Medtronic

Engineering the extraordinary

Localized drug delivery Patient access resource

For PROPEL™ mometasone furoate sinus implants and SINUVA™ (mometasone furoate) sinus implant

October 2025

Document overview and resources

Overview

This document outlines resources available to support patient access to PROPEL™ mometasone furoate sinus implants and SINUVA™ (mometasone furoate) sinus implant localized drug delivery procedures. Click on the links below to access resources within this document as well as links to external resources.

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Reimbursement, coding, and billing resources

Contact us

Sample operative report instructions

This document is a sample operative report to assist providers with documentation supporting medical necessity for the PROPEL™ mometasone furoate sinus implants family of products. This sample must be customized to the patient. This sample is for your consideration only and may not include all the information necessary to support your request. The requesting provider is responsible for ensuring the accuracy and adequacy of all information provided. Use of this letter does not guarantee authorization or eventual payment.

- Please do not include this instruction page to avoid misinterpretation of your request as a form letter. It is recommended that providers use their business letterhead as appropriate.
- Please customize this sample using information pertinent to you, your patient, and their condition/procedure.
- This letter is not intended to replace any professional judgment; it is merely to assist with the documentation required to support medical necessity.
- Providers are encouraged to include their professional expertise and experience with this procedure.
- It is important to contact the patient's insurance for timeline(s), submission process, and requirements.

PROPEL™ mometasone furoate sinus implants sample operative report

IN-OFFICE PLACEMENT OF PROPEL **[Insert Type: Regular, Mini or Contour]** SINUS IMPLANT

NASAL ENDOSCOPY WITH PLACEMENT OF PROPEL **[Insert Type: Regular, Mini or Contour]** SINUS IMPLANT

After the decision is made to perform nasal endoscopy with placement of a PROPEL **[insert type]** sinus implant, the patient is moved to a room equipped with a video tower. A protective gown/drape is provided. The physician ensures that proper nasal endoscope, suction, and video recording equipment are available and working. After the procedure and all risks, benefits, and alternatives have been discussed with the patient in detail, informed consent was obtained. The patient is positioned in an upright, seated position. The physician washes hands and dons sterile gloves. Topical decongestant with Afrin (or equivalent) and local anesthesia using cotton pledgets soaked in lidocaine (or equivalent) are administered in the sinus cavity and sufficient time is allowed to ensure satisfactory local anesthesia.

The nasal cavity is examined to ensure that there is adequate patency. Additional anesthetic on pledgets is applied with endoscopic direction to specific areas requiring more profound anesthesia (eg, middle meatus) to allow full visualization of key areas. After waiting for the additional topical anesthetic to take effect, a systematic nasal endoscopy is performed of all related nasal and sinus structures. Images are captured on the digital system. Pledgets are repositioned and/or applied in any region of minor hemorrhage as needed. Hemostatic sponges or other packing materials are removed (if applicable). The cavity is suctioned of any blood and secretions so as to allow complete endoscopic visualization.

A surgical probe is used to assess proper implant sizing and patient tolerance (if applicable). The middle turbinate is medialized (if applicable and necessary). The cavity is then assessed endoscopically for the most appropriate implant placement. Using sterile technique, the implant is inspected, compressed (crimped) with a crimper provided with the delivery system, and inserted into the distal tip of the delivery system by the physician. The tip of the delivery system is then inserted in the patient's nostril and advanced to the sinus cavity under endoscopic visualization. The physician positions the distal tip of the delivery system in the desired location and depresses the plunger of the delivery system to insert the implant. Upon insertion, the implant is designed to exert sufficient radial force to be self-retaining against the mucosa of the surgically enlarged sinus cavity and conforms to that space. Endoscopic instruments (e.g. elevator, cups forceps, ball-tipped seeker or other appropriate instrumentation) are utilized to manipulate the implant into the final position. This requires positioning and re-positioning to ensure accurate placement and mucosal contact. The placement and the implant stability are confirmed under endoscopic visualization. The delivery system is then removed and discarded.

Aftercare treatment and findings are explained to the patient (often through the use of the procedure video and archived images), including specific instructions regarding care of the implant. The subsequent therapeutic plan is explained to the patient. Images are saved on the digital video system. A procedure note is dictated and findings are communicated to the relevant care providers.

PROPEL™ mometasone furoate sinus implants sample operative report

NASAL ENDOSCOPY WITH PLACEMENT OF PROPEL **[Insert Type: Regular, Mini, or Contour]** SINUS IMPLANT, WITH BIOPSY, POLYPECTOMY OR DEBRIDEMENT

After the decision is made for the need for nasal endoscopy, including placement of a PROPEL **[insert type]** sinus implant and debridement, polypectomy and/or biopsy, the patient is moved to a room equipped with the video tower and a protective drape is placed on the patient. Vital signs are obtained and the physician ensures that the endoscopes, suction, air source for insufflation, and video recording equipment are available and functioning properly. After the procedure and all risks, benefits, and alternatives have been discussed with the patient in detail, informed consent was obtained. The physician washes hands and dons proper gloves. The patient is positioned in an upright, seated position. Topical decongestant with Afrin (or equivalent) and local anesthesia using cotton pledgets soaked in lidocaine (or equivalent) are administered in the sinus cavity and sufficient time is allowed to ensure satisfactory local anesthesia.

