AOA Practice Builder Session: Coding & Coverage of Drug-eluting Sinus Implants

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Disclaimer

The information provided in this presentation is not legal advice nor is it advice about how to code, complete or submit any particular claim for payment. The information is gathered from various sources and represents Intersect ENT’s understanding of coding, coverage and reimbursement policies. It is the health care provider’s responsibility to determine appropriate codes, charges, and modifiers, and submit bills for the services rendered. Any party may have different policies and coding requirements. In all coding and billing, it is the provider's responsibility to be truthful and not misleading and make full disclosures to the payor about how the product has been used and the procedures necessary to implant the product when seeking reimbursement for any product or procedure.

Introduction and Agenda
• Review the burden of illness of Chronic Rhinosinusitis
• Describe the clinical and health economic benefits of steroid-eluting sinus implants during the postoperative period following sinus surgery
• Examine the coding, coverage and payment associated with the use of drug-eluting sinus implants

Clinical Definition of Chronic Rhinosinusitis (CRS)

Chronic inflammation of the sinus lining leading to:
- Blockage of the natural drainage passageways
- Chronic infections
- Nasal obstruction
- Lasts for more than 12 weeks

Classifications:
- CRSwNP (with nasal polyps)
- CRSsNP (without nasal polyps)

Etiologies Driving Chronic Inflammatory Disease

“The inflammatory process is tightly regulated, involving mediators that initiate and maintain inflammation and mediators that shut the process down. In states of chronic inflammation, an imbalance between the two mediators leaves inflammation unchecked, resulting in cellular damage.”

Manifestations of Common Chronic Inflammatory Conditions
### The Clinical Burden of CRS is Profound

CRS has a profound impact on QOL and productivity. The indirect impact on overall QOL rivals other well-recognized conditions with significant clinical and health economic burden to society.

**SF-6D Utility Scores by Health State**

<table>
<thead>
<tr>
<th>Health State</th>
<th>Utility Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>0.00</td>
</tr>
<tr>
<td>Paralyzed</td>
<td>0.05</td>
</tr>
<tr>
<td>Blind</td>
<td>0.06</td>
</tr>
<tr>
<td>Dying</td>
<td>0.12</td>
</tr>
<tr>
<td>Stage IV</td>
<td>0.15</td>
</tr>
<tr>
<td>Peripheral</td>
<td>0.30</td>
</tr>
<tr>
<td>Hronic</td>
<td>0.32</td>
</tr>
<tr>
<td>Liver Failure</td>
<td>0.36</td>
</tr>
<tr>
<td>CRS requiring</td>
<td>0.37</td>
</tr>
<tr>
<td>Parkinson's</td>
<td>0.43</td>
</tr>
<tr>
<td>COPD</td>
<td>0.46</td>
</tr>
<tr>
<td>Diabetes</td>
<td>0.46</td>
</tr>
<tr>
<td>Asthma</td>
<td>0.46</td>
</tr>
<tr>
<td>ARDS</td>
<td>0.48</td>
</tr>
<tr>
<td>Diabetes II</td>
<td>0.49</td>
</tr>
<tr>
<td>Liver Cancer</td>
<td>0.50</td>
</tr>
<tr>
<td>AIDS</td>
<td>0.50</td>
</tr>
<tr>
<td>Perfect Health</td>
<td>1.00</td>
</tr>
</tbody>
</table>

**Annual US Productivity Costs by Disease**

<table>
<thead>
<tr>
<th>Disease</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma</td>
<td>$18.02B</td>
</tr>
<tr>
<td>Chronic Asthma</td>
<td>$17.61B</td>
</tr>
<tr>
<td>Cystic Fibrosis</td>
<td>$16.50B</td>
</tr>
<tr>
<td>Heart Disease</td>
<td>$16.00B</td>
</tr>
<tr>
<td>Diabetes</td>
<td>$15.21B</td>
</tr>
<tr>
<td>Diabetic Nephritis</td>
<td>$14.57B</td>
</tr>
<tr>
<td>COPD</td>
<td>$14.42B</td>
</tr>
<tr>
<td>Diabetes II</td>
<td>$13.71B</td>
</tr>
<tr>
<td>Liver Disease</td>
<td>$12.65B</td>
</tr>
<tr>
<td>Liver Cancer</td>
<td>$12.61B</td>
</tr>
<tr>
<td>AIDS</td>
<td>$12.57B</td>
</tr>
</tbody>
</table>

