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Medical Policy

Balloon Sinus Ostial Dilation

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Product Applicability	☒ **All Plan+ Products**
WellSense Health Plan ☒ NH Medicaid ☒ NH Medicare Advantage	**Boston Medical Center HealthNet Plan** ☒ MassHealth ACO ☒ MassHealth MCO ☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☒ Senior Care Options

+ Note: Disclaimer and audit information is located at the end of this document.

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) associated with inflammatory obstruction of the sinus passages when applicable Plan criteria are met. 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 as a stand-alone procedure for a pediatric member under the age of 18 on the date of service to be experimental and investigational or NOT medically necessary due to limited evidence demonstrating the clinical utility and clinical validity of the treatment when used to treat CRS or any other sinus condition. When a balloon catheter is used either as a tool during FESS or as a stand-alone procedure for the treatment of medically refractory CRS (as

determined by the member's attending surgeon), the type of balloon catheter used must have received FDA clearance and be utilized for its FDA-approved indication. The Plan considers the use of balloon ostial dilation (balloon catheter) NOT medically necessary for the treatment of nasal polyps and/or tumors.

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. It will be determined during the Plan's standard prior authorization review process if the requested treatment with balloon sinus ostial dilation (performed either as a stand-alone procedure or as part of FESS) 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 reimburse for balloon sinus ostial dilation as a stand-alone procedure** when medical necessity criteria are met, prior authorization is obtained, the provider follows the Plan's reimbursement guidelines (according to the Applicable Coding section of this policy and the Plan's reimbursement policies), and it is a covered service for the Plan member.

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 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, FESS without balloon sinus ostial dilation, other surgical procedures, and medical treatments). The Plan's prior authorization matrix, code look-up tools, medical policies, and reimbursement policies are available at www.bmchp.org for BMC HealthNet Plan members and posted at www.wellsense.org for WellSense Health Plan members.

Clinical Criteria

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 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 10:

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. Balloon sinus ostial dilation will be performed with only FDA-approved balloon sinus ostial device(s) (e.g., catheter, inflation device, system) and utilized according to FDA-approved indications and guidelines; AND

4. The member is age 18 or older on the date of service (with Plan Medical Director review required for prior authorization requests for members age 17 or younger on the date of service for individual consideration, as stated in the Limitations and Exclusions section); AND

5. 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

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

7. 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

8. Sinus computed tomography (CT) scan (with or without nasal endoscopy) has 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 f:

    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;

    e. Sinus opacification/bone remodeling; AND/OR

    f. Impaired air-fluid levels; AND

9. 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. Full course of either oral antibiotic therapy or systemic antibiotic therapy (preferably culture-directed) for three (3) or more weeks (unless antibiotic treatment is NOT indicated or contraindicated for the member, as determined by the treating provider and documented in the member's medical record); AND

    b. A course of topical intranasal corticosteroid therapy (generally for at least three (3) weeks unless corticosteroid therapy is NOT indicated or contraindicated for the member, as determined by the treating provider and documented in the member's medical record); AND

    c. Nasal saline irrigations (unless contraindicated for the member, as determined by the treating provider and documented in the member's medical record); AND

10. 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 and Exclusions

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. Plan Medical Director review is required for prior authorization requests for the use of balloon sinus ostial dilation as a stand-alone procedure for the treatment of chronic rhinosinusitis (CRS) or for any other condition for a Plan pediatric member under the age of 18 on the date of service (regardless of the member's gender). Individual consideration will be conducted by the Plan Medical Director based on the clinical documentation submitted by the treating provider. The Plan Medical Director will take into account the following factors: member's age; comorbidities and relevant past medical/surgical/pharmacotherapy history; diagnostic results; complications; progression of the member's clinical condition; and progress of conservative treatment. In addition, the treating provider must verify that each device used for the balloon sinus ostial dilation is FDA-approved for the pediatric member's age on the date of service and the member's medical condition, and the device will be used according to FDA-approved indications and guidelines.

3. The use of balloon ostial dilation is NOT medically necessary for treating sinonasal tumors (benign or malignant), sinonasal polyps, and/or mucoceles due to insufficient published clinical evidence supporting the safety and effectiveness 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 or NOT medically necessary due to 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 h:

    a. Acute rhinosinusitis, recurrent 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. Isolated ethmoid sinus disease; 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.

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.