A complete nasal endoscopy is performed using one or more telescopes. Polyps, polypoid tissue and devitalized tissue/bone are removed with thru-cutting instruments. Infected crusts are removed with grasping forceps. Inspissated mucus is cleared with straight and curved suctions. Hemostasis is achieved with application of cotton pledgets soaked with topical decongestant with appropriate wait time. Any residual bleeding sites are controlled with absorbable packing and/or cautery. Collection of tissue for biopsy may be performed. After removal of diseased and obstructive tissue, the cavity is prepared for placement of a PROPEL insert type sinus implant. Sufficient time is allowed to ensure there is no additional bleeding following the debridement/polypectomy/biopsy, which may require additional bipolar cauterization and/or use of hemostatic sponges or other materials. The hemostatic sponges or other packing materials are removed. The cavity is suctioned of any blood and secretions so as to allow complete endoscopic visualization. Additional anesthesia is applied as needed by the placement of cotton pledgets soaked with anesthestic and/or direct injection to the affected areas.

A surgical probe is used to assess proper implant sizing. The middle turbinate is medialized if necessary. The cavity is then assessed endoscopically for the most appropriate implant placement. Using sterile technique, the implant is visually inspected, prepared (which may requiring crimping) and inserted into the distal tip of the delivery system by the physician. The tip of the delivery system is then inserted in the patient's nostril and advanced to the sinus cavity under endoscopic visualization and deployed into the surgically-dissected cavity from posterior to anterior. Endoscopic instruments (e.g. elevator, cups forceps, ball-tipped seeker or other appropriate instrumentation) are utilized to manipulate the implant into the final position. This requires positioning and re-positioning to ensure accurate placement and mucosal contact in order to ensure appropriate delivery of the drug and bioabsorption of the implant. Implant placement and stability are confirmed under endoscopic visualization. The delivery system is then removed and discarded.

The patient is monitored during recovery period. Home restrictions (ie, diet, activity), treatment, and findings are explained to the patient using the procedure video recording and pointing out areas of normal anatomy and pathology. Subsequent evaluation and therapeutic plan are discussed. Additional patient instruction is provided to ensure appropriate care of the implant. Prescriptions are written for medications and supplies needed post discharge. Medication reconciliation is performed. The examination and any still images are saved on the digital recording system. The procedure note is dictated and findings communicated to the referring physician.

Sample letter instructions

This document is a sample letter of medical necessity to assist providers in obtaining approval for the PROPEL™ mometasone furoate sinus implants family of products and must be customized to the patient and payer. It is for your consideration and may not include all the information necessary to support your request. The requesting provider is responsible for ensuring the accuracy and adequacy of all information provided. Use of this letter does not guarantee authorization or eventual payment.

The provider has the responsibility to determine medical necessity and to submit appropriate codes and charges for the care provided. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other payers. Please contact your Medicare contractor, other payers, reimbursement specialists and/or legal counsel for interpretation of coding, coverage, and payment policies. This document provides assistance for FDA-approved or cleared indications.

Where coverage and reimbursement is sought for the use of a product that may be inconsistent with, or not expressly specified in, the FDA-cleared or approved labeling (e.g. instructions for use, operator's manual, or package insert), consult with your billing advisors or payers on handling such billing issues.

- Please do not include this instruction page to avoid misinterpretation of your prior authorization request as a form letter. It is recommended that providers use their business letterhead as appropriate.
- Please customize the sections in red italics using information pertinent to you, your patient, and their condition/procedure. The remaining letter content can also be edited.
- This letter is not intended to replace any professional judgment; it is merely to assist with the authorization request. Providers are encouraged to include their professional expertise and experience with this procedure.
- It is important to contact the patient's insurance for timeline(s), submission process, and requirements.

PROPEL™ mometasone furoate sinus implants sample letter of medical necessity

Provide the following information in the heading of the letter:
Date, Payer Name, Address and Phone Number, Patient Name, Policy Holder, ID#, Group #, Social Security or Patient Identification # and Date of Birth

Dear _____,

I am writing on behalf of my patient _____ to support the clinical use of PROPEL™ mometasone furoate sinus implants which I **[used/plan to use]** during a **[recent/upcoming]** sinus surgery procedure for treatment of **[insert diagnosis]**. This letter provides information about the patient's medical history and a statement summarizing my treatment rationale.

Patient's History and Diagnosis:

[Include information here regarding the patient's condition and specific diagnosis, including any medical history related to their condition. Include history and present illness.]

- Has the patient had prior sinus surgeries? If so, did the patient experience a lateralization of their middle turbinate, an occlusion of any of their sinuses, restenosis of their sinus, significant adhesions or scarring?
- Has the patient had clinically-significant post-surgical inflammation of their sinuses that would have been amenable to more effective INS delivery?
- Does the patient have polyposis? Is the patient compliant with their CRS-specific medical management but with limited or no efficacy?
- Are oral steroids medically contra-indicated or ineffective in this patient?
- Does the patient also have asthma, allergic rhinitis, aspirin allergy, Samter's Triad or any other co-diagnosis that would make CRS particularly refractory to medical management or less likely to have a successful ESS outcome?

