

Transitional Pass-Through Payment for SINUVA® (mometasone furoate) sinus implant

NEW UPDATE AS OF APRIL 1, 2021

SINUVA was previously granted transitional pass-through status, effective July 1, 2020, and assigned a new C-Code of C9122. **EFFECTIVE APRIL 1, 2021 CMS has officially deleted the C-Code assigned to SINUVA for pass-through billing and assigned it the new HCPCS code J7402 to be billed in all settings of care and for pass-through claims.** When a drug is granted pass-through status by CMS, ambulatory surgery centers and other outpatient facilities are eligible to receive separate payment for the pass-through drug in addition to the payment received for procedures furnished during the patient encounter.

Pass-through status for SINUVA will remain in effect for 3 years, and is applicable to **Medicare Fee-for-Service patients only.**

When billing Medicare, **as of April 1, 2021, J7402** and the corresponding NDC number **10599000301 Mometasone furoate sinus implant, (sinuva), 10 micrograms** should be billed on the claim form and reported with the CPT code(s) which most accurately describe the services performed in association with the placement of a drug eluting sinus implant.

Ambulatory Surgery Center/Hospital Outpatient Surgery Code	NDC Number	Billing Units	Billing Units
J7402	10599000301	1 unit for every 10 mcg = 135 billing units	Mometasone furoate sinus implant, (sinuva), 10 micrograms

INDICATION

SINUVA Sinus Implant is a corticosteroid-eluting (mometasone furoate) implant indicated for the treatment of nasal polyps in patients ≥ 18 years of age who have had ethmoid sinus surgery.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Patients with known hypersensitivity to mometasone furoate, or to any of the copolymers of the SINUVA Sinus Implant

Please see additional Important Safety Information on the next page.

Transitional Pass-Through Payment for SINUVA[®] (mometasone furoate) sinus implant

For more information on reimbursement or billing pertaining to the pass-through status of SINUVA please contact your Regional Reimbursement Director at Intersect ENT. To enroll a patient and check benefits contact Connect at 1-833-4SINUVA. To procure SINUVA please contact McKesson Specialty at 1-855-477-9800 or ASD Healthcare at 1-800-746-6273.

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS

Local Effects

Monitor nasal mucosa adjacent to the SINUVA Sinus Implant for any signs of bleeding (epistaxis), irritation, infection, or perforation. Avoid use in patients with nasal ulcers or trauma.

Ocular Effects

Glaucoma, cataracts, and clinically significant elevation of intraocular pressure were not observed in patients from the treatment group of one randomized controlled clinical study (N = 53) who underwent bilateral placement of SINUVA Sinus Implants. Close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts.

Hypersensitivity Reactions

Hypersensitivity reactions, including rash, pruritus, and angioedema have been reported with use of corticosteroids.

Immunosuppression

Persons who are using drugs that suppress the immune system are more susceptible to infections than healthy individuals. Corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculosis infection of the respiratory tract; untreated systemic fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex.

Hypercorticism and Adrenal Suppression

If corticosteroid effects such as hypercorticism and adrenal suppression appear in patients, consider sinus implant removal.

ADVERSE REACTIONS

The most common adverse reactions observed (> 1% of subjects and that occurred more frequently in the treatment group compared to control) in clinical studies were asthma, headache, epistaxis, presyncope, bronchitis, otitis media, and nasopharyngitis.

POSTMARKETING EXPERIENCE

The following adverse reactions have been identified during post-approval use of the SINUVA sinus implant. These events include implant migration, lack of efficacy, nasal pain, headache, epistaxis.

Rx only. Please see attached Full Prescribing Information for SINUVA also available at SINUVA.com/PI

DISCLAIMER

This is not a guarantee of payment, coverage, or reimbursement. Intersect ENT does not provide any advice, recommendation, guarantee, or warranty relating to coverage, reimbursement, or coding for any product or service. Healthcare providers are responsible for determining coverage and reimbursement information and ensuring the accuracy and completeness of claim submissions for their patients. Coding, coverage, and reimbursement vary significantly by payer, patient, and setting of care and are subject to change. Additional information may exist. Actual coverage and reimbursement decisions are made by individual payers. Healthcare providers are responsible for consulting payers' policies.