



BlueCross BlueShield  
of Alabama

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**Name of Blue Advantage Policy:**

**Aerosolized Antibiotics as a Treatment of Chronic Sinusitis**

Policy #: 193  
Category: Laboratory

Latest Review Date: March 2021  
Policy Grade: **Effective 02/06/2013: Active  
Policy but no longer  
scheduled for regular  
literature reviews and  
updates.**

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**BACKGROUND:**

*Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational\*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
  - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
  - *Furnished in a setting appropriate to the patient's medical needs and condition;*
  - *Ordered and furnished by qualified personnel;*
  - *One that meets, but does not exceed, the patient's medical need; and*
  - *At least as beneficial as an existing and available medically appropriate alternative.*

*In accordance with Title XVIII of the Social Security Act, Section 1862 (a)(10) cosmetic surgery or expenses incurred in connection with such surgery is not covered except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member.*

*\*Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare** for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

## **POLICY:**

**Blue Advantage will treat aerosolized antibiotics** as a technique of treating chronic sinusitis or acute exacerbations of chronic sinusitis as a **non-covered** benefit and as **investigational**.

*Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

## **DESCRIPTION OF PROCEDURE OR SERVICE:**

Chronic sinusitis is defined as a group of disorders characterized by inflammation of the mucosa of the nose and paranasal sinuses of at least 12 consecutive weeks duration. Clinical signs include purulent drainage and various imaging studies (e.g. CT, MRI, or plain film radiographs) may reveal polyps, edema, erythema or granulation tissue of the sinuses. Chronic sinusitis may be associated with asthma, allergies, dental disease, polyposis, cystic fibrosis and immunodeficiency syndromes. Chronic sinusitis represents a continuous spectrum of pathophysiologies ranging from a purely infectious etiology to noninfectious or allergic inflammation. In addition, it is possible the presence of bacteria colonization may aggravate a noninfectious inflammation. Conventional treatment for chronic sinusitis includes various combinations of oral antibiotics, decongestants, mucolytics and topical corticosteroids.

Functional endoscopic sinus surgery (FESS) to improve the ventilation within the osteomeatal complex may be offered to those patients who fail medical management. After FESS, the sinus ostia are patent and communicate with the nasal cavity. FESS is successful in approximately 80-90% of patients with recurrent or medically unresponsive chronic sinusitis.

Antibiotics aerosolized for this purpose include tobramycin, gentamicin, ciprofloxacin, levofloxacin and certain cephalosporins. Aerosolized antibiotics are not commercially available, but may be provided by a compounding pharmacy.

The SinuNEB is a device that uses compounded medications that are aerosolized to a particle size small enough to disperse within the sinus cavities. According to the manufacturer of the SinuNEB, administration of antibiotics via nebulization directly to the lining of the sinuses results in a more rapid response, greater effectiveness, reduced reinfection, and fewer side effects than oral or intravenous antibiotic administration.

## **KEY POINTS:**

The most recent literature search was through March 2021 with searches of the MEDLINE database.

**Summary of Evidence**

The data on use of aerosolized antibiotics for chronic sinusitis are very limited. Thus, use of aerosolized antibiotics in the treatment of sinusitis is considered investigational because its impact on clinical outcomes is not known.

**Practice Guidelines and Position Statements:**

No published guidelines on sinusitis management from leading professional medical organizations discuss any role for nebulized or nasally irrigated antibiotics. Thus, aerosolized or nasally irrigated anti-infectives are considered experimental and investigational for the treatment of sinusitis.

**KEY WORDS:**

Aerosolized antibiotics, nebulization, sinusitis, chronic sinusitis, functional endoscopic sinus surgery, FESS, nebulizer, compounding pharmacy, NasoNeb®, SinuNEB

**APPROVED BY GOVERNING BODIES:**

In June 2006, the LC® Star Reusable Nebulizer with Nasal Adapter (PARI Innovative Manufacturers, Inc) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for the inhalation treatment of aerosolized medications.

The SinuNEB (SinusPharmacy) is a device that nebulizes antibiotics, anti-fungals, and medications for the treatment of sinusitis.

The NasoNeb® System (2009) delivers a penetrating aerosol to the nasal and paranasal sinus cavities.

**BENEFIT APPLICATION:**

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

**CURRENT CODING:**

**HCPCS**

E0575	Nebulizer, ultrasonic, large volume
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## REFERENCES:

1. American Academy of Otolaryngology—Head and Neck Surgery. Aerosolized antibiotics prove to be safe and effective for treatment of chronic sinusitis, [www.entlink.net/entpress/12-02.cfm](http://www.entlink.net/entpress/12-02.cfm).
2. Blue Cross and Blue Shield Association. Medical Policy Reference Manual. Aerosolized antibiotics as a treatment of chronic sinusitis, September 2009.
3. Centers for Disease Control (CDC). National Center for Health Statistics. Chronic sinusitis, [www.cdc.gov/nchs/fastats/sinuses/htm](http://www.cdc.gov/nchs/fastats/sinuses/htm).
4. Desrosiers MY, Salas-Prato M. Treatment of chronic rhinosinusitis refractor to other treatment with topical antibiotic therapy delivered by means of a large particle nebulizer: Results of a controlled trial, *Otolaryngol Head Neck Surg* 2001; 125: 265-269.
5. Scheinberg PA, Otsuji A. Nebulized antibiotics for the treatment of acute exacerbations of chronic rhinosinusitis, *Ear Nose Throat Journal* 2002; 81: 648-652.
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7. Vaughan WC, Carvalho G. Use of nebulized antibiotics for acute infection in chronic sinusitis, *Otolaryngol Head Neck Surg* 2002; 127: 55-68.
8. Velepčič M, Manestar D, Perković I, Škalamera D, Braut T. Inhalation Aerosol Therapy in the Treatment of Chronic Rhinosinusitis: A Prospective Randomized Study. *J Clin Pharmacol*. 2019 Dec;59(12):1648-1655. doi: 10.1002/jcph.1471. Epub 2019 Jun 19.
9. Videler WJ, van Drunen CM et al. Nebulized bacitracin/colimycin: A treatment option in recalcitrant chronic rhinosinusitis with *Staphylococcus aureus*? A double-blind, randomized, placebo-controlled, cross-over pilot study. *Rhinology*, June 2008; 46(2): 92-98.

## POLICY HISTORY:

Adopted for Blue Advantage, March 2005

Available for comment May 1-June 14, 2005

Medical Policy Group, August 2006

Medical Policy Group, August 2008

Medical Policy Group, August 2010

Medical Policy Group, February 2013: Effective 02/06/2013: Active Policy but no longer scheduled for regular literature reviews and updates.

Medical Policy Group, September 2019

Medical Policy Group, March 2021

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*This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plans contracts.*