Clinical Rationale:

My patient, _____ is an appropriate candidate for PROPEL™ sinus implants because **[insert a brief statement here as to why this patient will benefit from PROPEL. Include information on the treatment up to this point, course of care and why the PROPEL. is necessary and how you expect PROPEL. to help the patient].**

Achieving the best outcomes following sinus surgery is dependent upon managing post-operative inflammation. Physicians frequently use oral steroids to manage mucosal inflammation after sinus surgery, but oral systemic steroids suffer from poor delivery to the site of inflammation and numerous side effects. The PROPEL™ sinus implant is a first-of-its-kind product that provides controlled localized delivery of a steroid directly to the sinus cavity over 30 days while also providing mechanical support without obstructing the cavity.

PROPEL™ sinus implant with mometasone furoate was FDA-approved in 2011. The implant provides stabilization of the middle turbinate, prevents obstruction by adhesions, and reduces inflammation.

Safety and efficacy of the PROPEL™ sinus implants with mometasone furoate have been studied in multiple prospective clinical trials conducted in the United States.

Two of the randomized controlled trials of PROPEL™ sinus implant were combined in a meta-analysis, which

PROPEL™ mometasone furoate sinus implants sample letter of medical necessity

represents the only level 1a evidence available for any product used in sinus surgery. In the two randomized controlled studies, each treated side received PROPEL™ sinus implant, a steroid-coated sinus implant, while a visually identical stent without a steroid coating was inserted into the contralateral side. This intra-patient control design controlled for intra-patient variability of a disease with wide differences in clinical presentation. All patients received standard postoperative care since the intent of the PROPEL™ sinus implant studies was to evaluate whether the *addition* of local steroid delivery provided additional benefit compared to traditional post-operative care alone without local steroid delivery. As a result, the clinical benefits demonstrated are inarguably related to the local drug delivery afforded by PROPEL™ sinus implant and nothing else.

The clinical benefits of PROPEL™ sinus implants are summarized in the level 1-A meta-analysis reported by Han et. Al[1]. and include:

- 35% relative reduction in the need for medical/surgical intervention*
- 40% relative reduction in need for oral steroids*
- 70% relative reduction in significant adhesions*
- 46% relative reduction in frank polyposis*
- 75% relative reduction in middle turbinate lateralization*

These benefits are not only important for my patient clinically but can lead to significant cost savings for [**insert payor name**] as well.

The PROGRESS study evaluated the use of a PROPEL™ Contour sinus implant when placed in the frontal sinus opening following sinus surgery. This randomized controlled blinded study demonstrated statistically significant improvement in outcomes when added to standard postoperative care when compared to surgery with standard postoperative care alone. Two separate cohorts were created, one to evaluate use of PROPEL™ Mini sinus implants and one to evaluate use of PROPEL™ Contour sinus implants, both of which are coated with the same drug and dose but have different shapes to address various anatomy.

Outcomes from the PROPEL Mini cohort of the PROGRESS study include:

- 38% relative reduction in need for post-operative medical or surgical intervention (p=0.0070)*
- 54% relative reduction in frontal sinus restenosis/occlusion (p=0.0002)**
- 56% relative reduction in the need for oral steroids (p=0.0015)**
- 75% relative reduction in need post-operative surgical intervention (p=0.0225)**

Similarly, outcomes from the PROPEL Contour cohort of the PROGRESS study include:

- 65% relative reduction in need for post-operative medical or surgical intervention (p=0.0023)*
- 63% relative reduction in frontal sinus restenosis/occlusion (p=<0.0001)**2
- 73% relative reduction in need post-operative surgical intervention (p=0.0156)**[2]

Finally, the American Rhinologic Society (ARS) published a medical position statement endorsing the utilization of drug-eluting implants for patients undergoing sinus surgery as follows:

"The American Rhinologic Society endorses the utilization of drug-eluting implants into the sinus cavities. Results in sinus surgery are often dependent on proper healing of the sinus cavity and the reduction of inflammation. Furthermore, reduction of polyp burden and inflammation can result in a decrease in the use of oral medications as well as delaying the time until revision surgery. There have been a number of well-controlled studies on drug-eluting implants in the paranasal sinuses, specifically implants that release steroids to the local tissues. These studies have demonstrated improvement of patient outcomes by reducing inflammation, decreasing scarring and middle turbinate lateralization and limiting the need for

oral steroids.

The American Rhinologic Society thus feels strongly that drug-eluting implants are not investigational and should be available to our patients, when selected by the physician, in order to maximize outcomes."

Similarly, the American Academy of Otolaryngology–Head and Neck Surgery (AAOHNS) published a medical position statement of FDA approved biomaterials to improve patient outcomes and reduce complications as follows:

"The American Academy of Otolaryngology–Head and Neck Surgery has determined that the use of FDA-approved biomaterials can be utilized in sinonasal procedures to improve patient outcomes and reduce complications. These items, such as implants, stents, and packing materials, have functions including, but not limited to, local drug delivery, stenting, and hemostasis. FDA-approved biomaterials for rhinologic application are not investigational, and the final decision regarding use of these biomaterials should be determined by the treating physician, factoring in best available scientific evidence, surgeon experience and the clinical situation, and individual patient preference."

