Medical Policy

Balloon Sinus Ostial Dilation

Policy Number: OCA 3.706
Version Number: 13
Version Effective Date: 12/01/17

Product Applicability

**All Plan** Products

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<th>Well Sense Health Plan</th>
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<td>☑ New Hampshire Medicaid</td>
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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

Balloon sinus ostial dilation (e.g., Balloon Sinuplasty™) is considered medically necessary in the outpatient setting as a stand-alone procedure or in combination with functional endoscopic sinus surgery (FESS) for the treatment of chronic rhinosinusitis (CRS) when applicable Plan criteria are met, as specified in the Medical Policy Statement and Limitations sections. Balloon sinus ostial dilation as a **stand-alone procedure** is medically necessary when used to treat medically refractory CRS in the outpatient setting for an adult member **age 18 or older** on the date of service (regardless of the member’s gender) and ALL applicable Plan medical criteria included in this policy are met and documented in the member’s medical record. The Plan considers balloon sinus ostial dilation to be

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**Plan prior authorization is required for balloon sinus ostial dilation when performed as a stand-alone procedure and/or when the treating provider will bill with an applicable code included in this Plan policy.** See the Medical Policy Statement section and Limitations section of this policy for applicable Plan medical criteria and prior authorization requirements. It will be determined during the Plan’s standard prior authorization review process if the requested treatment is considered either medically necessary or experimental and investigational for the requested indication. Review the Plan’s *Medically Necessary* medical policy (policy number OCA 3.14) for the product-specific definitions of medically necessary treatment. The Plan’s *Experimental and Investigational Treatment* medical policy (policy number OCA 3.12) includes the Plan’s product-specific definitions of experimental or investigational treatment.

The Plan will NOT reimburse separately for balloon sinus ostial dilation (balloon catheter) when used during FESS, even when balloon sinus ostial dilation is considered medically necessary. The Plan’s prior authorization and reimbursement guidelines for FESS would apply when the treatment is FESS in combination with balloon sinus ostial dilation or FESS without balloon catheter. If the treating provider will bill with an applicable code included in this Plan policy, the medical necessity criteria included in the Medical Policy Statement and Limitations sections of this policy must be met for the balloon sinus ostial dilation to be considered medically necessary (including balloon sinus ostial dilation performed in addition to FESS or balloon sinus ostial dilation as a stand-alone procedure). See the Plan’s *Prior Authorization/Notification Requirements Matrix* for a list of services that require prior authorization or Plan notification. In addition, review the Plan’s *Prior Authorization CPT Code Look-up Tool* and *Prior Authorization HCPCS Code Look-up Tool* for the prior authorization requirement for each of the requested service’s applicable, industry-standard billing codes (including applicable codes for FESS in combination with a balloon catheter or FESS without balloon sinus ostial dilation). The Plan’s prior authorization matrix, code look-up tools, medical policies, reimbursement policies, and the member’s applicable benefit documents are available at [www.bmchp.org](http://www.bmchp.org) for BMC HealthNet Plan members (with benefit documents for Senior Care Options members available at [www.SeniorsGetMore.org](http://www.seniorsgetmore.org)) and posted at [www.wellsense.org](http://www.wellsense.org) for Well Sense Health Plan members.

**Description of Item or Service**

**Balloon Sinus Ostial Dilation:** Balloon sinus ostial dilation (e.g., Balloon Sinuplasty™) is a minimally invasive surgical procedure used to treat chronic rhinosinusitis (CRS) 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 air to flow more easily through the sinuses.

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Balloon sinus ostial dilation (i.e., balloon sinus ostial dilation as a stand-alone procedure in the frontal, maxillary, and/or sphenoid ostium) or a balloon catheter may be used in conjunction with other instruments (e.g., microdebrider, forceps) as a tool during functional endoscopic sinus surgery (FESS) for the treatment of CRS. 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.

