Balloon Sinus Ostial Dilation (for Indiana Only)

Policy Number: CS138IN.02
Effective Date: August 1, 2021

Instructions for Use

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Related Policy

- Functional Endoscopic Sinus Surgery (FESS) (for Indiana Only)

Application

This Medical Policy only applies to the state of Indiana.

Coverage Rationale

For medical necessity clinical coverage criteria, refer to the Indiana Surgical Services Provider Reference Module.

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 June 21, 2021)

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 June 21, 2021)

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 June 21, 2021)

Additional Products

Acclarent Relieva FLEX® Sinus Guide Catheter, Acclarent® Balloon Inflation Device, Entellus Medical RS-Series System™, Entellus FinESS™ Endoscope, Entellus FinESS Sinus Treatment Kit, Entellus XprESS™ Pro Multi-Sinus Dilation System, Lenio® flex System for Sinus Ostia Dilation, Medtronic NuVent™ EM Balloon Sinus Dilation System, Medtronic Fusion® ENT Navigation System, Relieva Luma Sentry™ Sinus Illumination System and Accessories, MESIRE™ Balloon Sinus Dilatation System, Relieva SCOUT™ Sinus Dilation System, Relieva Seeker® Balloon Sinuplasty System, Relieva SIDEKICK™ Low Profile Handles, Relieva SIDEKICK Sinus Guide Catheter Handles, Relieva Solo Pro™ Sinus Balloon Catheter, Sinus Balloon Catheter, Relieva Solo™ Sinus Balloon Catheter, Relieva Ultirra™ Sinus Balloon Catheter, Relieva VIGOR® Sinus Guidewire, Relieva VORTEX® 2 Sinus Irrigation Catheter, Relieva® Spin Balloon Sinuplasty System, SinuSys AerOs™ Sinus Dilation System, SinuSys Vent-Os™ Sinus Dilation System, VENTERA® Sinus Dilation System, XprESS™ LoProfile Multi-Sinus Dilation System, XprESS Ultra Multi-Sinus Dilation System, XprESS Multi-sinus Dilation System.

References

Indiana Surgical Services Provider Reference Manual. https://www.in.gov/medicaid/providers/files/surgical-services.pdf. Accessed 07/22/2021.

Policy History/Revision Information

Date	Summary of Changes
08/01/2021	Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CS138IN.01

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.