### ...as is the Health Economic Burden of CRS

- More prevalent than arthritis and hypertension.™
- One of top 10 most costly conditions for employers.™
- 1 in 7 adults suffers.
- 25 missed work days per year.
- Most common reason for an adult antibiotic prescription.™
- 39 days lost to presenteeism and 21 household days lost related to daily sinus care requirements.™

### The Journey of a CRS Patient

At some point, most patients with CRS will undergo sinus surgery at least once. Surgical treatment is not considered curative for CRS. TM Evidence indicates that if persistent symptoms in adequately treated following surgery, the chance of revision surgical intervention is essentially eliminated over a nearly 8-year period.™

**The Underlying Inflammatory cascade can perpetuate disease.**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Symptomatic</td>
</tr>
<tr>
<td>2</td>
<td>Persistent</td>
</tr>
<tr>
<td>3</td>
<td>Requiring</td>
</tr>
<tr>
<td>4</td>
<td>Surgical</td>
</tr>
</tbody>
</table>
Common Complications & Interventions Following ESS

The most common reasons for surgical failure include scarring of the sinus ostia, adhesion formation, and middle turbinate lateralisation. Other common causes of failure that should be considered include poor post-operative care and patient non-compliance.2

<table>
<thead>
<tr>
<th>Setting</th>
<th>Office ASC</th>
<th>Office ASC</th>
<th>Office ASC</th>
<th>ASC HOPD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost</td>
<td>$912 $1,019</td>
<td>$981 $1,043</td>
<td>$2,800 $3,200</td>
<td>$6,563 $7,199</td>
</tr>
</tbody>
</table>

Post-Operative Standard of Care Recommendations

Practice guidelines recommend patient-tailored clinical strategies of multiple approaches to maintain sinus patency, reduce mucosal inflammation, and reduce infection.1

- **Debridement**: Can prevent potential scarring and sinus ostial stenosis. Schedule and frequency are based on physical examination.
- **Antibiotics**: Recommended as needed based on patient symptoms, correlated with potential infection.
- **Nasal Saline Irrigation**: Benefit to nasal mucosa during the early post-op period, net documentation, less highly dependent on patient compliance.1,2
- **Topical Steroids**: Treated nasal irrigation up to two weeks following ESS. Effective mucosal inflammation.

Limitations of Topical Steroids

"Post-operatively, persistent inflammation of the frontal recess can lead to scarring and long term stenosis with clinical sequela."1 Only 2% of the active drug in topical nasal sprays actually reaches the sinus cavity due to post-operative inflammation.2

MRI doses of budesonide subjects 5, 20, and 60 minutes after administration of radiolabeled Mometasone Furoate.

60% of the active drug in a metered dose nasal steroid spray is removed by mucociliary clearance within 15 minutes.3

References for Evidence:

In the primary care setting, a prospective cohort of 15,961 patients in a primary care network was identified. The overall rate of non-adherence was 31.3%. The incidence of not filling prescriptions for treatment of rhinitis was nearly 40%.2

<table>
<thead>
<tr>
<th>Pharmacologic Class</th>
<th>Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hormones/Synthetics</td>
<td>36.3%</td>
</tr>
<tr>
<td>Cardiovascular Drugs</td>
<td>34.7%</td>
</tr>
<tr>
<td>Ear/Nose/Throat Preparations</td>
<td>14.2%</td>
</tr>
</tbody>
</table>

*Patients whose cavities become normal on endoscopic inspection after surgery are much less likely to require revision surgery.*2

The Solution: Drug-eluting Sinus Implants
PROPEL® (Mometasone Furoate Sinus Implant)

FDA INDICATION: The PROPEL sinus implants are intended for use after sinus surgery to maintain patency and to locally deliver steroid to the sinus mucosa. PROPEL for use in the ethmoid sinus, PROPEL® for use in the ethmoid sinus and frontal sinus opening, and PROPEL Contour for use in the frontal and maxillary sinus cavities.

