An Innovative Treatment Option for Patients with Recurrent Nasal Polyps

Burden of illness and management of Chronic Sinusitis with Nasal Polyps

Continuum of care and polyp recurrence

Clinical and health economic value of SINUVA™ for treatment of nasal polyps
Societal Burden of Chronic Sinusitis (CS)

Affects 29 million Americans

Increased incidence of depression

Sleep quality comparable to obstructive sleep apnea

$10,077 per year in lost productivity costs

2016 direct and indirect costs of $21 Billion

39 days per year of work missed


Nasal Polyps

- Nasal polyps are soft, painless, noncancerous growths lining the nasal passages or sinuses.  
- Caused by chronic inflammation due to asthma, recurring infection, allergies, drug sensitivity or certain immune disorders.  
- Polyps lead to breathing problems, facial pain/headache, anosmia and frequent infections.  
- Nasal Polyps are present in ~31% of patients with Chronic Sinusitis.
- Patients with Chronic Sinusitis and nasal polyps may persist for a longer duration, be relatively recalcitrant to medical management, more frequently lead to surgical management and/or require more surgeries to address.

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Current Treatment Continuum

Symptom Resolution is Most Important to Patients, Public and Practitioners

Maximal Medical Therapy Employed Upon Diagnosis

Surgery Performed for Patients that Fail MMT

257,000 sinus surgeries are performed in US per year.\(^1\)

Recurrence of Nasal Polyps

38% of patients experience polyp recurrence within 1 year post-op.\(^4\)

Post-operative Symptoms and Complications Managed

Patients whose cavities became normal on inspection after surgery and postop care are much less likely to require revision surgery.\(^3\)

Prevalence of Polyps Post Surgery

The rate of nasal polyp recurrence was documented in a study of 363 patients having undergone ESS with polypectomy. For patients in the study, 244 underwent graded postoperative endoscopies during the 18 month follow-up period.\(^1\)

Polyp Recurrence

<table>
<thead>
<tr>
<th>Time</th>
<th>Recurrence Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months</td>
<td>35%</td>
</tr>
<tr>
<td>12 months</td>
<td>38%</td>
</tr>
<tr>
<td>18 months</td>
<td>40%</td>
</tr>
</tbody>
</table>

\(^1\) Orlandi et al; Cochrane Corner: Extracts from The Cochrane Library: Intranasal Steroids for CRS. Otolaryngology-Head and Neck Surgery 2017; Vol. 156(3)397-402.
\(^3\) Kennedy DW, Wright IO, Goldberg AN. Objective and subjective outcomes in surgery for chronic sinusitis. Laryngoscope. 2000 Mar;110.
A NEW TREATMENT OPTION

SINUVA™ (mometasone furoate) Sinus Implant

<table>
<thead>
<tr>
<th>FDA Approval Type</th>
<th>Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA Approval Path</td>
<td>NDA</td>
</tr>
<tr>
<td>FDA Approval Date</td>
<td>December 8, 2017</td>
</tr>
<tr>
<td>Drug Component</td>
<td>Mometasone Furoate 1,350 µg</td>
</tr>
<tr>
<td>Drug Release Period</td>
<td>90 days</td>
</tr>
</tbody>
</table>

FDA INDICATION: The SINUVA Sinus Drug Implant is indicated for treatment of nasal polyps in patients ≥ 18 years of age who have had ethmoid sinus surgery.

The images shown represent a single patient outcome and may not be typical. The average nasal obstruction reduction score was -0.80 on a scale of 0 to 3 and the average polyp grade reduction score was -0.56 on a scale of 0 to 4 for patient in the experimental arm of the RESOLVE II study.1

Differentiation of Drug-Eluting Sinus Implants

PROPEL®
(Mometasone Furoate Sinus Implant, 370 µg)
FDA-Cleared as DEVICE via PMA in 2011

Clinical Application:
• Maintain sinus patency following surgery
• Reduce inflammation
• Decrease need for medical and surgical re-intervention following surgery

Clinical Setting:
• Following surgery in O.R. (HOPD or ASC)
• Adjunct surgical supply cost to facility

SINUVA
(Mometasone Furoate Sinus Implant, 1,350 µg)
FDA-Approved as a DRUG via NDA in 2017

Clinical Application:
• Treatment of nasal polyps in patients ≥ 18 years of age who have had ethmoid sinus surgery

Clinical Setting:
• Office/Clinic alternative for patients with recurrent disease eligible for revision surgery