Summary:

In summary, in order to provide improved care in a more cost effective way[3], i.e., reducing the need for post-operative interventions, I request your approval to use PROPEL™ sinus implant in the management of my sinus patient following sinus surgery. I have extensive experience using PROPEL™ sinus implants and have been very impressed with the clinical outcomes associated with its use. The PROPEL™ sinus implant is medically necessary for this patient's condition. I request a specialty matched, board certified Otolaryngologist, who can review the current peer reviewed literature, specialty society opinions, and is able to assess the clinical facts regarding this patient's situation and render an independent decision. Please contact me if any additional information is required to ensure the prompt approval of the PROPEL™ sinus implant for this patient.

Respectfully,
_____, MD

*Based on Independent Panel at Day 30
**Based on Clinical Investigator at Day 30

1. Han, et al. Int Forum Allergy Rhinol. 2012; 2:271–279
2. Secondary endpoints judged by clinical investigators. P-values for secondary efficacy endpoints were adjusted for multiplicity.
3. Rudmik L and Smith TL. Economic evaluation of a steroid-eluting sinus implant following endoscopic sinus surgery for chronic rhinosinusitis. Otolaryngoly Head Neck Surg. 2014; 151(2):359-366.

Sample letter instructions

This document is a sample letter of medical necessity to assist providers in obtaining approval for the SINUVA™ (mometasone furoate) sinus implant and must be customized to the patient and payer. It is for your consideration and may not include all the information necessary to support your request. The requesting provider is responsible for ensuring the accuracy and adequacy of all information provided. Use of this letter does not guarantee authorization or eventual payment.

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Where coverage and reimbursement is sought for the use of a product that may be inconsistent with, or not expressly specified in, the FDA-cleared or approved labeling (e.g. instructions for use, operator's manual, or package insert), consult with your billing advisors or payers on handling such billing issues.

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SINUVA™ (mometasone furoate) sinus implant sample letter of medical necessity

Provide the following information in the heading of the letter:
Date, Payer Name, Address and Phone Number, Patient Name, Policy Holder, ID#, Group #, Social Security or Patient Identification # and Date of Birth

Dear _____,

I am writing on behalf of my patient **[insert patient name]** to support the clinical use of the SINUVA™ (mometasone furoate) sinus implant which I **[used/plan to use]** during a **[recent/upcoming]** office visit for treatment of [insert diagnosis]. This letter provides information about the patient's medical history and a statement summarizing my treatment rationale.

Patient's Medical History and Diagnosis:

[Include information here regarding the patient's condition and specific diagnosis, including any medical history related to their condition. Include history and present illness.]

- Does the patient currently have nasal polyps? What prior treatments have they tried/failed for their nasal polyps?
- The patient had ethmoid sinus surgery and what was the outcome? Has patient had multiple ethmoid sinus surgeries?
- Is the patient compliant with their medical therapy?
- Are oral steroids medically contra-indicated or ineffective in this patient?
- Does the patient also have asthma, allergic rhinitis, aspirin allergy, Samter's Triad or any other co-diagnosis that would make CRS particularly refractory to medical management or less likely to have a successful ESS outcome?

Clinical Rationale:

My patient, **[insert patient name]** is an appropriate candidate for the SINUVA (mometasone furoate) sinus implant because **[Insert a brief statement here as to why this patient will benefit from SINUVA. Include information on the treatment up to this point, course of care and why SINUVA is necessary and how you expect SINUVA to help the patient]**.

Topical therapies such as intranasal steroid sprays, or nasal rinses are used to treat nasal polyps, but the efficacy of the topical treatment is reduced due to poor patient compliance[1] or inability of the medication to reach the sinus cavity.[2,3] Systemic steroids are prescribed to those patients who do not respond to topical therapies. The effect of systemic therapy is short lived and has numerous adverse reactions.[4] Those patients who do not respond to maximum medical therapy typically require sinus surgery to relieve their symptoms.[5] Recurrence of nasal polyps after sinus surgery is common.[6]

SINUVA™ sinus implant is placed in the ethmoid sinus, directly in contact with nasal polyps, and provides sustained, localized delivery of steroid over 90 days. One SINUVA™ sinus implant contains 1350 mcg of mometasone furoate.

SINUVA™ sinus implant was approved by the FDA in December, 2017. The efficacy of the SINUVA™ sinus implant was supported by Study 2, a randomized, controlled, double-blind, multicenter, US-based study with 300 patients: 201 patients were assigned to the treatment group and underwent bilateral placement of the SINUVA sinus implant in the ethmoid sinuses in the office setting. The remaining 99 patients were assigned to the control group and underwent a placebo (sham) procedure. All patients [treatment (T) and

control (C) groups] were required to use 200 mcg of mometasone furoate nasal spray once daily through day 90. The safety of the SINUVA™ sinus implant is based on the combined data from Study 1 and Study 2 (N= 400).[7]

The study population consisted of adult patients (≥ 18 years of age) diagnosed with CRS who had undergone previous total bilateral ethmoidectomy. These patients were indicated for revision endoscopic sinus surgery because they presented with recurrent nasal obstruction/congestion symptoms and recurrent nasal polyps despite the use of intranasal steroid sprays and recent high dose steroid treatment.

