To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.

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1.0 Description of the Procedure, Product, or Service

Balloon Ostial Dilation (BOD) also known as balloon dilation sinuplasty, balloon catheter sinusotomy, sinus ostial dilation or balloon sinuplasty, is a procedure that involves placing a balloon in the sinus ostium and inflating the balloon to stretch the opening. BOD can be performed as a stand-alone procedure for chronic rhinosinusitis, or as an adjunctive procedure to the traditional endoscopic sinus surgery, Functional Endoscopic Sinus Surgery (FESS).

Several procedure approaches have been proposed for balloon sinus ostial dilation. The first type of approach is done through the nostrils by inserting a small balloon through a tube placed in the nasal cavity where the blocked sinus is located using fluoroscopic guidance. The second type of approach is the transantral approach, which is done by creating a small entry point under the lip. In most instances, the procedure is performed under general anesthesia and in some cases local anesthesia. Potential advantages of sinus balloon catheterization consist of minimal mucosal damage, minimal intraoperative bleeding, minimal discomfort, and equally effective when compared with the more invasive procedure of FESS. This policy does not address FESS.

1.1 Definitions

1.1.1 Acute sinusitis

Acute sinusitis is rhinosinusitis lasting less than four consecutive weeks.

1.1.2 Subacute sinusitis.

Subacute sinusitis is rhinosinusitis lasting four weeks to twelve consecutive weeks.

1.1.3 Chronic rhinosinusitis (CRS)

Chronic rhinosinusitis is rhinosinusitis lasting longer than 12 consecutive weeks.

Recurrent Acute Rhinosinusitis (RARS)
A subtype of CRS (four or more acute rhinosinusitis episodes within a twelve-month period after medical therapy has failed.

1.1.4 Functional Endoscopic Sinus Surgery (FESS)

FESS involves the insertion of the endoscope, a very thin fiber-optic tube, into the nose for a direct visual examination of the openings into the sinuses. With state-of-the-art micro-telescopes and instruments, abnormal and obstructive tissues are then removed. In the majority of cases, the surgical procedure is performed entirely through the nostrils, leaving no external scars. There is little swelling and only mild discomfort.

1.1.5 Medical Therapy

Medical therapy consists of:

1. A minimum of two different oral antibiotics of two to four weeks duration for a beneficiary with chronic rhinosinusitis (culture-directed if possible)
2. A minimum of two different oral antibiotics with multiple one to three-week courses for a beneficiary with recurrent acute rhinosinusitis (at the discretion of the physician)
3. Oral or nasal steroids (at the discretion of the physician)
4. Optional nasal saline irrigations
5. Optional oral, nasal decongestants, or antihistamines if not contraindicated
6. Treatment of concomitant allergic rhinitis consisting of avoidance measures, pharmacotherapy, or immunotherapy (at the discretion of the physician).

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(*The term "General" found throughout this policy applies to all Medicaid policies*)

a. An eligible beneficiary shall be enrolled in the NC Medicaid Program *(Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
b. Provider(s) shall verify each Medicaid beneficiary's eligibility each time a service is rendered.
c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

2.1.2 Specific

(***The term "Specific" found throughout this policy only applies to this policy***)

a. <u>Medicaid</u>

Medicaid beneficiaries may be eligible for BOD, when the beneficiary meets the criteria in **Subsection, 3.2** and is 18 years of age and older. The final decision to perform BOD must be the responsibility of the otolaryngologist who takes into consideration the suitability of the case for BOD alone and FDA approved indications for use. The Otolaryngologist shall comply with age requirement as noted in Subsection 2.1.2(a).

2.2 Special Provisions

2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. **42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]**

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health

problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

b. **EPSDT and Prior Approval Requirements**

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide,* and on the EPSDT provider page. The Web addresses are specified below.

   NCTracks Provider Claims and Billing Assistance Guide: https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

   EPSDT provider page: https://medicaid.ncdhhs.gov/

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

3.1 General Criteria Covered

Medicaid shall cover the procedure, product, or service related to this policy when medically necessary, and:

a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;
b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by Medicaid

Medicaid shall cover stand-alone BOD (limited to the frontal, maxillary, or sphenoid sinuses) for a beneficiary who meets all of the following criteria:

a. Has either chronic rhinosinusitis lasting longer than 12 consecutive weeks; or four or more documented episodes of RARS in twelve calendar months.

b. Has documented attempts and failure of medical therapy (**refer to Subsection 1.1.5**) and

c. Has been reported by confirmation of computed tomography (CT) that the sinus to be dilated, demonstrates at least **ONE** of the following radiological findings:

1. bone remodeling and thickening;
2. mucosal thickening greater than two millimeters;
3. complete opacification; or
4. Obstruction of the ostiomeatal complex.

