Medical Policy

Balloon Sinus Ostial Dilation

Policy Number: OCA 3.706
Version Number: 11
Version Effective Date: 01/01/16

Product Applicability

<table>
<thead>
<tr>
<th>Well Sense Health Plan</th>
<th>Boston Medical Center HealthNet Plan</th>
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</thead>
<tbody>
<tr>
<td>☑ New Hampshire Medicaid</td>
<td>☑ MassHealth</td>
</tr>
<tr>
<td>☑ NH Health Protection Program</td>
<td>☑ Qualified Health Plans/ConnectorCare/Employer Choice Direct</td>
</tr>
<tr>
<td></td>
<td>☑ Senior Care Options ◊</td>
</tr>
</tbody>
</table>

Notes:
+ Disclaimer and audit information is located at the end of this document.
◊ The guidelines included in this Plan policy are applicable to members enrolled in Senior Care Options only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request. Review the member’s product-specific benefit documents at www.SeniorsGetMore.org to determine coverage guidelines for Senior Care Options.

Policy Summary

Generally, the Plan considers the use of balloon sinus ostial dilation as a stand-alone procedure for the treatment of any sinus condition to be experimental and investigational. It will be determined during the Plan’s standard prior authorization review process if the procedure is considered experimental and investigational for the requested indication. See the Plan’s policy, Experimental and Investigational Treatment (policy number OCA 3.12), for the product-specific definitions of experimental or investigational treatment.
Description of Item or Service

Balloon Sinus Ostial Dilation: Balloon sinus ostial dilation (e.g., Balloon Sinuplasty™) is a minimally invasive surgical procedure that is used to treat a sinus condition that is associated with inflammatory obstruction of the sinus passages. This procedure uses a small balloon-like device that is inflated to push the sinus tissue and/or bone out of the way in order to create a larger airway passage and allow drainage of nasal secretions. This approach may be used alone to dilate a sinus ostium (i.e., frontal, maxillary, or sphenoid ostium) or in conjunction with other instruments (e.g., microdebrider, forceps). The balloon catheter displaces soft tissue and/or bone but does not remove it from the operative site, which differs from functional endoscopic sinus surgery (FESS). FESS is performed to remove soft tissue and/or bone to surgically enlarge sinus ostia or create openings from the sinuses into the nose, nasopharynx, or adjacent sinuses.

Medical Policy Statement

Balloon sinus ostial dilation (e.g., Balloon Sinuplasty™) as a stand-alone procedure is considered experimental and investigational for the treatment of any sinus condition.

Limitations

The use of a balloon-like device (e.g., Balloon Sinuplasty™) as a stand-alone procedure for the treatment of a sinus condition is considered experimental and investigational. A balloon catheter may be used as a tool during functional endoscopic sinus surgery (FESS), as determined by the attending surgeon, if the device has received FDA clearance and is utilized for its FDA-approved indication, but the balloon catheter is not reimbursed separately.

Applicable Coding

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United Stated by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy, even if an applicable code
appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description: Codes Considered Experimental and Investigational</th>
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<tbody>
<tr>
<td>31295</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (e.g., balloon dilation), transnasal or via canine fossa</td>
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<tr>
<td>31296</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (e.g., balloon dilation)</td>
</tr>
<tr>
<td>31297</td>
<td>Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (e.g., balloon dilation)</td>
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**Clinical Background Information**

Sinusitis is defined as an inflammation of the nasal sinuses which may be caused by infection, allergy, or autoimmune diseases. Acute sinusitis is often associated with upper respiratory infections or irritation due to allergic reactions that cause a temporary blockage of the nasal sinuses. Chronic sinusitis is a prolonged or recurrent infection and/or inflammation of the nasal sinuses causing blockage of the nasal sinuses for a longer period of time that can lead to damage and destruction of the sinus tissue. The treatment of chronic sinusitis usually involves antibiotics if the infection is bacterial. Other treatments include sinus decongestants, nasal sprays, and steroids. Sinus surgery may be necessary in more severe cases to drain the sinuses and clear the infection. Sinus surgery is most commonly done endoscopically using thin fiberoptic tools that are passed through the nostrils to open the sinus passages by destroying the sinus tissue.