Balloon sinus ostial dilation is performed under fluoroscopic guidance or with a transilluminating guidewire or catheter tip to allow the surgeon visualization of the sinonasal region. Balloon sinuplasty requires specialized endoscopy instruments, and the procedure differs slightly by device. Examples of devices used for balloon sinus ostial dilation include the Relieva Sinus Balloon System (Acclarent Inc.) and the XprESS Multi-Sinus Dilation System (Entellus Medical Inc.); both of these systems can be used to treat more than one (1) sinus in an individual patient but otherwise cannot be reused. The Relieva Sinus Balloon System is a single-use device intended to dilate the sinus ostia and spaces within the paranasal sinus cavities. The XprESS Multi-Sinus Dilation System is a single-use device used to access the maxillary ostia/ethmoid infundibula for patients two (2) years of age or older and/or to treat frontal ostia/recesses in patients 12 years of age and older.

Balloon sinus ostial dilation (e.g., Balloon Sinuplasty™) represents an alternative treatment to functional endoscopic sinus surgery (FESS) or may be used in conjunction with FESS. FESS has been considered the gold standard treatment for CRS. FESS is performed under general anesthesia and involves tissue and bone excision (with the associated risk of complications). Balloon sinus ostial dilation as a stand-alone procedure represents a less invasive and nontraumatic treatment for CRS. Balloon sinus ostial dilation is usually performed in an outpatient/office setting with local anesthesia and clinical studies have demonstrated the procedure results in less tissue damage, faster recovery, and fewer postoperative complications than FESS.

Medical Policy Statement

Balloon sinus ostial dilation (e.g., Balloon Sinuplasty™) is considered medically necessary in the outpatient setting as a stand-alone procedure or in combination with functional endoscopic sinus surgery (FESS) for treating documented chronic rhinosinusitis (CRS) when applicable Plan criteria are met. The Plan will NOT reimburse separately for balloon sinus ostial dilation (balloon catheter) when used during FESS, even when the balloon sinus ostial dilation is considered medically necessary. The Plan’s prior authorization and reimbursement guidelines for FESS would apply when the treatment is FESS in combination with balloon sinus ostial dilation or FESS without balloon catheter.

Plan prior authorization is REQUIRED for balloon sinus ostial dilation when performed as a stand-alone procedure and/or when the treating provider will bill with an applicable code included in this Plan policy. When balloon sinus ostial dilation is used as a stand-alone procedure to treat medically

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refractory CRS in the outpatient setting for an adult member as an alternative to other endoscopic sinus surgery (or an applicable code for balloon sinus ostial dilation will be billed by the treating provider), ALL of the following applicable criteria must be met and documented in the member’s medical record for the Plan to consider the treatment medically necessary, as specified below in items 1 through 8:

1. The treating provider has documented that the member is an appropriate candidate for endoscopic sinus surgery based on a complete anterior and posterior nasal exam, nasopharynx examination, nasal endoscopy, and/or specialty evaluation (e.g., dental, neurologic, ophthalmologic, pulmonary); AND

2. Balloon sinus ostial dilation will be performed either as a stand-alone procedure or as part of functional endoscopic sinus surgery (FESS); AND

3. The member is age 18 or older on the date of service; AND

4. Balloon sinus ostial dilation is limited to the frontal, maxillary, and/or sphenoid sinuses for the treatment of CRS in the corresponding sinus cavity (i.e., frontal sinusitis, maxillary sinusitis, and/or sphenoid sinusitis); AND

5. The member has NO medical history of a balloon procedure (or failed balloon procedure) in the frontal, maxillary, and/or sphenoid sinuses; AND

6. Member has documented CRS and ALL of the following criteria are met, as specified below in items a through c:
   a. The CRS has persisted for longer than 12 consecutive weeks (with or without acute exacerbations); AND
   b. The member reports to the treating provider that the symptoms of CRS have negatively impacted the member’s quality of life (for physical pain and social functioning); AND
   c. The member’s symptoms include facial pain, sinus pressure, postnasal drip, headache, and rhinorrhea; AND