SINUVA Clinical Evidence Program

Pilot Study
Non-Randomized Open Label Single Cohort (SINUVA Implant)

n = 12 patients
4 sites
6 months

PK
Non-Randomized Single Cohort Pharmacokinetic Study

n = 5 patients
1 site
30 days

RESOLVE1,4*
Randomized 1:1 Blinded Controlled: Parallel Groups (SINUVA Implant vs. sham)

n = 100 patients
18 sites
6 months

RESOLVE II5
Randomized 2:1 Blinded Controlled: Parallel Groups (SINUVA Implant vs. sham)

n = 300 patients
34 sites
3 months

Follow-up:
PMID: 29350846 [Efficacy study].
RESOLVE II: Study Methods

<table>
<thead>
<tr>
<th>Patients</th>
<th>Clinical Sites</th>
<th>Randomization</th>
</tr>
</thead>
<tbody>
<tr>
<td>300</td>
<td>34 (all in US)</td>
<td>2:1</td>
</tr>
</tbody>
</table>

- **Treatment group**: in-office bilateral implant placement in the ethmoid sinuses
- **Control group**: in-office bilateral sham procedure; patients blindfolded and ear-muffed
- **All patients** used mometasone furoate nasal spray (MFNS) once daily (200 mcg) through day 90 follow-up

RESOLVE II: Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Treatment</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total no. of subjects</td>
<td>201</td>
<td>99</td>
</tr>
<tr>
<td>Male</td>
<td>63%</td>
<td>57%</td>
</tr>
<tr>
<td>Age (y)</td>
<td>51</td>
<td>48</td>
</tr>
<tr>
<td>Medical history:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asthma</td>
<td>74%</td>
<td>62%</td>
</tr>
<tr>
<td>Allergic rhinitis</td>
<td>77%</td>
<td>80%</td>
</tr>
<tr>
<td>Aspirin exacerbated respiratory disease</td>
<td>15%</td>
<td>17%</td>
</tr>
<tr>
<td>ESS history:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of prior ESS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>41%</td>
<td>41%</td>
</tr>
<tr>
<td>2 or more</td>
<td>59%</td>
<td>59%</td>
</tr>
<tr>
<td>CRS symptoms despite ongoing use of INCS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nasal obstruction/blockage</td>
<td>92%</td>
<td>91%</td>
</tr>
<tr>
<td>Post-nasal discharge</td>
<td>91%</td>
<td>84%</td>
</tr>
<tr>
<td>Altered sense of smell/taste</td>
<td>87%</td>
<td>90%</td>
</tr>
<tr>
<td>Facial pain/pressure/fullness</td>
<td>38%</td>
<td>44%</td>
</tr>
</tbody>
</table>

RESOLVE II: Statistically Significant Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Treatment (mean)</th>
<th>Control (mean)</th>
<th>Btw Group Difference</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co-Primary Efficacy Endpoints</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nasal obstruction/congestion score change (baseline to day 30, patient reported)</td>
<td>-0.80</td>
<td>-0.56</td>
<td>-0.23</td>
<td><strong>0.0074</strong></td>
</tr>
<tr>
<td>Bilateral polyp grade change (baseline to day 90 by independent blinded panel)</td>
<td>-0.56</td>
<td>-0.15</td>
<td>-0.35</td>
<td><strong>0.0073</strong></td>
</tr>
<tr>
<td>Secondary Efficacy Endpoints</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients still indicated for repeat sinus surgery at day 90</td>
<td>78/200 (39%)</td>
<td>62/98 (63%)</td>
<td></td>
<td>0.0004</td>
</tr>
<tr>
<td>Percent ethmoid sinus obstruction (baseline to day 90 by independent blinded panel)</td>
<td>-11.3</td>
<td>-1.9</td>
<td>-7.96</td>
<td>0.0007</td>
</tr>
<tr>
<td>Nasal obstruction/congestion score change (baseline to day 90, patient reported)</td>
<td>-0.93</td>
<td>-0.69</td>
<td>-0.27</td>
<td>0.0248</td>
</tr>
<tr>
<td>Decreased sense of smell score change (baseline to day 90, patient reported)</td>
<td>-1.20</td>
<td>-0.76</td>
<td>-0.46</td>
<td>0.0470</td>
</tr>
</tbody>
</table>


Economic Value Proposition

The clinical benefits of SINUVA have been demonstrated as an alternative to surgery in patients with recurrent nasal polyps. In RESOLVE II, control pts had 2.7x higher risk of remaining indicated for revision surgery than treated patients at six months.¹

Cost per implant: $1,275 (assumes bilateral)
Cost of related services: ~$450

Surgery

$14,175³

$3,000

² CMS National Average Payment for CPT 31231/31237. Assumes bilateral procedure with applicable payment reduction plus cost of two SINUVA implants @ $1,275 WAC.
SINUVA Offers a Safe, Non-surgical Option to Patients With Recurrent Polyp Disease

Proposed Payor Coverage Criteria for SINUVA

• Diagnosis of Nasal Polyps
• Over age 18
• At least one prior ethmoid sinus surgery *(note: prior ethmoidectomy is required to accommodate implant size/shape)*
• Suboptimal response to appropriate medical therapy including:
  o INCS (intranasal corticosteroids) and/or oral steroids (unless ineligible or refused due to contraindications or intolerance)