Balloon Sinus Ostial Dilation (for North Carolina Only)

Policy Number: CSNCT0571.04
Effective Date: November 1, 2023

Instructions for Use

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Related Policy

- Functional Endoscopic Sinus Surgery (FESS) (for North Carolina Only)

Application

This Medical Policy only applies to the state of North Carolina.

Coverage Rationale

Balloon sinus ostial dilation is proven and medically necessary under certain circumstances. For clinical coverage criteria, refer to the North Carolina Medicaid Clinical Coverage Policy No: 1A-42, Balloon Ostial Dilation.

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
31299	Unlisted procedure, accessory sinuses

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

North Carolina Medicaid, Division of Health Benefits, Physician Clinical Coverage Policies, Balloon Ostial Dilation, No: 1A-42. https://medicaid.ncdhhs.gov/1a-42-balloon-ostial-dilation/download?attachment. Accessed June 07, 2023.

Policy History/Revision Information

Date	Summary of Changes
11/01/2023	**Coverage Rationale** • Added language to indicate 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 **Supporting Information** • Updated *FDA* and *References* sections to reflect the most current information • Archived previous policy version CSNCT0571.03

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 may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies 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.