Both co-primary endpoints in Study 2 met statistical significance:

- Change from baseline to day 30 in **nasal obstruction/congestion score**, as determined by patients using a daily diary [Difference (SD) T vs. C: -0.23 (-0.39, -0.06), p=0.0074]
- Change from baseline to day 90 in **bilateral polyp grade**, as determined by an independent panel of 3 sinus surgeons who were masked to treatment assignment [Difference (SD) T vs. C: -0.35 (-0.60, -0.09), p=0.0073]

Percent ethmoid sinus obstruction (100 mm VAS) was a prespecified secondary efficacy endpoint adjusted for multiplicity and was judged by the independent panel [Difference (SD) T vs. C: -7.96 (−12.10, −3.83) p=0.004], This secondary endpoint is included in the SINUVA Prescribing Information.

Other prespecified secondary endpoints[7] that showed statistically significant improvements from baseline to 90 days were[8]:

- **Proportion of patients still indicated for repeat sinus surgery** [T 39% vs C 63.3%, p=0.0004]
- **Nasal obstruction/congestion score** [Difference (SD) T vs. C: −0.27 (−0.48, −0.07), p=0.0248]
- **Decreased sense of smell score** [Difference (SD) T vs. C: −0.46 (−0.85 −0.06), p=0.0470]

Prespecified secondary endpoints were adjusted for multiplicity.

Facial pain/pressure score secondary endpoint did not meet statistical significance [Difference (SD) T vs. C: 0.01 (-0.25, 0.27), p=0.9130]

Per the SINUVA Prescribing Information, safety data was evaluated in 400 patients in Study 1 and Study 2. The following common adverse events (in greater than 1% of subjects) occurred more frequently in patients with SINUVA compared to those with mometasone furoate alone: asthma, headache, epistaxis, pre-syncope, bronchitis, otitis media, and nasopharyngitis. Study 1 monitored patients from Day 90 through 6 months. Hypersensitivity (4% (n=2) vs. 0), chronic sinusitis (11% (n=6) vs. 9% (n=4)), and upper respiratory tract infections (8% (n=4) vs. 2% (n=1)) were reported in more than 2 subjects in the treatment group, and more commonly than the control group during this time-period.

The safety of repeat administration of the SINUVA sinus implant was evaluated in Study 3 that was an open-label, single-arm, multicenter study in 50 patients. All patients underwent an in- office bilateral placement of the SINUVA sinus implant in each ethmoid sinus (totaling 2 implants) and were followed for 365 days. Patients were required to use mometasone furoate nasal spray once daily (200 mcg of mometasone furoate) through 365 days. At 90 days, the remaining implants were removed. To maximize the size of the safety population, patients with ethmoid sinus polyps grade ≥ 1 on any side were considered for repeat implant placement. Acute sinusitis (29%, n=12), upper respiratory infection (17%, n=7) epistaxis (12%, n=5), nasal discomfort or rhinalgia (12%, n=5), headache (7%, n=3), were the common adverse reactions that occurred in at least 3 subjects who underwent repeat placement during the study period.

Summary:
In summary, in order to provide improved care in a more cost effective way by reducing the need for

SINUVA™ (mometasone furoate) sinus implant sample letter of medical necessity

repeat sinus surgery for nasal polyps, I request your approval to use the SINUVA™ sinus implant in the management of my patient with nasal polyps. The SINUVA™ sinus implant is medically necessary for this patient's condition. I request a specialty matched, board certified Otolaryngologist, who can review the current peer reviewed literature, specialty society opinions, and is able to assess the clinical facts regarding this patient's situation and render an independent decision. Please contact me if any additional information is required to ensure the prompt approval of the SINUVA™ sinus implant for this patient.

Respectfully,
_____, MD

1. Loh CY, Chao SS, Chan YH. A clinical survey on compliance in the treatment of rhinitis using nasal steroids. Allergy. 2004 Nov;59(11):1168-72.
2. Aggarwal R, Cardozo A, Homer JJ. The Assessment of Topical Nasal Drug Distribution. Clin Otolaryngol Allied Sci. 2004 Jun;29(3):201-5.
3. Lipworth BJ, Jackson CM. Safety of inhaled and intranasal corticosteroids: lessons for the new millennium. Drug safety. 2000;23(1):11-33.
4. Howard BE, Lal D. Oral steroid therapy in chronic rhinosinusitis with and without nasal polyposis. Curr Allergy Asthma Rep. 2013;13(2):236-4
5. Philpott C, Hopkins C, Erskine S, Kumar N, Robertson A, Farboud A, et al. The burden of revision sinonasal surgery in the UK-data from the Chronic Rhinosinusitis Epidemiology Study (CRES): a cross-sectional study. BMJ Open. 2015;5(4):e006680
6. DeConde AS, Mace JC, Levy JM, Rudmik L, Alt JA, Smith TL. Prevalence of polyp recurrence after endoscopic sinus surgery for chronic rhinosinusitis with nasal polyposis. Laryngoscope. 2016;127(3):550-5.
7. SINUVA- Prescribing information Jan 2023.
8. Kern RC, Stolovitzky JP, Silvers SL, et al. A phase 3 trial of mometasone furoate sinus implants for chronic sinusitis with recurrent nasal polyps. Int Forum Allergy Rhinol. 2018;XX:1–11 (ePub 1/19/2018).