ProPEl Sinus Implant: 3 Clinical Trials, 386 Subjects

- **Pilot Study**
  - n=38, 4 sites
  - Randomized
  - Controlled
  - Double Blind
  - Intra-patient Control

- **ADVANCE Study**
  - n=50, 7 sites
  - Non-Randomized
  - Single Arm
  - Safety / Symptoms to 6 months

- **ADVANCE II Pilotal Trial**
  - n=405, 11 sites
  - Randomized
  - Controlled
  - Double Blind
  - Intra-patient Control

Meta-Analysis
- n=143
- Level 1A Evidence

Technology Differentiation; Predictable Local Drug Delivery

The steroid chosen in the development process for the PROPEL sinus implant was deliberate based on characteristics to ensure optimal local drug delivery.
A combined level 1-A meta-analysis of efficacy results from the two randomized controlled studies of PROPEL sinus implants (Pilot and ADVANCE II) demonstrated statistically significant improvements in clinically meaningful endpoints.

143 combined patients (280 sinuses) from 2 RCTs at 15 US sites

Clinical Program Overview – Frontal Sinus

Two RCTs using an intra-patient control design were conducted to evaluate whether the ADDITION of local steroid delivery provided a superior benefit to traditional post-operative care alone in the frontal sinus.

PROGRESS Frontal Sinus Study Data

An RCT confirms the use of PROPEL Mini sinus implant in the frontal sinus provides improved outcomes over surgery alone. FDA approval was expanded to the frontal sinus in March 2016.
QOL Scores Significantly Better at Six Months

An independent clinical study of 136 patients demonstrated improvement in patient-reported QOL and endoscopic appearance six months after placement of a steroid-eluting implant following ESS, irrespective of the presence of polyposis or eosinophilia.  

Drug-eluting Sinus Implants: Coding, Coverage & Payment

General Concepts

Coding

Codes exist to report the work of placement of a drug-eluting sinus implant whether performed during or immediately following ESS or performed as a stand-alone procedure.

Regardless of procedure codes reported, a HCPCS code for drug-eluting sinus implant should also be listed separately.

Coverage

Payors commonly create investigational policies for new technology which can create barriers to access.

Negative coverage does not impact access under all contractual arrangements (e.g. PMPM, ACO, bundled payment).

Payment

Whether PROPEL sinus implants are paid separately is dependent on the site of service and the provider’s (facility or physician) contractual arrangement.
Use of Category III Codes & HCPCS Codes for Drug-eluting Sinus Implants

31295, 31296 & S1090/J3490 Product codes may not be reported when performed as an integral part of the sinus surgery procedure performed. These codes may be reported when performed separately, or as a result of complications of the previously performed sinus surgery procedure.

When using the Category III CPT codes (or the endoscopic sinus surgery codes) during which the implant is placed concurrently, you must report a HCPCS code for the implant itself.

Reimbursement Overview – Coding & Payment

The work associated with the implant placement is integral to the sinus surgery procedure performed. Therefore, no separate payment is made to physicians for implant placement, therefore no overuse potential.

Payment of a drug-eluting sinus implant is NOT separately reportable when performed following an endoscopic sinus procedure in the office.