Note: CT scans can be nonspecific for diagnosing RARS, therefore, clinical findings are required to support surgical intervention.

3.2.2 Medicaid Additional Criteria Covered

None Apply.

4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid shall not cover the procedure, product, or service related to this policy when:

a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0;**
b. the beneficiary does not meet the criteria listed in **Section 3.0;**
c. the procedure, product, or service duplicates another provider's procedure, product, or service; or

d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by Medicaid

Medicaid shall not cover BOD for any of the following conditions:

a. Nasal polyps or tumors.
b. Samter's Triad (aspirin sensitivity);
c. Severe sinusitis secondary to autoimmune or connective tissue disorders such as sarcoidosis or Wegener's granulomatosis;
d. Severe sinusitis secondary to ciliary dysfunction such as cystic fibrosis;
e. Contraindication to, or inability to tolerate local or topical anesthetic;
f. History of failed balloon procedure in the sinus to be treated;
g. Sinusitis with extensive fungal disease; **or**
h. Significant neo-osteogenesis confirmed by CT.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

5.1 Prior Approval

Medicaid shall require prior approval for BOD.

5.2 Prior Approval Requirements

5.2.1 General

The provider(s) shall submit to the Department of Health and Human Services (DHHS) Utilization Review Contractor the following:

a. the prior approval request; and
b. all health records and any other records that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy.

5.2.2 Specific

In addition to the requirements listed in **Subsection 5.2.1**, the Otolaryngologist shall submit all of the following to the DHHS Utilization Review Contractor:

a. Signed letter of medical necessity by the attending physician requesting BOD, and a summary of the beneficiary's clinical history and evaluation.
b. Documentation of what sinus is involved;
c. Documentation of attempted and failed medical therapy (refer to subsection 1.1.5) for persistent chronic or recurrent acute rhinosinusitis;
d. Documentation of one or more of the following CT scan findings; (as noted in **Subsection 3.2.1.C**):
    1. mucosal thickening greater than two millimeters;
    2. complete opacification;
    3. bone remodeling and thickening; or

4. obstruction of the ostiomeatal complex.

   Note: CT scans can be nonspecific for diagnosing RARS, therefore, clinical findings are required to support surgical intervention.

5.3 Additional Limitations or Requirements

With prior approval, Medicaid will pay each code (31295, 31296, 31297, 31298) one time, per sinus, per beneficiary lifetime.

6.0 Provider(s) Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

a. meet Medicaid qualifications for participation;
b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

BOD shall be performed by an Otolaryngologist.

6.2 Provider Certifications

None applied.

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

7.1 Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

8.0 Policy Implementation and History

Original Effective Date: February 1, 2018

History:

Date	Section or Subsection Amended	Change
February 1, 2018	All Sections and Attachment(s)	New policy documenting a new service.
April 1, 2018	Subsection 5.3	CPT 2018 update. Added CPT code 31298
03/15/2019	Table of Contents	Added, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP."
03/15/2019	All Sections and Attachments	Updated policy template language.
12/12/2019	Table of Contents	Updated policy template language, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP."
12/12/2019	Attachment A	Added, "Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
8/15/2023	All Sections and Attachments	Updated policy template language due to North Carolina Health Choice Program's move to Medicaid. Policy posted 8/15/2023 with an effective date of 4/1/2023.

Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid:

A. Claim Type

Institutional (UB-04/837I transaction)
Professional (CMS-1500/837P transaction)

Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.

B. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)

Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.

C. Code(s)

Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy.

If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

CPT Code(s)
31295
31296
31297
31298

Unlisted Procedure or Service
CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions for use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service.

D. Modifiers

Provider(s) shall follow applicable modifier guidelines.

E. Billing Units

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).

F. Place of Service

Inpatient hospital, outpatient hospital, ambulatory surgical clinic, and office.

G. Co-payments

For Medicaid refer to Medicaid State Plan:
https://medicaid.ncdhhs.gov/meetings-notices/medicaid-state-plan-public-notices

H. Reimbursement

Provider(s) shall bill their usual and customary charges.
For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/

BOD used as an adjunct during (FESS) is considered integral to the primary FESS procedure and not separately reimbursable.