SINUVA™ (mometasone furoate) sinus implant sample letter of appeal

Provide the following information in the heading of the letter:
Date, Payer Name, Address and Phone Number, Patient Name, Policy Holder, ID#, Group #, Social Security or Patient Identification # and Date of Birth

Dear _____,

This letter is regarding your denial for **[select prior authorization/pre-determination or payment]** of benefits for the use of SINUVA™ (mometasone furoate) sinus implant(s) for the above referenced patient. According to the denial letter dated **[XX/XX/XX]**, this product has been denied for payment because it has been deemed **[insert reason for denial]**.

SINUVA™ sinus implant is regulated by the FDA as a drug, which is indicated for adult patients with chronic rhinosinusitis with nasal polyps (CRSwNP) who have had prior ethmoid sinus surgery. SINUVA is considered an alternative to surgery for these patients.

My patient, **[insert patient name]** is an appropriate candidate for SINUVA™ sinus implant(s) and their only other option at this time is to undergo repeat sinus surgery, which may be associated with complications and is more costly to both the patient and **[insert payor name]**. [**Insert patient name]** is an appropriate candidate because: **[insert a brief statement here for this patient in particular – include history of present illness, past surgeries, failed medical therapies, current symptoms and activity limitations. If post-SINUVA denial, describe the benefits of SINUVA in this patient]**.

I am writing to appeal this denial to a higher level of review and to address several misconceptions that may have formed the basis for this coverage decision.

My primary goal of treating patients with nasal polyps is to reduce the size of the polyps to help improve symptoms of nasal obstruction/congestion without surgery. Standard of care for CRSwNP includes intranasal and systemic corticosteroids.[1] The majority of topical drug delivered via these nasal sprays is deposited in the anterior nasal passage and oropharynx, leaving a relatively small amount to reach the sinus cavity.[2] Oral corticosteroid administration has shown to improve symptoms; however, the duration of improvement is short term and is associated with side effects such as gastrointestinal bleeding, transient adrenal suppression, insomnia and increased bone turnover.[3]

Patients with nasal polyps whose symptoms persist despite medical therapy are typically referred for endoscopic sinus surgery and are twice as likely to require revision surgery.[4] While surgery is effective, polyp recurrence is common after surgery. In a study by DeConde et.al, the recurrence of nasal polyps was reported as 35% 6 months after surgery, 38% after 12 months and 40% after 18 months.[5]

SINUVA™ sinus implant is a bioabsorbable corticosteroid-eluting (mometasone furoate) implant delivered in the ethmoid sinus under endoscopic visualization during an office visit. It is placed in the ethmoid sinus to gradually release 1350 mcg of mometasone furoate over 90 days. The implant is removed by day 90, or earlier, per physician discretion.

SINUVA™ sinus implant is FDA-approved for the treatment of CRSwNP in patients ≥ 18 years of age who have had ethmoid sinus surgery. The efficacy of the SINUVA™ sinus implant was evaluated in 300 patients, 18 years of age and older, with nasal polyps and history of total bilateral ethmoidectomy. SINUVA's safety profile is based upon the combination of 2 clinical studies totaling 400 patients.

SINUVA™ (mometasone furoate) sinus implant sample letter of appeal

EFFICACY:

The **efficacy** of the SINUVA™ sinus implant is based on **Study 2**, which was a randomized, controlled, single-blind, multicenter US-based study with 300 patients: 201 patients were assigned to the treatment group and underwent bilateral placement of the SINUVA sinus implants in the ethmoid sinuses. The remaining 99 patients were assigned to the control group and underwent a placebo (sham) procedure. All patients [treatment (**T**) and control (**C**) groups] were required to use 200 mcg of mometasone furoate nasal spray once daily through day 90. The **safety** of SINUVA is based on the combined data from Study 1 and Study 2.[6]

The **study population** consisted of adult patients (≥ 18 years of age) diagnosed with chronic sinusitis who had undergone previous total bilateral ethmoidectomy. These patients were indicated for revision endoscopic sinus surgery because they presented with recurrent nasal obstruction/ congestion symptoms (patient-reported) and nasal polyps (confirmed by independent panel) despite the use of intranasal steroid sprays and a recent high dose steroid treatment.

The results of the study showed significant improvement in both co-primary endpoints:

- Change from baseline to day 30 in nasal obstruction/congestion score on a 4-point scale of 0 (no symptoms) to 3 (severe) scale, as determined by patients using a daily diary [Difference (SD) T vs. C: -0.23, (-0.39, -0.06), p=0.0074]
- Change from baseline to day 90 in bilateral polyp grade on an 8-point scale that represented a sum of 0 (no polyp) to 4 (totally obstructing nasal passage) on each side, as determined by an independent panel of 3 sinus surgeons who were masked to treatment assignment [Difference (SD) T vs. C: -0.35, (-0.60, -0.09), p=0.0073]

Percent ethmoid sinus obstruction (100 mm VAS) was a prespecified secondary efficacy endpoint adjusted for multiplicity and was judged by the independent panel [Difference (SD) T vs. C: -7.96 (−12.10, −3.83) p=0.0007] This secondary endpoint is included in the SINUVA Prescribing Information.

Other prespecified secondary endpoints[7] that showed statistically significant improvements from baseline to 90 days were:

- **Proportion of patients still indicated for repeat sinus surgery** [T 39% vs C 63.3%, p=0.0004]
- **Nasal obstruction/congestion score** [Difference (SD) T vs. C: −0.27 (−0.48, −0.07), p=0.0248]
- **Decreased sense of smell score** [Difference (SD) T vs. C: −0.46 (−0.85 −0.06), p=0.0470]

Prespecified secondary endpoints were adjusted for multiplicity.