7. Sinus computed tomography (CT) scan and nasal endoscopy have been performed to provide objective evidence of CRS, stage the extent of the disease, identify anatomical (structural) variants and impaired mucus clearance (with drainage pathway impairment), and to rule out obstruction from neoplasm and at least ONE (1) of the following findings is documented, as specified below in items a through e:
   a. Infraorbital narrowing the drainage pathway of the maxillary sinuses or supraorbital ethmoid cells narrowing the drainage pathway of the frontal sinuses;
b. Mucosal thickening;

c. Inflammation of paranasal sinuses;

d. Ostial narrowing or obstruction; AND/OR

e. Sinus opacification/bone remodeling; AND

8. Member has documented CRS that is refractory to medical treatment and ALL of the following conservative treatments have failed, as specified below in items a through c:

a. At least a four (4)-week trial of oral antibiotic therapy or systemic antibiotic therapy; AND

b. Course of steroid treatment (i.e., systemic steroids or topical nasal steroid sprays); AND

c. Nasal saline irrigations; AND

9. Allergic and immune etiologies of symptoms have been ruled out or treated appropriately with avoidance measures, pharmacotherapy (e.g., antihistamines, decongestants, leukotriene modifiers, mucolytics), and/or allergen immunotherapy, as determined by the treating provider.

Limitations

1. The use of a balloon catheter (e.g., Balloon Sinuplasty™) that has NOT received FDA clearance or an FDA-approved device that is NOT utilized according to its FDA-approved indication(s) and guidelines is considered experimental and investigational when used for the treatment of any sinus condition.

2. The Plan considers balloon sinus ostial dilation as a stand-alone procedure for the treatment of chronic rhinosinusitis (CRS) or for any other condition to be experimental and investigational for a Plan pediatric member under the age of 18 on the date of service (regardless of the member’s gender).

3. The use of balloon ostial dilation is NOT medically necessary for treating nasal polyps and/or tumors due to insufficient published clinical evidence supporting the safety and effective for this indication.

4. ONE (1) or more of the following indications for balloon sinus ostial dilation (e.g., Balloon Sinuplasty™) as a stand-alone procedure is considered experimental and investigational due to

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the limited documentation of the clinical utility and clinical validity of this treatment (as a stand-alone procedure) for any of these conditions, as specified below in items a through j:

a. Acute rhinosinusitis and/or air-fluid levels consistent with acute rhinosinusitis; OR

b. Aspirin-exacerbated respiratory disease (AERD)/NSAID-exacerbated respiratory disease (NERD)/Samter’s triad; OR

c. Complications of sinusitis that extend to adjacent structures such as the orbit or central nervous system; OR

d. Ethmoid sinusitis; OR

e. Extensive fungal disease causing sinusitis; OR

f. Fibrous dysplasia; OR

g. Past medical/surgical history of prior balloon procedure or failed balloon procedure in any of the sinuses; OR

h. Severe sinusitis secondary to autoimmune disorder, connective tissue disorder, or ciliary dysfunction; OR

i. Sinonasal polyposis; OR

j. Suspected or known sinonasal benign tumor, malignant tumor, and/or mucoceles.

The Plan will NOT reimburse separately for the balloon catheter when used during functional endoscopic sinus surgery (FESS), even when balloon sinus ostial dilation is considered medically necessary. The Plan’s prior authorization and reimbursement guidelines for FESS would apply when the treatment is FESS in combination with balloon sinus ostial dilation or FESS without balloon catheter. **If the treating provider will bill with an applicable code included in this Plan policy,** either for balloon sinus ostial dilation in addition to FESS (with the provider NOT reimbursed additionally for the balloon catheter used during FESS) or for balloon sinus ostial dilation as a stand-alone procedure, **the medical necessity criteria included in this policy must be met for the balloon sinus ostial dilation to be considered medically necessary.**

**Definitions**

**Aspirin-exacerbated Respiratory Disease (AERD):** Also called NSAID-exacerbated respiratory disease (NERD), AERD is a combination of asthma, chronic rhinosinusitis (CRS) with nasal polyposis, and acute upper and lower respiratory tract reactions to ingestion of aspirin (acetylsalicylic acid, ASA) and other cyclooxygenase-1 (COX-1)-inhibiting nonsteroidal anti-inflammatory drugs (NSAIDs). In 1968, a
condition that included asthma, aspirin sensitivity, and nasal polyps was described and became known as Samter's triad.