Variations

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for Senior Care Options (SCO) members and WellSense Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, no applicable clinical guidelines were found from CMS. Verify CMS criteria in effect for the requested service on the date of the prior authorization request for a SCO or WellSense Medicare Advantage HMO member. When there is no guidance from CMS for the requested service for the specified indication on the date of the prior authorization request, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

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). Since 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 Clinical Criteria and Limitation and Exclusions sections 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 this Applicable Coding section. Review the Plan's reimbursement policies for Plan billing guidelines. Coverage for services is subject to benefit eligibility under the member's benefit plan in effect at the time of the service. Member benefit documents are available at the following websites: www.bmchp.org for BMC HealthNet Plan members, www.SeniorsGetMore.org for Senior Care Options members, www.wellsense.org for WellSense New Hampshire Medicaid members, and www.WellSense.org/Medicare for WellSense Medicare Advantage HMO members.

CPT Codes	Description: Codes Considered Medically Necessary
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

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Policy History

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: 01/01/12
*Effective Date for WellSense Plan New Hampshire Medicaid Product: 01/01/13
*Effective Date for Senior Care Options Product: 01/01/16
*Effective Date for the WellSense Medicare Advantage HMO Product: 01/01/22

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

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date and Version Number**	**Approved by**
11/24/09	Updated references, no clinical criteria change.	Version 2	11/24/09: MPCTAC 12/23/09: QIC
11/10/10	Updated references, no clinical criteria changes.	Version 3	11/23/10: MPCTAC 12/22/10: QIC

Policy Revisions History			
11/01/11	Updated references, no clinical criteria changes.	Version 4	11/16/11: MPCTAC 12/20/11: QIC
07/30/12	Off cycle review for WellSense Health Plan, revised Summary section, revised Medical Policy Statement section.	Version 5	08/15/12: MPCTAC 09/26/12: QIC
08/01/12	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.	Version 6	08/03/12: MPCTAC 09/05/12: QIC
08/14/13 and 08/15/13	Off cycle review. Incorporate policy revisions dated 08/01/12 (as specified above) for the WellSense 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.	Version 7	08/14/13: MPCTAC (via electronic vote) 08/15/13: QIC
08/21/13	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.	12/01/13 Version 8	08/21/13: MPCTAC 09/19/13: QIC
09/01/14	Review for effective date 11/01/14. Clarified language in the Policy Summary, Medical Policy Statement, and Limitations sections without changing Plan criteria. Updated and added references.	11/01/14 Version 9	09/17/14: MPCTAC 10/08/14: QIC
09/01/15	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.	11/01/15 Version 10	09/16/15: MPCTAC 10/14/15: QIC

Policy Revisions History			
	Updated Clinical Background Information and References sections.		
11/25/15	Review for effective date 01/01/16. Revised language in the Applicable Coding section.	01/01/16 Version 11	11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
09/01/16	Review for effective date 12/01/16. Revised Summary, Clinical Background Information, References, and References to Applicable Laws and Regulations sections.	12/01/16 Version 12	10/19/16: MPCTAC 11/09/16: QIC
09/01/17	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. Criteria revised in the Medical Policy Statement and Limitations sections.	12/01/17 Version 13	09/20/17: MPCTAC
01/23/18	Review for effective 01/01/18. Added new CPT code 31298 to Applicable Coding section as industry-wide code update effective 01/01/18.	01/23/18 Version 14	Not applicable because industry-wide code change (and network notification is therefore not required).
09/01/18	Review for effective date 12/01/18. Revised criteria in the Medical Policy Statement and Limitations sections. Administrative changes made to the Definitions, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections.	12/01/18 Version 15	09/19/18: MPCTAC
09/01/19	Review for effective date 12/01/19. Criteria revised in the Limitations section. Administrative changes made to the Policy Summary, References and Reference to Applicable Laws and Regulations sections.	12/01/19 Version 16	09/18/19: MPCTAC
12/01/19	Review for effective date 01/01/20. Industry-wide updates to code descriptions included in the Applicable Coding section.	01/01/20 Version 17	Not applicable because industry-wide code changes.
07/01/20	Review for effective date 08/01/20.	08/01/20	07/15/20: MPCTAC

Policy Revisions History			
	Administrative changes made to the Medical Policy Statement, Clinical Background Information, and References sections.	Version 18	
08/01/21	Review for effective date 09/01/21. Administrative changes made to the Policy Summary, Limitations, and References sections.	09/01/21 Version 19	08/27/21: MPCTAC (electronic vote)
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, the Medical Policy Statement section renamed the Clinical Criteria section, and the Limitations section renamed the Limitations and Exclusions section. Added WellSense Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Applicable Coding, and References sections.	12/01/21 Version 20	11/17/21: MPCTAC

Next Review Date

07/01/22

Authorizing Entity

MPCTAC

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.

[+] *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 WellSense Health Plan.

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.