Facial pain/pressure score secondary endpoint did not meet statistical significance [Difference (SD) T vs. C: 0.01 (-0.25, 0.27), p=0.9130]

The results of the analysis showed significantly more patients receiving SINUVA than sham experienced clinically meaningful improvement in nasal obstruction/congestion score and bilateral polyp grade.[7]

- Change from baseline to day 30 in nasal obstruction/congestion score by ≥ 0.5-point: [T vs C: 62.8%vs 50.5%, p=0.044], and ≥ 1.0-point score [T vs C: 44.2% vs 25.8% p=0.0022]
- Change in bilateral grade from baseline to day 90 in polyp grade by clinical investigators by ≥ 1.0-point [T vs C: 72% vs 36.7%, p=<0.0001] and ≥ 2.0-point [T vs C: 47.5% vs 16.3%, p=<0.0001] as judged by clinical investigators

SAFETY:

SINUVA™ (mometasone furoate) sinus implant sample letter of appeal

The safety data was evaluated in the 400 patients from Study 1 and Study 2. The following common AEs (in greater than 1% of subjects) occurred more frequently in patients with SINUVA compared to those with mometasone furoate alone include asthma, headache, epistaxis, pre-syncope, bronchitis, otitis media, and nasopharyngitis. Study 1 monitored patients from Day 90 through 6 months. Hypersensitivity (4% (n=2) vs. 0), chronic sinusitis (11% (n=6) vs. 9% (n=4)), and upper respiratory tract infections (8% (n=4) vs. 2% (n=1)) were reported in more than 2 subjects in the treatment group, and more commonly than the control group during this time-period.7 There were no drug related adverse events, 2.5% device related adverse events and 4% implant procedure related adverse events.[7]

One pharmacokinetics study was conducted with SINUVA to evaluate the potential for systemic exposure to mometasone furoate from the sinonasal route of administration following bilateral placement of SINUVA.6 The results of the study showed that six out of fifteen PK samples from five subjects had measurable mometasone furoate plasma concentrations from Day 3 to Day 14. All measurable concentrations were within 2.5-fold of the lower limit of quantification. No PK samples had measurable mometasone furoate plasma concentrations after Day 14.

In summary, the benefits of improvement of symptoms of nasal obstruction/congestion and bilateral polyp grade, along with reduction in the need for repeat endoscopic sinus surgery are not only important for **[insert patient name]** clinically but may lead to significant cost savings for **[insert payor name]** as well.

For these reasons, I do not agree with your assessment that the SINUVA™ sinus implant is considered investigational, which implies a lack of evidence to support its value. Further, if not approved, the only other alternative for this patient is surgery, which will create a professional dilemma for me to recommend when I have full knowledge that a less invasive alternative exists with fewer risks. Therefore, my justification for subjecting my patient to this option will be solely based on this denial of coverage.

I respectfully recommend your re-assessment of the medical policy, as well as your re-consideration of this request for coverage/payment of SINUVA™ sinus implant(s) for my patient. Thank you in advance for your thorough review of this information.

Respectfully,
_____, MD

1. Orlandi RR, Kingdom TT, Hwang PH, Smith TL, Alt JA, Baroody FM, et al. International Consensus Statement on Allergy and Rhinology: Rhinosinusitis. International forum of allergy & rhinology. 2016;6 Suppl 1:S22-S209.
2. 2Lipworth BJ, Jackson CM. Safety of inhaled and intranasal corticosteroids: lessons for the new millennium. Drug safety. 2000;23(1):11-33.
3. Howard BE, Lal D. Oral steroid therapy in chronic rhinosinusitis with and without nasal polyposis. Curr Allergy Asthma Rep. 2013;13(2):236-43.
4. Philpott C, Hopkins C, Erskine S, Kumar N, Robertson A, Farboud A, et al. The burden of revision sinonasal surgery in the UK-data from the Chronic Rhinosinusitis Epidemiology Study (CRES): a cross-sectional study. BMJ Open. 2015;5(4):e006680.
5. DeConde AS, Mace JC, Levy JM, Rudmik L, Alt JA, Smith TL. Prevalence of polyp recurrence after endoscopic sinus surgery for chronic rhinosinusitis with nasal polyposis. Laryngoscope. 2016;127(3):550-5.
6. SINUVA- Prescribing information Jan. 2023. Click here to view
7. Kern RC, Stolovitzky JP, Silvers SL, et al. 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. (ePub 1/19/2018).

SINUVA™ (mometasone furoate) sinus implant acquisition pathways

SINUVA™ (mometasone furoate) sinus implant may be obtained for physician office use through two pathways which depend on how a patients individual insurance covers the drug. The first is through the pharmacy benefit, handled by a specialty pharmacy. The second is through the medical benefit, managed by a specialty distributor.

1

Specialty Pharmacy via Pharmacy Benefit:

When SINUVA™ sinus implant is covered under a patients pharmacy benefit, the case will be directed to Gentry Specialty Pharmacy, which can be reached at 844-443-6879. Gentry will handle its own benefit verification. Once SINUVA™ sinus implant is ready for shipment, the patient will receive a call from the specialty pharmacy via an 800 number to collect any patient responsibility before shipping. After payment is collected, the specialty pharmacy will contact the physician's office to confirm the address and arrange shipment to the office.

