BlueCross BlueShield of Arizona
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MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

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BALLOON OSTIAL DILATION FOR TREATMENT OF CHRONIC SINUSITIS

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Balloon ostial dilation (also known as balloon sinuplasty) has been investigated in the treatment of sinusitis. A balloon catheter is placed in the sinus ostium and the balloon is inflated to stretch the opening and improve sinus drainage. General anesthesia may be required to minimize individual's discomfort.

BALLOON OSTIAL DILATION FOR TREATMENT OF CHRONIC SINUSITIS (cont.)

Criteria:

- Balloon sinuplasty for the treatment of sinusitis is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

Resources:

1. 7.01.105 BCBS Association Medical Policy Reference Manual. Balloon Ostial Dilation for Treatment of Chronic Sinusitis. Re-issue date 11/14/2013, issue date 07/20/2006.

2. American Academy of Otolaryngology - Head and Neck Surgery. Sinus Balloon Catheterization Position Statement. 03/05/2007.

3. American Academy of Otolaryngology - Head and Neck Surgery. Dilation of Sinuses, Any Method (Balloon). 06/28/2010.

4. American Rhinologic Society. Sinuplasty. Accessed 05/25/2012.

5. External Consultant Review. Ear, Nose and Throat. 12/16/2013.

6. Stankiewicz J, Truitt T, Atkins J, et al. Two-year results: transantral balloon dilation of the ethmoid infundibulum. *Int Forum Allergy Rhinol.* Feb 15 2012.

7. TEC Clearinghouse News. Update on Balloon Sinuplasty: American Rhinologic Society Position Statement. Oct.13, 2006.

8. Vaughan WC. Review of balloon sinuplasty. *Curr Opin Otolaryngol Head Neck Surg.* 2008 Feb;16(1):2-9.

BALLOON OSTIAL DILATION FOR TREATMENT OF CHRONIC SINUSITIS (cont.)

Resources: (cont.)

FDA 510K Summary for Entellus Medical RS Series System:

- FDA-approved indication: To access and treat the maxillary sinus ostium and the ethmoid infundibulum in adults with a trans-antral approach. The bony sinus outflow tract is remodeled by balloon displacement of adjacent bone and paranasal sinus structures.

FDA 510K Summary for Entellus Medical FinESS™ Sinus Treatment:

- FDA-approved indication: To access and treat the sinus and its outflow tract with a trans-antral approach in adults. The bony sinus outflow tract is remodeled by balloon displacement of adjacent bone and paranasal sinuses.

FDA 510K Summary for XprESS™ Multi-Sinus Dilation Tool:

- FDA-approved indication: To access and treat frontal recesses, sphenoid sinus ostia and maxillary ostia/ethmoid infundibula in adults using a trans-nasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures.

FDA 510K Summary for Entellus Medical Balloon Device:

- FDA-approved indication: To access and treat the frontal recesses and sphenoid sinus ostia in adults using a trans-nasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures.