



Balloon Sinus Ostial Dilation Clinical Coverage Criteria

Description

Balloon ostial dilation, also known as balloon sinuplasty, is a technique used for dilating obstructed sinuses (maxillary, frontal, or sphenoid) related to refractory cases of chronic rhinosinusitis. The procedure involves passing a catheter through the nasal cavity to the blocked sinus. A guidewire is then advanced through the blockage before a balloon dilating catheter is advanced to the narrowest point of the blockage. Once in position, the balloon is briefly inflated thus widening the drainage tract of the sinus by creating tiny fractures in the surrounding bone. The balloon is then deflated and removed. While there is no evidence of a clinical advantage to balloon ostial dilation over the more traditional functional endoscopic sinus surgery, the procedure is less invasive with fewer expected complications and a quicker recovery time.

Policy

This Policy applies to the following Fallon Health products:

- Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)
- MassHealth ACO
- NaviCare HMO SNP
- NaviCare SCO
- PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
- Community Care

Balloon sinus ostial dilation requires prior authorization.

Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Medicare statutes and regulations do not have coverage criteria for balloon sinus ostial dilation. Medicare does not have a National Coverage Determination (NCD) for balloon sinus ostial dilation. National Government Services, Inc. does not have a Local Coverage Determinations (LCD) for balloon sinus ostial dilation (MCD search 02/12/2024).

Coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, therefore, Fallon Health Clinical Coverage Criteria are applicable.

MassHealth ACO

Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

MassHealth does not have Medical Necessity Guidelines for balloon sinus ostial dilation (MassHealth website search 02/12/2024), therefore the Plan's Clinical Coverage Criteria are applicable.

NaviCare HMO SNP, NaviCare SCO

For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health Clinical Coverage Criteria

Effective June 1, 2024, Fallon Health will use InterQual® criteria when making medical necessity determinations for balloon sinus ostial dilation for plan members 18 years of age or older.

For coverage criteria, refer to the InterQual criteria in effect on the date of service: ***InterQual® CP:Procedures, Balloon Ostial Dilation.***

Fallon Health makes InterQual criteria available to the public through the transparency tool on our website, effective January 1, 2024.

Requests for balloon sinus ostial dilation for plan members under 18 years of age will be reviewed on an individual case-by-case basis.

Exclusions

- Any use of balloon sinus ostial dilation other than outlined above. This includes but is not limited to balloon sinus ostial dilation for treatment of recurrent acute sinusitis and for the treatment of chronic rhinosinusitis with nasal polyposis.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Code	Description
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)
C1726	Catheter, balloon dilatation, non-vascular

CPT codes 31295, 31296, 31297 and 31298 describe endoscopic dilation of the sinus ostia as a standalone procedure. CPT 31295 is reported when endoscopic dilation is performed on the maxillary sinus ostium. CPT 31296 describes endoscopic dilation of the frontal sinus ostium. CPT 31297 describes endoscopic dilation of the sphenoid sinus ostium. CPT 31298 describes endoscopic dilation of the frontal and sphenoid sinus ostium.

Endoscopic dilation of the sinus ostia is typically, but not specifically associated with balloon dilation of sinus ostia. There are other techniques of endoscopic dilation that do not use balloon technology, but rather reusable fixed dilators costing considerably less than the balloons. Dilation of the sinus ostia that does not utilize balloon technology should be coded using CPT code 31299 (unlisted procedure, accessory sinuses). When performed in the office setting, the balloon catheter is a direct practice expense. Reimbursement for CPT codes 31295, 31296, 31297 and 31298 includes reimbursement for the supply.¹

HCPCS Level II C Codes

HCPCS Level II C-Codes only apply to hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) claims reimbursed under Medicare payment methodology.

- When performed in the hospital outpatient or ASC setting, reimbursement for the procedure (CPT codes 31295, 31296, 31297 and 31298) includes reimbursement for the supply (C1726). Pass-through status for C1726 (Catheter, balloon dilatation, non-vascular) expired on 12/31/2002.
- Per CMS guidance, hospitals reimbursed under Medicare OPPS payment methodology should report device category HCPCS codes on claims whenever they are provided in the hospital outpatient setting (Medicare Claims Processing Manual, Chapter 4, Section 10.4), regardless of whether payment for the services is made separately or packaged. Conversely, ASCs should not report packaged codes since they are not reportable under the ASC payment system.

HCPCS Level II C-Codes are not payable under MassHealth.

Adjunct/Hybrid Balloon Sinus Ostial Dilation

There are instances in which the balloon catheter is used to establish a pathway, through the frontal recess to the frontal sinus followed by tissue removal (mucosa, polyps, scar, tumor and/or bony partitions) with traditional instrumentation such as forceps and/or the microdebrider. In this instance, the balloon is used as an adjunct to traditional instrumentation. For example, when the result is a frontal sinusotomy and tissue has been removed, the appropriate code is CPT 31276, and the dilation is not separately reported. Similar rationale would apply to surgery involving the maxillary and sphenoid sinuses.²

What is a stand-alone vs. a hybrid procedure and how does the coding differ?³

- A. A stand-alone procedure is the utilization of a balloon or other device used to dilate a sinus ostium under endoscopic visualization when no tissue is removed. The appropriate coding for

¹ American Academy of Otolaryngology-Head and Neck Surgery. Coding Alert, available at: <https://bulletin.entnet.org/home/article/21247655/coding-alert>. Accessed 02/14/2024.

² American Academy of Otolaryngology-Head and Neck Surgery. Consensus Opinion: How to Code Balloon Sinus Dilation. Published October 25, 2013. Available at: <https://bulletin.entnet.org/home/article/21245904/consensus-opinion-how-to-code-balloon-sinus-dilation>. Accessed 02/14/2024.

³ Acclarent Coding and Reimbursement Frequently Asked Questions, available at: https://www.jnjmedtech.com/sites/default/files/user_uploaded_assets/pdf_assets/2019-05/083567-181022_Acclarent%20Reimbursement%20FAQs.pdf. Accessed 02/14/2024.

a standalone procedure is to use one or more of the balloon dilation codes (31295, 31296, 31297, 31298).

- B. A hybrid procedure is the utilization of a balloon as an adjunct tool during a FESS procedure to establish a pathway through the frontal recess to the frontal sinus followed by tissue removal (mucosa, polyps, scar, tumor and/or bony partitions) with traditional instrumentation such as forceps and/or the microdebrider. When the result is a frontal sinusotomy and tissue has been removed, the appropriate code is 31276 and the dilation is not separately reported. Similar rationale would apply to surgery involving the maxillary and sphenoid sinuses. When the balloon is used as part of a FESS procedure, it is not separately paid, but included in the payment of the FESS procedure.

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Policy history

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Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.