many of the studies evaluated hybrid procedures, which creates difficulties in determining the specific role of balloon sinus ostial dilation in treatment outcomes. Additional studies are needed to confirm that balloon sinus ostial dilation is safer and more effective over the long term than FESS or adenoidectomy, particularly well-designed trials that randomize patients to balloon sinus ostial dilation or to standard treatment for chronic sinusitis.

V. CODING INFORMATION

ICD-10 Codes that may apply:

- J32.0 Chronic maxillary sinusitis
- J32.1 Chronic frontal sinusitis
- J32.3 Chronic sphenoidal sinusitis
- J32.4 Chronic pansinusitis
- J32.8 Other chronic sinusitis
- J32.9 Chronic sinusitis, unspecified

CPT/HCPCS Codes:

- 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)
31298  Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (eg, balloon dilation)

Not Covered:
0406T  Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant
0407T  Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant; with biopsy, polypectomy or debridement
C2625  Stent, noncoronary, temporary, with delivery system
S1090  Mometasone furoate sinus implant, 370 micrograms

VI. REFERENCES


27. Hayes Inc., Propel Bioabsorbable Steroid-Releasing Sinus Implant https://www.hayesinc.com/subscribers/displaySubscriberArticle.do?articleId=15106&searchStore=%24search_type%3Dall%24icd%3D%24keywords%3Dpropel%2Csinus%2Cimplant%24status%3Dall%24page%3D1%24from_date%2D%24to_date%2D%24report_type_options%3D%24technology_type_options%3D%24organ_system_options%3D%24specialty_options%3D%24order%2DosSearchRelevance


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