Drug-eluting sinus implants

Clinical Policy ID: CCP.1310

Recent review date: 7/2025

Next review date: 11/2026

Policy contains: Drug-eluting sinus implants; chronic sinusitis; Propel; Sinuva.

FirstChoice VIP Care has developed clinical policies to assist with making coverage determinations. FirstChoice VIP Care's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered, on a case by case basis, by FirstChoice VIP Care when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. FirstChoice VIP Care's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. FirstChoice VIP Care's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, FirstChoice VIP Care will update its clinical policies as necessary. FirstChoice VIP Care's clinical policies are not guarantees of payment.

Coverage policy

Drug-eluting sinus implants following endoscopic sinus surgery for chronic rhinosinusitis are clinically proven and, therefore, may be medically necessary for treating mucosal inflammation of the paranasal sinus when all of the following criteria are met (American Academy of Otolaryngology-Head and Neck Surgery, 2023; American Rhinologic Society, 2023; Calvo-Henriquez, 2024):

- Member is 18 years of age or older.
- Member is a candidate for revision endoscopic sinus surgery.
- Member has persistent nasal obstruction/congestion despite use of intranasal steroid irrigations or sprays.
- Member has no contraindications to drug-eluting sinus implants.

For any determinations of medical necessity for medications, refer to the applicable state-approved pharmacy policy.

Limitations

All other uses of drug-eluting sinus implants, including repeat stent implantation, are investigational/not clinically proven and, therefore, not medically necessary.

Contraindications to drug-eluting sinus implants include (Marple, 2012; Murr, 2011):

- Insulin dependent diabetes.
- Oral steroid dependent condition.
- Glaucoma, ocular hypertension, or posterior subcapsular cataracts.
- Middle turbinate resection.
- Clinical evidence of acute bacterial sinusitis or invasive fungal sinusitis.
- Allergy or intolerance to corticosteroids.

Alternative covered services

Foam dressings, nasal packing, meatal spacers, and medicinal treatments to relieve mucosa edema and promote wound healing after endoscopic sinus surgery.

Background

Chronic rhinosinusitis is an inflammation of the nasal and paranasal sinus mucosa. Medical treatments (topical or oral steroids) offer relief to many persons with the condition, but some cases require surgery. Functional endoscopic sinus surgery may be performed to remove bone or polyps and to debride tissue within the sinus cavity. Post-operative inflammation, formation of polyps, and adhesions of the nasal mucous lining may require treatment to decrease edema of the mucosa and hasten wound healing and restore sinus ventilation and drainage (Huang, 2015).

Topical and systemic corticosteroids remain the standard medical treatment for reducing post-operative inflammation and the consequent risk of polyp formation and nasal obstruction. Topical intranasal corticosteroid sprays have been associated with poor efficacy and patient compliance, while systemic corticosteroids are limited by transient efficacy and dose-dependent side effects.

Drug-eluting stents or implants have been developed to overcome these limitations. Drug-eluting implants are surgically inserted scaffolds that provide continuous, controlled release of a corticosteroid. Some are made of a biodegradable material that is absorbed by the body (Huang, 2015).

The U.S. Food and Drug Administration approved the first bioabsorbable drug-eluting sinus stent, PROPEL (Intersect ENT, Inc., Palo Alto, California), in 2011 for use following ethmoid sinus surgery to maintain patency. PROPEL is a bioabsorbable scaffold that expands in a spring-like fashion to conform to the walls of a dissected ethmoid cavity. Mometasone furoate (370 µg) is released gradually over a 30-day period, directly into the sinus cavity. PROPEL works by separating mucosal tissues, stabilizing the middle turbinate, preventing obstruction by adhesions, and reducing edema, thereby reducing the need for post-operative intervention. Approval for a smaller version, the PROPEL Mini, followed on September 21, 2012. PROPEL Contour received approval on February 23, 2017 as an adjunct to frontal and maxillary sinus surgery. All three are indicated for persons age 18 or over (U.S. Food and Drug Administration, 2025).

