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Medicare Advantage Policy Manual **Policy ID:** M-SUR153

Balloon Ostial Dilation for Treatment of Sinusitis

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Balloon ostial dilation is proposed as a less invasive alternative to traditional endoscopic sinus surgery. In this procedure, a balloon catheter is placed in the opening of the sinus and inflated to widen the opening, allowing for better drainage of secretions.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	None

Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	None
Medical Policy Manual	*Medicare coverage guidance is not available for balloon ostial dilation for any indication, including treatment of sinusitis. Therefore, the health plan's medical policy is applicable.* Balloon Ostial Dilation for Treatment of Sinusitis, Surgery, Policy No. 153 *(see "NOTE" below)*

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- History and physical/chart notes
- Indication for the requested service
- If indication is chronic rhinosinusitis:
    - Documentation of chronic rhinosinusitis including length of time present and interference with lifestyle;
    - CT and/or nasal endoscopy report;
    - Failure of maximum medical therapy including saline nasal irrigations/nasal spray, two or more antibiotic courses or one minimum 21 day course, and nasal steroid trial.
- If indication is recurrent acute rhinosinusitis:
    - Documentation of four or more documented and treated episodes of acute rhinosinusitis over 12 months;
    - CT report.

REGULATORY STATUS

- March 2008: The “Relieva Sinus Balloon Catheter” (Acclarent, Menlo Park, CA) device was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. It was determined this device was substantially equivalent to existing devices for use in dilating the sinus ostia and paranasal spaces in adults and maxillary sinus spaces in children. Subsequent devices developed by Acclarent, such as the Relieva Spin Sinus Dilation System® (August 2011) and the Relieva Seeker Balloon Sinuplasty System® (November 2012), have also been granted 510(k) approval.
- June 2008: The FinESSTM Sinus Treatment (Entellus Medical, Inc, Maple Grove, MN) device was cleared for marketing by the FDA through the 510(k) process. It is indicated to access and treat the maxillary ostia/ethmoid infundibulum in adults using a transantral approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures. The ENTrigue® Sinus Dilation System and the XprESS® Multi-Sinus Dilation Tool also received 510(k) approval in August, 2012
- 2013: A sinus dilation system (Medtronic Xomed, Jacksonville, FL), later named the NuVent™ EM Balloon Sinus Dilation System, was cleared for marketing by the FDA through the 510(k) process for use in conjunction with a Medtronic computer-assisted surgery system when surgical navigation or image-guided surgery may be necessary to locate and move tissue, bone, or cartilaginous tissue surrounding the drainage pathways of the frontal, maxillary, or sphenoid sinuses.
- 2013: A sinus dilation system (ArthroCare, San Antonio, TX), later named the Ventera™ Sinus Dilation System, was cleared for marketing through the 510(k) process to access and treat the frontal recesses, sphenoid sinus ostia, and maxillary ostia/ethmoid infundibula in adults using a transnasal approach.

Note, the fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, Medicare or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149

Balloon Dilation of the Eustachian Tube, Surgery, Policy No. M-206

REFERENCES

None

CODING

Codes	Number	Description
CPT	31295	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); maxillary sinus ostium, transnasal or via canine fossa
	31296	; frontal sinus ostium
	31297	;sphenoid sinus ostium
	31298	Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (eg, balloon dilation)
	31299	Unlisted procedure, accessory sinuses
HCPCS	C1726	Catheter, balloon dilatation, non-vascular

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*