Balloon sinus ostial dilation is a recently develop technique that has been proposed as an alternative to functional endoscopic sinus surgery (FESS). A balloon sinus ostial dilation uses a balloon catheter to dilate the maxillary, frontal, and/or sphenoid natural ostia without bone or soft-tissue removal. An example of this technology includes the Acclarent Relieva™ Sinus Balloon Catheter; this manufacturer refers to the procedure that uses its device as Balloon Sinuplasty™. The FDA determined that 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 have also been granted 510(k) marketing clearance; these include the Relieva Spin Sinus Dilation System® cleared in August 2011, and the Relieva Seeker Balloon Sinuplasty System® cleared in November 2012.

Another balloon sinus ostial dilation device, the Entellus FinESS™ device, received FDA clearance in June of 2008 for the treatment of the sinus and its outflow tract using a transantral approach in adults. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures. Two (2) other balloon sinus ostial dilation devices by Entellus Medical, Inc. also

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received 510(k) approval in August 2012; these are the ENTrigue® Sinus Dilation System, and the XprESS® Multi-Sinus Dilation Tool.

At the current time, there is insufficient scientific evidence in the peer reviewed medical literature to support the effectiveness of balloon sinus ostial dilation as a treatment for a sinus condition. The published literature to date consists of very small, non-randomized case studies. Additional studies are needed to determine whether or not this treatment provides a clinical benefit to health outcomes.

References


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<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date* and Version Number</th>
<th>Policy Owner</th>
<th>Approved by</th>
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<tbody>
<tr>
<td>Regulatory Approval: N/A</td>
<td>03/01/09 Version 1</td>
<td>Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) and member of Quality Improvement Committee (QIC)</td>
<td>MPCTAC, QIC, and Utilization Management Committee (UMC)</td>
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<tr>
<td>Internal Approval: 11/25/08: MPCTAC 11/25/08: UMC 12/16/08: QIC</td>
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*Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12
*Effective Date for Well Sense Health Plan New Hampshire Medicaid Product(s): 01/01/13

(Policy formerly titled Balloon Sinuplasty for the Treatment of Sinusitis until 11/31/13.)

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### Policy Revisions History

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date and Version Number</th>
<th>Approved by</th>
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<tr>
<td>11/24/09</td>
<td>Updated references, no clinical criteria change.</td>
<td>Version 2</td>
<td>11/24/09: MPCTAC 12/23/09: QIC</td>
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<tr>
<td>11/10/10</td>
<td>Updated references, no clinical criteria changes.</td>
<td>Version 3</td>
<td>11/23/10: MPCTAC 12/22/10: QIC</td>
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<tr>
<td>11/01/11</td>
<td>Updated references, no clinical criteria changes.</td>
<td>Version 4</td>
<td>11/16/11: MPCTAC 12/20/11: QIC</td>
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<tr>
<td>07/30/12</td>
<td>Off cycle review for Well Sense Health Plan, revised Summary section, revised Medical Policy Statement section.</td>
<td>Version 5</td>
<td>08/15/12: MPCTAC 09/26/12: QIC</td>
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<tr>
<td>08/01/12</td>
<td>Updated references. Revised language in the following sections: Summary, Clinical Guideline Statement, and Applicable Coding. Revised language regarding FDA-approved devices and moved text to Clinical Background section.</td>
<td>Version 6</td>
<td>08/03/12: MPCTAC 09/05/12: QIC</td>
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<tr>
<td>08/14/13 and 08/15/13</td>
<td>Off cycle review. Incorporate policy revisions dated 08/01/12 (as specified above) for the Well Sense Health Plan product; these policy revisions were approved by MPCTAC on 08/15/12 and QIC on 09/26/13 for applicable Plan products. Additional review of policy conducted.</td>
<td>Version 7</td>
<td>08/14/13: MPCTAC (via electronic vote) 08/15/13: QIC</td>
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<tr>
<td>08/21/13</td>
<td>Review for effective date 12/01/13.</td>
<td>12/01/13</td>
<td>08/21/13: MPCTAC</td>
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<th>Date</th>
<th>Revision Description</th>
<th>Version</th>
<th>Review Date</th>
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<tr>
<td>09/01/14</td>
<td>Updated references. Changed the name of the procedure from “balloon sinuplasty” to “balloon sinus ostial dilation” throughout the document (including the policy title). Changed the indication from “sinusitis” to any “sinus condition.” Revised Summary, Description of Item or Service, Medical Policy Statement, Limitations, and Clinical Background Information sections.</td>
<td>Version 8</td>
<td>09/19/13: QIC</td>
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### Last Review Date

11/25/15

### Next Review Date

09/01/16

### Authorizing Entity

QIC

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Other Applicable Policies

Medical Policy - *Experimental and Investigational Treatment*, policy number OCA: 3.12

Disclaimer Information: *

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.