Balloon Sinus Ostial Dilation (for Kentucky Only)

Policy Number: CS138KY.10
Effective Date: November 1, 2023

Instructions for Use

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Related Policies

- Functional Endoscopic Sinus Surgery (FESS) (for Kentucky Only)
- Rhinoplasty and Other Nasal Procedures (for Kentucky Only)

Application

This Medical Policy only applies to the state of Kentucky.

Coverage Rationale

Balloon sinus ostial dilation is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Balloon Ostial Dilation.

Click here to view the InterQual® criteria.

Self-expanding absorptive sinus ostial dilation is unproven and not medically necessary for evaluating or treating sinusitis and all other conditions due to insufficient evidence of efficacy.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
31295	Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); maxillary sinus ostium, transnasal or via canine fossa
31296	Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); frontal sinus ostium
31297	Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); sphenoid sinus ostium
31298	Nasal/sinus endoscopy, surgical, with dilation (e.g., balloon dilation); frontal and sphenoid sinus ostia

CPT Code	Description
31299	Unlisted procedure, accessory sinuses

Description of Services

Individuals who have persistent or chronic rhinosinusitis that has failed medical therapy may require surgery. Chronic rhinosinusitis is defined as rhinosinusitis lasting longer than 12 weeks (Rosenfeld et al., 2015; Peters et al., 2014). Functional endoscopic sinus surgery (FESS) is an accepted procedure for chronic rhinosinusitis refractory to medical therapy. FESS is a minimally invasive technique in which the sinus air cells and ostia are opened and drained under direct visualization. Polyps and infected tissue can be removed at the same time.

Balloon sinus ostial dilation, also known as balloon dilation sinuplasty or balloon catheter sinusotomy, has been proposed as an alternative or an addition to traditional endoscopic sinus surgery. Several procedural approaches have been proposed for balloon sinus ostial dilation. The first type of approach is done through the nostrils by inserting a small balloon through a tube placed in the nasal cavity where the blocked sinus is located. Using navigation or endoscopic visualization, the balloon is gradually inflated to compress tissue and bone and widen the sinus ostium or outflow tract. The balloon is then removed, and an endoscope may be used to assess the width of the nasal passage. The second type of approach is the transantral approach which is done by creating a small entry point under the lip. The balloon catheter is then directly inserted into the target sinus. Potential advantages of sinus balloon catheterization include minimal mucosal damage, minimal intraoperative bleeding, and minimal discomfort. Balloon sinus ostial dilation can be performed as a stand-alone procedure or with FESS. When performed with FESS, it may be referred to as a hybrid procedure.

Self-expanding absorptive sinus ostial dilation has been proposed as an alternative to standard balloon sinus ostial dilation. The self-expanding device is inserted into the sinus ostia and starts absorbing moisture and begins to expand providing gradual dilation of the sinus ostia. When the device is fully expanded, it is removed. The SinuSys Vent-OS Sinus Dilation System is a self-expanding device that has been cleared by the FDA. These devices are being studied to determine their safety and effectiveness.

Clinical Evidence

Self-Expanding Absorptive Sinus Ostial Dilation

The evidence is insufficient to support the use of self-expanding absorptive sinus ostial dilation devices. Studies with control groups are needed to demonstrate the efficacy of these devices.

Hathorn et al. (2014) conducted a pilot study to determine the safety and performance of a maxillary sinus ostium (MSO) self-dilation device. Twelve CRS patients presenting with maxillary sinus inflammation requiring FESS were enrolled. The device was inserted into the MSO at the start of surgery and removed after 60 minutes. Endoscopic evaluation for patency was performed immediately after removal, and at one week, one month, and three months. Adverse events were recorded intraoperatively and at each subsequent visit. The device was successfully inserted in 100% of cases attempted (19/19 MSOs, 12 patients). Seventeen (89%) devices remained in the MSO for 60 minutes and dilated to a mean diameter of 4.8 ±0.5 mm. One patient was withdrawn from the study. No adverse events occurred during insertion or removal of the device. At three months postinsertion, 14 of 15 MSO dilated (93%) were confirmed patent. The investigators concluded that the placement of an osmotic self-dilating expansion device in human MSO is safe, achievable, and effective at dilating the ostia. This study is limited by a small sample size and lack of a comparison group.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The FDA classifies devices used for balloon catheter dilation for treating chronic sinusitis under product code LRC (instrument, ENT, manual surgical). This is a broad product code category that includes a variety of devices used in ear, nose, and throat surgeries (e.g., knives, hooks, injection systems, dilation devices). Additionally, this product code is 510(k)-exempt. Although

manufacturers may voluntarily submit product information via the 510(k) process, it is not a requirement. All manufacturers are, however, required to register their establishment and submit a "Device Listing" form; these records can be viewed in the Registration and Device Listing Database (search by product code, device, or manufacturer name). Refer to the following website for more information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm. (Accessed April 3, 2023)

In 2013, the FDA granted 510k clearance to the SinuSys Vent-OS Sinus Dilation System for dilation of the maxillary sinus ostia and associated spaces in adults. Refer to the following for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf13/K133016.pdf. (Accessed April 3, 2023)

To view all 510(k) substantial equivalence summaries for ENT manual surgical instruments, search [Product Code: LRC] at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 3, 2023)

References

Hathorn I, Habib AR, Santos RD, et al. The safety and performance of a maxillary sinus ostium self-dilation device: a pilot study. Int Forum Allergy Rhinol. 2014 Aug;4(8):625-31.

Policy History/Revision Information

Date	Summary of Changes

11/01/2023	**Related Policies**
	• Added reference link to the Medical Policy titled *Rhinoplasty and Other Nasal Procedures (for Kentucky Only)*
	Coverage Rationale
	• Removed language indicating balloon sinus ostial dilation is unproven and not medically necessary for treating the following due to insufficient evidence of efficacy:
	  ○ Nasal polyps or tumors
	  ○ All other conditions that do not meet the InterQual® criteria [listed in the policy]
	Supporting Information
	• Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
	• Archived previous policy version CS138KY.09

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Kentucky Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.