**Ciliary Dysfunction:** Cilia are fine hair-like projections from certain cells. In the respiratory tract, cilia are complex structures found in the paranasal sinus mucosa and are critical to respiratory defense. Cilia beat in a coordinated manner to clear pathogens and debris inspired during normal respiration from the paranasal sinus cavities and upper airway. Ciliary dysfunction is caused by mechanical, chemical, hormonal, pH, and/or thermal stimuli disrupting the normal cilia motility or coordination. Ciliary dysfunction may be caused by a primary/intrinsic ciliopathy (i.e., genetic mutations encoding defective proteins) and/or secondary/acquired condition (i.e., environmental factors such as pollutants or tobacco smoke, infections, and/or inflammatory stimuli). Patients with chronic rhinosinusitis (CRS) have been found to have impaired mucociliary clearance. Disorders associated with ciliary dysfunction include but are not limited to cystic fibrosis and primary ciliary dyskinesia (PCD)/Kartagener syndrome.

**Chronic Rhinosinusitis (CRS):** A clinical disorder characterized by symptomatic inflammation of sinonasal mucosa of the nose and paranasal sinuses with associated signs and symptoms for a duration of at least 12 consecutive weeks. CRS is characterized by two or more symptoms, one of which is nasal blockage/obstruction/congestion or nasal discharge (anterior/posterior nasal drip), with or without facial pain/pressure and reduction or loss of smell with endoscopic evidence of mucopurulence, edema, and/or polyps and/or CT presence of mucosal thickening or air-fluid levels in the sinuses. In children, CRS is defined as an inflammation of the nose and paranasal sinuses characterized by 8 or more weeks to 12 weeks with 2 or more of the following symptoms: nasal obstruction, congestion or discharge, postnasal drip, facial pain or pressure, cough, and a reduction in smell.

CRS is one of the more prevalent chronic illnesses in the United States. The etiology of CRS is likely to be multifactorial with the following risk factors: allergy; asthma; sinonasal anatomy; bacterial, viral, or fungal infection; mucociliary impairment; nasal polyps; immunologic disorders; and cystic fibrosis. CRS typically starts as acute rhinosinusitis that recurs and does not respond well to conservative medical therapy. CRS can affect the frontal sinuses, the maxillary sinuses, the sphenoid sinuses, and the ethmoid sinuses. Medical management of CRS includes topical and systemic antibiotics, topical and systemic steroids, saline irrigation, mucolytics, decongestants, antihistamines, and leukotriene modifiers. The diagnosis of CRS is confirmed by endoscopy and CT. Patients with chronic symptoms will often undergo allergy testing, blood tests to rule out immunodeficiency disorders, and tests to detect intranasal bacterial or fungal infection. CT findings in patients with rhinosinusitis are typically scored by the Lund MacKay staging system, which assigns numeric scores for the quality of the sinuses and osteomeatal complex. Mucosal thickening and obstruction or narrowing of the outflow tracts of the paranasal sinuses would be considered CT findings of chronic sinusitis. Air-fluid levels alone are more likely from an acute infection. Both acute and chronic findings can be seen at the same time. Patients with CRS who have persistent or recurring symptoms that fail to respond to medical management may require surgery (e.g., functional endoscopic sinus surgery/FESS and/or balloon sinus ostial dilation).
**Fibrous Dysplasia:** Skeletal disorder in which bone-forming cells fail to mature and produce too much fibrous, or connective, tissue. Areas of healthy bone are replaced with this fibrous tissue. The replacement of normal bone in fibrous dysplasia can lead to pain, misshapen bones, and fracture, especially when it occurs in the long bones (arms and legs). When it occurs in the skull, there can also be a replacement of the normal bone with fibrous tissue, resulting in changes in the shape of the face or skull, pain, and, in rare circumstances, hearing or vision loss. Examples of associated conditions include Paget’s disease (Source: NIH.)