The Sinuva Sinus Implant (Intersect ENT, Inc., Menlo Park, CA), initially approved in 1987, was approved with a new dose (1,350 µg mometasone furoate) in 2017 under a New Drug Application (NDA 209310) for the treatment of nasal polyps in patients at least 18 years of age following ethmoid sinus surgery. The corticosteroid is released over 90 days during which time the bioabsorbable implant softens, but then must be surgically removed (U.S. Food and Drug Administration, 2017).

Related instruments include the Stratus MicroFlow Spacer (Acclarent, Irvine, CA), and the Sinu-Foam Spacer. The Relieva Stratus MicroFlow Spacer was approved only for use with saline solution, and was withdrawn from

market in May, 2013. Off-label use of the Sinu-Foam Spacer has yet to demonstrate improvement in endoscopic outcomes (Parikh, 2014).

Findings

Guidelines

The American Rhinologic Society (2023) endorsed drug-eluting sinus implants based on studies demonstrating improved patient outcomes by reducing inflammation, decreasing scarring and middle turbinate lateralization, limiting the need for oral steroids, and potentially delaying the need for revision surgery.

The American Academy of Otolaryngology-Head and Neck Surgery (2023) considers drug-eluting implants in the paranasal sinuses proven and effective therapeutic options for mucosal inflammation based on results suggesting the efficacy and safety of drug-eluting implants in controlling sinonasal inflammation after sinus surgery. A consensus statement by the Academy on the treatment of pediatric rhinosinusitis did not address drug-eluting sinus implants after surgery; these devices are not approved for persons under age 18 (Brietzke, 2014).

Evidence reviews

Trial results of the PROPEL and Sinuva devices have appeared in some peer-reviewed articles, but studies to date are relatively few. The available randomized controlled trials are well-designed, but with small and heterogeneous samples and short follow-up periods. All studies were industry-sponsored, and the presence of publication bias cannot be assessed.

The evidence suggests drug-eluting sinus implants are safe for patients with chronic rhinosinusitis who are candidates for repeat endoscopic sinus surgery. Compared to non-drug-eluting stents or mometasone furoate nasal spray alone, drug-eluting sinus implants may offer superior short-term efficacy in terms of the reduced postoperative intervention, inflammation, polyp formation, adhesion formation, and oral steroid use at day 90 following implantation. Objective systematic reviews stress the need for independent study with longer-term follow up to confirm these findings and other patient-reported outcomes, and to identify the optimal treatment regimen and candidate.

In the ADVANCE trial (Forwith, 2011), which was the basis for regulatory approval of PROPEL, 90 participants were given PROPEL after endoscopic sinus surgery and followed for one month. Subjects had a low prevalence of polypoid edema (10.0%), significant adhesions (1.1%), and middle turbinate lateralization (4.4%), indicating the implant was safe and effective. This finding corroborated results of a study of 86 sinuses published several months earlier (Murr, 2011). The ADVANCE II trial included participants with 210 sinuses given PROPEL, compared to sinuses given implants that did not release drugs; significant decreases in post-operative infections, lysis of adhesions, and frank polyposis were observed in the drug group (Marple, 2012).

A Cochrane review (Huang, 2015) was unable to identify any randomized controlled trials that met their inclusion criteria. Only 21 of 159 trials met some of the criteria. Thus, the authors could not assess the technology, and concluded that well-structured randomized controlled trials are needed to assess any potential benefits.

A systematic review (Rizan, 2016) identified seven studies, including five randomized controlled trials, that followed patients from two to six months after steroid-eluting intranasal devices. Six of the seven studies demonstrated effectiveness in reducing adhesion formation, polyp formation, inflammation, Lund-Kennedy scores, and perioperative sinus endoscopy scores. The authors concluded that data on this procedure were limited, and that further studies are needed to optimize dosing regimens, compare devices, and provide long-term outcomes.

A meta-analysis of seven studies (n = 888) compared steroid-eluting stents, including PROPEL Mini and Contour and Sinuva, and controls after endoscopic surgery for chronic rhinosinusitis. Results showed superior results for stents in postoperative need for intervention ($P < .001$), surgery ($P < .001$), and oral steroid use ($P < .004$), along with frontal sinus ostia patency ($P < .001$), moderate-to-severe adhesion/scarring ($P < .002$), and increase in polyp score ($P = .002$). Authors note all studies were industry-sponsored, and publication bias could not be ruled out. Other study limitations included heterogeneous patient populations and outcome measures, as well as short follow-up durations, and further independent evaluations were warranted (Goshtasbi, 2019).

