Clinical Policy Title: Propel (drug eluting devices after sinus surgery)

Clinical Policy Number: CCP.1310

Effective Date: July 1, 2017
Initial Review Date: May 19, 2017
Most Recent Review Date: June 4, 2019
Next Review Date: May 2020

Related policies:
None.

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’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 by Select Health of South Carolina 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. Select Health of South Carolina’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. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers the use of PROPEL drug-eluting devices after sinus surgery to be investigational/experimental, and therefore, not medically necessary (Huang, 2015; Rizan, 2016).

Limitations:
None.

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 U.S. Food and Drug Administration (FDA). 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 U.S. 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 FDA approval on February 23, 2017. 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 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, and allegations by the government 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).

**Searches**

Select Health of South Carolina searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

We conducted searches on April 26, 2019. Search terms were: “drug eluting device,” “drug eluting sinus implant,” “mometasone furoate implant,” “Sinu-Foam Spacer,” and “PROPEL sinus.”

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
• **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**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, the lack of long-term evidence, and inadequate evidence on 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.

We identified two systematic reviews of drug-eluting sinus implants. The first (Huang, 2015), a Cochrane review, 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.

The second systematic review (Rizan, 2016), identified seven studies, including five randomized controlled trials, that followed patients from 2 to 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.

In the ADVANCE trial (Forwith, 2011) that was the basis for Food & Drug Administration approval of PROPEL, participants had a total of 90 sinuses that were given PROPEL after endoscopic sinus surgery and followed for 1 month. They showed a low prevalence of polypoid edema (10.0 percent), significant adhesions (1.1), and middle turbinate lateralization (4.4), indicating the implant was safe and effective. This was corroborated results 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).

Several studies were controlled and randomized. Han’s (2014) analysis found the treatment arm (n=53 post-surgical patients with recurrent sinonasal polyposis treated with a steroid-eluting implant) had a significantly lower polyp burden, a lower ethmoid sinus obstruction, and a greater improvement in nasal
obstruction after 3 months, compared to 47 controls. Additionally, the treated group had a significantly greater percent of patients no longer indicated for repeat surgery (53 to 23 percent), compared to controls. Another randomized controlled study (Forwith, 2016) that compared 57 implant with 43 control patients for 6 months after surgery resulted in significantly lower nasal obstruction and bilateral polyp grade among the treated group.

A Canadian study (Lavigne, 2014) of 24 steroid-eluting implants in sinuses found significantly lower polyp grades after 6 months, when 64 percent of patients were no longer candidates for sinus surgery. Other 2014 publications of 20 implants (Matheny, 2014), and 10 implants (Ow, 2014) found the treatment to be effective and safe, but outcomes were measured after 1 month.

While earlier studies tested efficacy of drug-eluting implants into the ethmoid sinus, more recent studies have begun to review effects on the frontal sinus. PROGRESS (Smith, 2016), a randomized blinded trial of 80 sinuses, documented a reduced need for post-operative interventions (oral steroid, surgery, and restenosis), lower inflammation score, and greater diameter of the frontal sinus compared to surgery alone after 90 days. An evaluation of post-operative sinus implants for patients undergoing frontal sinus surgery found a significant potential for growth in the use of these implants (Bury, 2017).

Average costs of steroid-eluting and nonsteroid-eluting sinus implant strategies were estimated at $1,572.91 and $365.18 (Rudmik, 2014). For a hypothetical U.S. health plan of 1.5 million members, incorporating PROPEL into its covered services ranged from estimates of -$.003 to +$.036 per member per month (Rizzo, 2016).

**Policy updates:**

In March, 2018, we did not identify any new guidelines or peer-reviewed publications.

In April, 2019, we added three publications to the policy. No policy changes are warranted at this time. The policy ID changed from 10.03.07 to CCP.1310.

**References**

**Professional society guidelines/other:**


Peer-reviewed references:


**Centers for Medicare & Medicaid Services National Coverage Determinations:**

No National Coverage Determinations identified as of the writing of this policy.

**Local Coverage Determinations:**

No Local Coverage Determinations identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<td>Mometasone furoate sinus implant, 370 micrograms</td>
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