**Functional Endoscopic Sinus Surgery (FESS):** A minimally invasive, mucosal-sparing surgical technique in which the sinus air cells and ostia are opened and drained under direct visualization. FESS is utilized to treat medically refractory CRS with or without polyps or recurrent acute rhinosinusitis. Polyps and infected tissue can be removed at the same time. Balloon sinus ostial dilation can be performed with FESS.

**Nasal Polyposis:** The pathogenesis of nasal polyposis is unknown but has been associated with chronic inflammation, autonomic nervous system dysfunction, and genetic predisposition. Conditions resulting in chronic inflammation in the nasal cavity can cause nasal polyps and are more common in patients with nonallergic asthma (13%) than with allergic asthma (5%), and only 0.5% of 3000 atopic individuals have nasal polyps. (Source: McClay, Medscape.)

**Paranasal Sinus Mucoceles:** Epithelium-lined cystic masses usually resulting from obstruction of sinus ostia. The close proximity of paranasal sinus mucoceles to the orbit and skull base may result in significant patient morbidities with ophthalmologic, rhinological, and/or neurological symptoms. Paranasal sinus mucoceles most frequently occur in the frontal and ethmoid sinuses. Surgical excision is the standard treatment.

**Primary Ciliary Dyskinesia (PCD):** Also known as immotile ciliary syndrome or Kartagener syndrome, PCD is a genetically heterogeneous disorder characterized by ciliary dysfunction and impaired mucociliary clearance and is typically autosomal recessive in nature. The respiratory manifestations of PCD include chronic bronchitis leading to bronchiectasis, chronic rhinosinusitis, and chronic otitis media. The diagnostic test for PCD is an electron microscopic ultrastructural analysis of respiratory cilia obtained by nasal scrape or bronchial brush biopsy.

**Rhinosinusitis:** Symptomatic inflammation of the paranasal sinuses and nasal cavity and is usually accompanied by inflammation of contiguous nasal mucosa. Rhinosinusitis is classified as acute (lasting less than 4 weeks) or chronic (lasting greater than 12 weeks with or without acute exacerbations). The difference between chronic rhinosinusitis and recurrent acute rhinosinusitis is vague, so the two diseases are often viewed and treated as the same indication.
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 States 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.

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<tr>
<th>CPT Codes</th>
<th>Description: Codes Considered Medically Necessary</th>
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<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 occurs when air-filled cavities of the face (the sinuses) become inflamed. 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.

Chronic sinusitis may be related to other systemic illnesses such as asthma, connective tissue disorder, uncontrolled allergic or inflammatory disease, or systemic immunologic dysfunction. Medical
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 performed in more severe cases to drain the sinuses and clear the infection when conservative medical therapy does not resolve functional obstruction of normal sinus ostia by intranasal swelling or obstruction of the nasal passage (related to inflammatory disease such as polyps or recalcitrant sinus opacification). Most sinus-related surgical cases in the United States are functional endoscopic sinus surgery (FESS) for the treatment of chronic sinusitis; FESS endoscopically uses thin fiberoptic tools that are passed through the nostrils to open the sinus passages and destroy the sinus tissue. Studies have demonstrated comparable outcomes between FESS and balloon sinus ostial dilation as a stand-alone procedure, with balloon ostial dilation producing faster recovery, less postoperative pain, and fewer debridements than FESS. Balloon sinus ostial dilation as a stand-alone procedure is an effective treatment in patients with uncomplicated CRS who meet the criteria for medically necessary FESS.