In 2022, we added data on the Sinuva implant to the policy. Two studies published after the Goshtasbi (2019) review period confirmed the safety and short-term efficacy of the Sinuva implant in patients diagnosed with refractory chronic rhinosinusitis with nasal polyps who were candidates for repeat endoscopic sinus surgery, using data from the RESOLVE trials (Kern, 2018; Stolovitzky, 2019). Stolovitzky (2019) also found patients without asthma ($P = .0218$) and with only one prior endoscopic sinus surgery ($P = .0142$) achieved the largest treatment effect on nasal obstruction/congestion scores. Those with recent surgery less than 24 months prior and a bilateral polyp grade > 5 showed the largest effect on both endoscopic endpoints and the continued need for revision endoscopic sinus surgery.

From 2011 to 2020, 22 patient-related adverse events and six device-related events were reported to the U.S. Food and Drug Administration Manufacturer and User Facility Device Experience database, and all related to the PROPEL implants. The most common complications were postoperative infection (39%, including four cases of periorbital cellulitis and five cases of fungal infection) and stent migration (21%). Eight patients (29%) required reintervention and device removal (Narwani, 2022).

An independent randomized controlled trial (n = 40) found no significant improvement in postoperative outcomes (followed for up to three months) with PROPEL when compared to nonabsorbable Merocel packs (Rawl, 2020). The new findings confirm the need for additional independent research to determine the relative effectiveness of drug-eluting sinus stents. No policy changes are warranted.

In 2023, we identified no newly published, relevant research to add to the policy but added a new position statement from the American Academy of Otolaryngology-Head and Neck Surgery. No policy changes are warranted.

In 2024, we updated the American Rhinologic Society consensus statement and added findings of a systematic review. We changed the policy to medically necessary based on guideline recommendations and the new systematic review findings presented below.

A systematic review of 29 studies of mixed designs (n = 3,012 total participants in the intervention group, n = 2,826 controls) examined the safety and efficacy of four steroid-eluting sinus implants: PROPEL (n = 2,397); Sinuva (n = 332), and two others not available in the United States (n = 283). The evidence suggests steroid-eluting sinus implants are safe, may reduce healthcare utilization associated with endoscopic sinus surgery, and have no apparent systemic absorption or effect on intraocular pressure or cataract formation. Efficacy appears to depend on the chronic rhinosinusitis subtypes in the study population (i.e., with or without polyps or recurrent polyps), implant used, outcome measures used, and setting (Calvo-Henriquez, 2024):

- Strong evidence suggests PROPEL following endoscopic sinus surgery is safe and effective for improving healing and decreasing polyp regrowth as a treatment for chronic rhinosinusitis of mixed subtypes. There was insufficient evidence supporting other outcomes.
- The combined results for all implant types suggest steroid-eluting sinus implants may improve surgical healing (strong evidence) and decrease polyp regrowth (strong evidence) in patients with chronic rhinosinusitis with and without polyps.

- As an in-office procedure, Sinuva implants may decrease the need for repeat surgery in patients with recurrent chronic rhinosinusitis with polyps (strong evidence). There is insufficient evidence supporting: a positive impact on olfaction; superiority to other resorbable materials impregnated with steroids; cost effectiveness after endoscopic sinus surgery; cost effectiveness as an in-office procedure; or efficacy as a primary treatment without previous endoscopic sinus surgery.

In 2025, we updated the references with no policy changes warranted.

References

On May 6, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “sinusitis/surgery” (MeSH), “drug eluting stents” (MeSH), “drug eluting sinus implant,” “mometasone furoate,” “Sinuva,” and “PROPEL.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

5/2017: initial review date and clinical policy effective date: 7/2017

3/2018: Policy references updated.

4/2019: Policy references updated. Policy ID changed from 10.03.07 to CCP.1310.

3/2020: Policy references updated.

5/2021: Policy references updated.

5/2022: Policy references updated.

5/2023: Policy references updated.

7/2024: Policy references updated. Coverage changed to medically necessary.

7/2025: Policy references updated.