This Category III codes can only be reported when implant placement is the only procedure performed in the endonasal sinus surgery. The payment for implant placement is the same as the payment for the procedure when the implant is not reportable for the procedure at the office. When covered, payment is schedule rate for drug-eluting sinus implants tied to HCPCS S1090 and pay similar to other physician administered drugs and drug implants (i.e., Lipitor® ASP plus 6%). This minimizes potential for inappropriate use.
Case Studies

Bilateral Ethmoid Debridement

CPT | Description
---|------------------
31237 | Nasal/sinus endoscopy, surgical; with biopsy, polypectomy or debridement (separate procedure)
Bilateral Ethmoid Debridement with Bilateral Placement of Drug-eluting Sinus Implants in the Ethmoid Sinuses

**CPT Description**
S1090 Mometasone furoate sinus implant, 370 micrograms

**HCPCS Description**
S1090 Mometasone furoate sinus implant, 370 micrograms

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Bilateral Frontal Balloon Dilation with Bilateral Insertion of Drug-eluting Sinus Implants in the Frontal Sinuses

**CPT Description**
0406T Nasal endoscopy, surgical; with polypectomy, biopsy or debridement

**HCPCS Description**
S1090 Mometasone furoate sinus implant, 370 micrograms

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The Path to Payor Acceptance of New Technology

Even the most intuitive medical innovation is not always readily accepted by payors due to up-front costs, uncertain return-on-investment, or potential over-utilization.

**What Patients & Providers See**
- Improved clinical outcomes
- Reduced complications
- Reduced length of stay
- Reduced pain
- Reduced absenteeism

**What Payors See**
- Increased cost
- Increased number of patients
- Potential for abuse/overuse
- Lack of ROI
Payor Education Opportunities

There are several key messages related to use of drug-eluting sinus implants which resonate with payors and are unique from other technologies:

- "Reducing postoperative healing time is key.
- "Reducing hospital stay benefits the patient.
- "Reducing cost associated with medical intervention.
- "Reducing outcomes benefit the practice.
- "Reducing complications benefit the practice.
- "Reducing patient satisfaction benefits my practice.

Factors Driving Payor Coverage of New Technology

Not only do payors need to evaluate the clinical evidence to support new technology, they need to hear from physicians who want to use it.

- Peer-reviewed publications of well-designed clinical trials
- Compelling unmet clinical need
- Cost effectiveness and affordability data
- Local physician outreach
- Claims burden
- Specialty society support

Cost Savings for Payors

Results from an ICER-based cost-effectiveness study reveal placement of a steroid-eluting sinus implant following ESS for refractory CRS is a cost-effective intervention for preventing a postoperative intervention after surgery.¹

A budget impact analysis indicates the upfront cost of PROPEL sinus implant is offset by savings associated with reduced probability for post-ESS intervention. The budget impact for a payor is therefore negligible.²

<table>
<thead>
<tr>
<th>Intervention needed during 6 months post-ESS</th>
<th>Cost Savings</th>
<th>Other Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision surgery</td>
<td>2.2%</td>
<td>6.7%</td>
</tr>
<tr>
<td>Lysis of Adhesions</td>
<td>15.4%</td>
<td>39.8%</td>
</tr>
<tr>
<td>Severe Poly recurrence</td>
<td>7.3%</td>
<td>23.5%</td>
</tr>
</tbody>
</table>


Cost Savings with Care Migration

The absence of additional payment for new technology commonly used in sinus surgery often drives more cases to the HOPD setting, where higher payment rates create more viability.

Potential Savings: $3,128

Payors Benefit from Reducing Complications following ESS

Coverage by various managed care organizations that benefit from reductions in overall cost of care.

Drug-eluting sinus implants are considered a covered benefit. Separate payment varies by place of service.

Summary

• For use of drug-eluting sinus implants in the OR setting, like other technology, the product cost is typically accommodated in the facility payment.

• For clinically appropriate use of drug-eluting sinus implants in the office setting, CPT and HCPCS codes are in place. Coverage and payment are possible if providers are willing to advocate to payors based on medical necessity and the documented clinical and health economic benefits.

• Payor coverage/payment resistance is a normal part of the medical technology evolution process. Payor adoption is dependent upon persistent provider demand.