The first U.S. Food and Drug Administration (FDA)-approved dilating balloon catheter system for obstructed paranasal sinus drainage pathways was introduced in September 2005. Balloon sinus ostial dilation (e.g., Balloon Sinuplasty™) may be used as a tool during FESS and has recently been utilized as a stand-alone procedure as an alternative to FESS. A balloon sinus ostial dilation uses a balloon catheter introduced through the nose via a flexible tube to keep the sinus passages open and unobstructed by dilating the maxillary, frontal, and/or sphenoid natural ostia by gently inflating the small balloon without removal of bone or soft tissue. Balloon sinus dilation represents the first step toward tissue preservation technique and away from the destructive access techniques necessary for FESS.

An example of balloon sinus ostial dilation 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 received 510(k) approval in August 2012; these are the ENTrigue® Sinus Dilation System, and the XprESS® Multi-Sinus Dilation Tool.

At the time of the Plan’s most recent policy review, no clinical guidelines were found from the Centers for Medicare & Medicaid Services (CMS) for balloon sinus ostial dilation (including balloon sinuplasty) for the treatment of sinusitis or any other indication. Determine if applicable CMS criteria are in effect.
for the specified service and the indication for treatment in a national coverage determination (NCD)
or local coverage determination (LCD) on the date of the prior authorization request for a Senior Care Options member.

References


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Regulatory Approval: N/A
Internal Approval:
11/25/08: Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)
11/25/08: Utilization Management Committee (UMC)
12/16/08: Quality Improvement Committee (QIC)

Original Approval Date

Original Effective Date* and Version Number

Policy Owner

Original Policy Approved by

Regulatory Approval: N/A

Internal Approval:
11/25/08: Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)
11/25/08: Utilization Management Committee (UMC)
12/16/08: Quality Improvement Committee (QIC)

03/01/09 Version 1

Medical Policy Manager as Chair of MPCTAC

MPCTAC, QIC, and UMC

*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
*Effective Date for Senior Care Options Product(s): 01/01/16

(Policy formerly titled Balloon Sinuplasty for the Treatment of Sinusitis until 11/30/13.)

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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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<td>Version 3</td>
<td>11/23/10: MPCTAC 12/22/10: QIC</td>
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<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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<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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<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</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. 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>12/01/13 Version 8</td>
<td>08/21/13: MPCTAC 09/19/13: QIC</td>
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<td>09/01/15</td>
<td>Review for effective date 11/01/15. Updated list of applicable products, including the removal of Commonwealth Care, Commonwealth Choice, and Employer Choice because the products are no longer available. Updated Clinical Background Information and References sections.</td>
<td>11/01/15 Version 10</td>
<td>09/16/15: MPCTAC 10/14/15: QIC</td>
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<td>11/25/15</td>
<td>Review for effective date 01/01/16. Revised language in the Applicable Coding section.</td>
<td>01/01/16 Version 11</td>
<td>11/25/15: MPCTAC (electronic vote) 12/09/15: QIC</td>
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<tr>
<td>09/01/16</td>
<td>Review for effective date 12/01/16. Revised Summary, Clinical Background Information, References, and References to Applicable Laws and Regulations sections.</td>
<td>12/01/16 Version 12</td>
<td>10/19/16: MPCTAC 11/09/16: QIC</td>
</tr>
<tr>
<td>09/01/17</td>
<td>Review for effective date 12/01/17. Administrative changes made to the Policy Summary, Description of Item or Service, Definitions, Clinical Background Information, References, Other Applicable Policies, and References to Applicable Laws and Regulations sections.</td>
<td>12/01/17 Version 13</td>
<td>09/20/17: MPCTAC</td>
</tr>
</tbody>
</table>

Balloon Sinus Ostial Dilation

*Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.
Balloon Sinus Ostial Dilation

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<table>
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<tr>
<th>Policy Revisions History</th>
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**Last Review Date**

09/01/17

**Next Review Date**

09/01/18

**Authorizing Entity**

MPCTAC

**Other Applicable Policies**

Medical Policy - *Medically Necessary*, policy number OCA 3.14
Medical Policy - *Experimental and Investigational Treatment*, policy number OCA: 3.12

**Reference to Applicable Laws and Regulations**


**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

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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.

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