BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

SINUVA™ (mometasone furoate)

Policy #: 708
Latest Review Date: February 2023
Category: Pharmacy

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.*

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 the **use of implantable nasal/sinus drug-eluting implants (i.e. SINUVA™)** as a **non-covered benefi**t and as **investigational** for the following, including, but not limited to:

- postoperative treatment following endoscopic sinus surgery;
- for treatment of recurrent sinonasal polyposis.

DESCRIPTION OF PROCEDURE OR SERVICE:

Placed during a routine physician office visit, Sinuva™ (mometasone furoate) expands into the sinus cavity and delivers an anti-inflammatory steroid directly to the site of polyp disease for 90 days. Sinuva may be an alternative to surgery and other treatment options for adults who have already had ethmoid sinus surgery. Sinuva is marketed to shrink nasal polyps and reduce nasal obstruction and congestion.

KEY POINTS:

The most recent literature update was performed through January 6, 2023.

Summary of Evidence:

Drug eluting sinus implants may prove to have a role in nasal polyposis; however, additional positive results from well-designed RCTs are needed to confirm the results of the available RCTs. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements:

International Consensus Statement on Allergy and Rhinology

In 2021, the International Consensus Statement on Allergy and Rhinology was updated and included the following recommendation:

"Corticosteroid-eluting implants can be considered as an option in a previously operated ethmoid cavity with recurrent nasal polyposis."

The recommendation noted, "Corticosteroid eluting implants have been shown to have beneficial impact on ethmoid polyposis and obstruction, and 1 study has shown them to be cost-effective in preventing revision ESS. Experience is early and although evidence is high level, only short-term outcomes are currently available."

U.S. Preventive Services Task Force Recommendations:

Not Applicable.

KEY WORDS:

Sinuva (mometasone furoate), sinus implant, Intersect ENT, nasal polyp, ethmoid sinus surgery

APPROVED BY GOVERNING BODIES:

SINUVA™ Sinus Implant (Intersect ENT, Inc., Menlo Park, CA) was initially approved in 1987. In 2017, the SINUVA™ Sinus Implant was approved with a new dose (1350 µg mometasone furoate) under a New Drug Application (NDA 209310). The corticosteroid is released over 90 days and the bioabsorbable polymers soften over this time. The implant is removed at Day 90 or earlier using standard surgical instruments. The SINUVA™ Sinus Implant is indicated for the treatment of nasal polyps in adult patients who have had ethmoid sinus surgery.

BENEFIT APPLICATION:

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

CURRENT CODING:

CPT CODES:

30999	Unlisted procedure, Nose
31299	Unlisted procedure, accessory sinuses

HCPCS CODES:

J7402	Mometasone furoate sinus implant (Sinuva), 10 micrograms (Effective 4/01/21)

PREVIOUS CODING:

J7401	Mometasone furoate sinus implant, 10 micrograms (Effective 10/1/19, Deleted 03/31/21)
S1090	Mometasone furoate sinus implant, 370 micrograms (Deleted 9/30/19)

REFERENCES:

1. Forwith KD, Han JK, Stolovitzky JP, et al. RESOLVE: bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis after sinus surgery: 6-month outcomes from a randomized, controlled, blinded study. Int Forum Allergy Rhinol. 2016;6(6):573-81.
2. Goshtasbi K, Abouzari M, Abiri A, Yasaka T, Sahyouni R, Bitner B, Tajudeen BA, Kuan EC. Efficacy of steroid-eluting stents in management of chronic rhinosinusitis after endoscopic sinus surgery: updated meta-analysis. Int Forum Allergy Rhinol. 2019 Dec;9(12):1443-1450. doi: 10.1002/alr.22443. Epub 2019 Sep 20.

3. Han JK, Forwith KD, Smith TL, et al. RESOLVE: a randomized, controlled, blinded study of bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis. Int Forum Allergy Rhinol. Nov 2014; 4(11):861-870.
4. Han JK, Marple BF, Smith TL. Effect of steroid-releasing sinus implants on postoperative medical and surgical interventions: an efficacy meta-analysis. Int Forum Allergy Rhinol 2012; 2(4):271-9.
5. https://www.sinuva.com/. Accessed December 31, 2019.
6. IOM (Institute of Medicine). 2011. Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press.
7. Kern RC, Stolovitzky JP, Silvers SL, et al; RESOLVE II study investigators. A phase 3 trial of mometasone furoate sinus implants for chronic sinusitis with recurrent nasal polyps. Int Forum Allergy Rhinol. 2018;8(4):471-481.

POLICY HISTORY:

Adopted for Blue Advantage, January 2020
Medical Policy Group, March 2021: Quarterly Coding Update. Added new code J7402. Moved deleted code J7401 from current coding to previous coding.
Medical Policy Group, July 2021
Medical Policy Group, February 2022
Medical Policy Group, February 2023
