Propel (drug eluting devices after sinus surgery)

Clinical Policy ID: CCP.1310

Recent review date: 6/2021

Next review date: 10/2022

Policy contains: Drug-eluting sinus implants; Propel; steroids for rhinosinusitus.

AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' 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 by AmeriHealth Caritas 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. AmeriHealth Caritas' 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. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.

Coverage policy

The use of PROPEL drug-eluting devices after sinus surgery is investigational/experimental, and therefore, not medically necessary (Huang, 2015; Rizan, 2016).

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

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

Medicinal treatments to relieve mucosa edema and 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, most often endoscopic surgery. Post-operative inflammation, formation of polyps, and adhesions of the nasal mucous lining

are not uncommon, and require treatment to decrease edema of the mucosa and hasten wound healing, and restore sinus ventilation and drainage (Huang, 2015).

The PROPEL mometasone-eluting stent, created by Intersect ENT of Palo Alto CA, is the first device for delivering a sustained steroid medication localized into the ethmoid cavity after surgery approved by the Food and Drug Administration. The implant is a biodegradable polymer that expands in a spring-like fashion to conform to the walls of a dissected ethmoid cavity. Mometasone furoate (370 mg) is released gradually over a 30-day period, directly into the sinus (Wei, 2012).

The Food & Drug Administration approved PROPEL, an implant for ethmoid sinus surgery, on August 11, 2011. Approval for PROPEL Mini, an implant for ethmoid and frontal sinus surgery, followed on September 21, 2012. The most recent product, PROPEL Contour – for frontal and maxillary sinus surgery – received approval on February 23, 2017 (Food and Drug Administration, 2021). All three are indicated for persons age 18 or over. Intersect ENT Inc. (2017) asserts that more than 150,000 patients have been treated with PROPEL products as of early 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, after a series of events that included Food & Drug Administration denial of a request for expanded use of the device. Federal officials alleged that the manufacturer had intended and marketed the device for use with a corticosteroid (U.S. Department of Justice, 2016). Off-label use of the Sinu-Foam Spacer has yet to demonstrate improvement in endoscopic outcomes (Rudmik, 2012).

The Sinuva sinus implant is another drug eluting device used after surgery, and was approved by the Food and Drug Administration in 2017 (Food and Drug Administration, 2017).

Findings

The only guideline on the use of drug-eluting sinus implants that we identified (National Institute for Health and Care Excellence, 2016) recommends that based on limited evidence of efficacy, patient-reported outcomes, and quality of life, the procedure “should be used only with special arrangements for clinical governance, consent, and audit or research.” A consensus statement (Brietzke, 2014) on the treatment of pediatric rhinosinusitis did not address drug eluting sinus implants after surgery; PROPEL is not approved for persons under age 18.

Results of use of the PROPEL devices have appeared in some peer-reviewed articles, but studies to date are relatively few, with small and heterogeneous samples, lack control groups for comparison, and have short follow-up periods.

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.

An early meta-analysis of two randomized trials (n = 143, or 286 ethmoid sinuses) assessed steroid-releasing implants through post-surgical grading by three otolaryngologists. Implants reduced postoperative interventions by 35% (P = .0008), lysis of adhesions by 51% (P = .0016), and oral steroid need by 40% (P = .0023), compared to controls. Relative reduction in frank polyposis was 46% (P <of .0001) (Han, 2012).

A literature review of drug eluting implants for chronic rhinosinusitis found significant variability outcomes in maintenance of sinus patency and drug release to the affected sinus mucosa. Authors conclude further research is needed for demonstration of efficacy (Parikh, 2014).A systematic review (Rizan, 2016), identified seven studies, including five randomized controlled trials, that followed patients from 2 - 6 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 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 steroids (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 (Goshtasbi, 2019).

In the ADVANCE trial (Forwith, 2011) that was the basis for Food & Drug Administration 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 review of sales data showed that, after the initial 2011 Food and Drug Administration approval, sales of corticosteroid-eluting sinus stents soared from 8,400 to 103,400 between 2012 and 2016. Authors caution otolaryngologists considering adoption of these devices in clinical practice to be mindful of limitations in clinical evidence, especially for ethmoid and frontal sinus indications (Gadkaree, 2019).

References

On March 19, 2020, 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 “drug eluting device,” “drug eluting sinus implant,” “mometasone furoate implant,” “Sinu-Foam Spacer,” and “PROPEL sinus.” 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.