2

Specialty Distributor via Medical Benefit:

When SINUVA™ sinus implant is covered under a patients medical benefit, the physician's office can choose from three Medtronic-partnered distributors: McKesson, Cencora, and ASD Healthcare. (Note: ASD Healthcare is a division of Cencora, previously part of AmerisourceBergen.)

ASD Healthcare	Cencora	McKesson
800-746-6273 service@asdhealthcare.com	800-543-2111	855-571-2100
Item #: 10246393 https://abcorder.amerisourcebergen.com	Item # 10240233	Item # 1181728 https://mms.mckesson.com/
For support with access/logins, please contact: customersystems@amerisourcebergen.com		New customer account setup: https://mms.mckesson.com/portal/customer-setup-contact

Additional resources

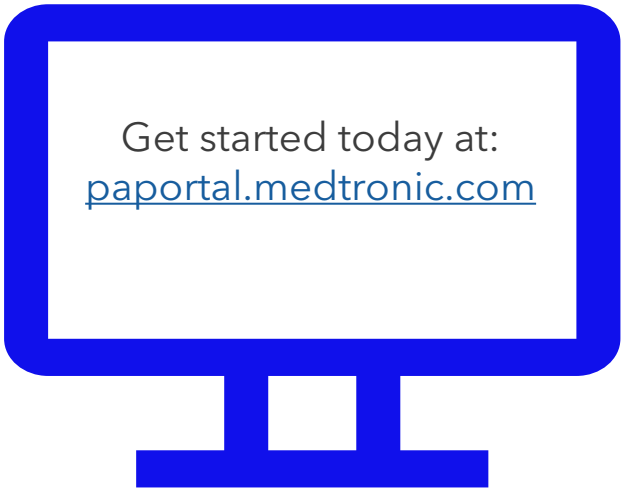
Patient Access Support (PAS)

Patient Access Support (PAS) is available to facilitate patient access to Medtronic's PROPEL™ mometasone furoate sinus implants and SINUVA™ (mometasone furoate) sinus implant products by providing HCPs who request PAS on behalf of their patients with assistance in obtaining patient coverage decisions from payers.

Patient Access Connect (PAC)

The Medtronic Patient Access Connect (PAC) is a digital solution for streamlining the prior authorization process so patients can access PROPEL™ mometasone furoate sinus implants and SINUVA™ (mometasone furoate) sinus implant products more efficiently.

- Simple submissions: Leverage an intuitive, user-friendly interface.
- Real-time case tracking: Monitor progress of submissions in real time.
- Automated notifications: Receive instant updates and notifications for case statuses.
- Centralized case access: Access prior authorization records from one convenient location.
- Data insights: Gain insights into submission trends and approval rates.



Additional resources

Reimbursement, coding, and billing resources

Click here to access our ENT Office HUB page, which provides resources specific to procedures done in the office site of care.

Click here for access to Commonly Billed Coding Guides for ENT Procedures.

Contact us

The Health Economics Manager (HEM) team is a diverse group that works closely with sales, customers, commercial and government payers with the goal of improving access to patients for our therapies.

For additional information, contact your local Medtronic HEM Reimbursement Support team member:

Email: ent.us.reimbursement@medtronic.com

IMPORTANT SAFETY INFORMATION

About SINUVA™ (mometasone furoate) sinus implant

INDICATION

SINUVA sinus implant is a corticosteroid-eluting implant indicated for the treatment of chronic rhinosinusitis with nasal polyps in adult patients ≥ 18 years of age who have had ethmoid sinus surgery.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Patients with known hypersensitivity to mometasone furoate and any of the ingredients of the SINUVA sinus implant.

WARNINGS AND PRECAUTIONS

Local Nasal Adverse Reactions: 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.

Glaucoma and Cataracts: Nasal steroids may result in development of glaucoma and/or cataracts. 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 the use of corticosteroids. Immunosuppression and Risk of Infections: Persons who are using drugs that suppress the immune system, such as corticosteroids, including SINUVA sinus implant are more susceptible to infections than healthy individuals. The safety and effectiveness of SINUVA sinus implant have not been established in pediatric patients less than 18 years of age and SINUVA is not indicated for use in this population. 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) 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 Full Prescribing Information for SINUVA available at SINUVA.com/hcp.

About PROPEL™ mometasone furoate sinus implants

Indications, contraindications, and precautions

The PROPEL™ sinus implants are intended to maintain patency and locally deliver steroid to the sinus mucosa in patients ≥18 years of age following sinus surgery: PROPEL™ for the ethmoid sinus, PROPEL™ Mini for the ethmoid sinus/frontal sinus opening, and PROPEL™ Contour for the frontal/maxillary sinus ostia. Contraindications include patients with confirmed hypersensitivity or intolerance to mometasone furoate (MF) or hypersensitivity to bioabsorbable polymers. Safety and effectiveness of the implant in pregnant or nursing females have not been studied. Risks may include, but are not limited to, pain/pressure, displacement of the implant, possible side effects of intranasal MF, sinusitis, epistaxis, and infection. For full prescribing information see IFU at http://www.manuals.medtronic.com. Rx only.