Innovative Approaches and New Technology to Gain Access

The following is intended only for presentation to the Reimbursement and Access 2017 audience, August 17, 2017.

This information is not for promotional use or further distribution.
Objectives

• Discuss challenges around the assessment of an innovative, combination therapy
• Misaligned Incentives
• Physician challenges
• Getting your value message to the right people
The OR Is the Gateway to the Opioid Epidemic
Opioid monotherapy, the current standard of care for postsurgical pain management, may lead to issues

**THE SITUATION**

73%

of inpatient surgeries report moderate to extreme pain after surgery

**THE CURRENT STANDARD OF CARE**

99%

of patients receive opioids to manage postsurgical pain

**THE OUTCOME**

92%

of postsurgical patients who receive opioids report adverse events

References:
Opioid therapy may lead to multiple adverse events\textsuperscript{1-3}

**Common adverse events**
- Nausea
- Pruritus
- Sedation
- Constipation
- Urinary retention

**Clinically significant adverse events**
- Ileus
- Bowel obstruction
- Vomiting
- Confusion
- Dysphoria

**Life-threatening adverse events (\leq 3\%)**
- Respiratory depression
- Respiratory arrest

Acute and Chronic Consequences of Opioid Use in Acute Surgical Setting

Patients experiencing clinically significant opioid related adverse events¹:

- 55% longer hospital stays
- 47% higher costs
- 36% higher readmission rate at 30 days

1 in 15 Patients who receive opioids after surgery become chronic users

Resulting in the rapid proliferation of new opioid users coming from the acute care setting²,³

References:
A Multimodal Pain Management Strategy Focuses on Minimizing Opioid Use and Reducing Adverse Events

EXPAREL® (bupivacaine liposome injectable suspension)—Non-Opioid, Patient-Focused Pain Control

- EXPAREL can be an important part of multimodal pain management
- Indicated for single-dose administration into the surgical site to produce postsurgical analgesia
- Reduces the need for opioids while providing long-lasting postsurgical pain control*
- Uses DepoFoam® technology to encapsulate the local anesthetic bupivacaine in multivesicular liposomes

Used in more than 3 million patients since 2012¹

*The clinical benefit of the decrease in opioid consumption was not demonstrated in the pivotal trials.

Please see Important Safety Information at the end of this presentation.
Full Prescribing Information is available at www.EXPAREL.com.

The benefits of opioid therapy may carry hidden costs and risks

**Accepted Benefits**
- Effective
- Low cost

**Hidden Costs and Risks**
- $300 PCA can cost more than $300 per patient day\(^1\),\(^a\)
- $4707 Increased length of stay may cost up to $4707 per patient\(^2\)
- $17,052 Annual healthcare costs per opioid-abuse patient may be as high as $17,052\(^3\)

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PCA: Patient-controlled analgesia; a computerized pump called the patient-controlled analgesia pump, which contains a syringe of pain medication as prescribed by a doctor, is connected directly to a patient's intravenous (IV) line. The patient pushes a button to deliver opioid medication.

\(^a\)Includes costs related to PCA adverse events.

**References:**
“Disruptive innovation is disruptive.”

Dr David Nash
Dean, Population Health
Thomas Jefferson
Challenges around the assessment of innovative, combination therapy
# Postsurgical Pain Economics

<table>
<thead>
<tr>
<th>Components</th>
<th>PCA device</th>
<th>Elastomeric pump</th>
<th>EXPAREL® (bupivacaine liposome injectable suspension)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
<td>Pump</td>
<td>Anesthesia</td>
<td>Medication</td>
</tr>
<tr>
<td></td>
<td>Tubing</td>
<td>Pump</td>
<td>$315</td>
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<td></td>
<td>Cartridges</td>
<td>Tubing</td>
<td>Prep $25</td>
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<td>Sterile fill</td>
<td>Catheter</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medication</td>
<td>Sterile fill</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nursing</td>
<td>Medication</td>
<td></td>
</tr>
<tr>
<td></td>
<td>KVO pump</td>
<td>Nursing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Saline</td>
<td>Stabilization brace</td>
<td></td>
</tr>
<tr>
<td>Total costs</td>
<td>~$285-460</td>
<td>~$477-630</td>
<td>~$340</td>
</tr>
</tbody>
</table>

*Need to look at whole picture, not just pharmacy costs*

Overall costs of postsurgical analgesia

Number of surgical cases

<table>
<thead>
<tr>
<th>Postsurgical analgesia interventions</th>
<th>Baseline use</th>
<th>Posturgical analgesia costs (per case)</th>
<th>Posturgical analgesia costs (all cases)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV opioids using PCA device</td>
<td>25%</td>
<td>$11,239</td>
<td>$1,009,085</td>
</tr>
<tr>
<td>Continuous nerve block using elastomeric pump</td>
<td>25%</td>
<td>$10,605</td>
<td></td>
</tr>
<tr>
<td>Continuous wound infiltration using elastomeric pump</td>
<td>25%</td>
<td>$10,473</td>
<td></td>
</tr>
<tr>
<td>Continuous epidural using PCA device</td>
<td>25%</td>
<td>$11,246</td>
<td></td>
</tr>
<tr>
<td>Liposomal bupivacaine</td>
<td>0%</td>
<td>$7,265</td>
<td></td>
</tr>
<tr>
<td>100%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Proposed use</th>
<th>Posturgical analgesia costs (all cases)</th>
<th>Estimated savings (all cases)</th>
<th>Estimated savings (per case)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>$992,237</td>
<td>$96,848</td>
<td>$968</td>
</tr>
<tr>
<td>25%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25%</td>
<td></td>
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</tr>
</tbody>
</table>

Postoperative analgesia costs (per case)

Postoperative analgesia costs (per case, excluding length of stay)

Detailed cost of postsurgical analgesia per case

<table>
<thead>
<tr>
<th>Postsurgical analgesia interventions</th>
<th>Medication</th>
<th>Equipment</th>
<th>Physician</th>
<th>ORAEs</th>
<th>Other AEs</th>
<th>Length of stay</th>
<th>Readmission</th>
<th>Allied health</th>
<th>Total costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV opioids using PCA device</td>
<td>$146</td>
<td>$96</td>
<td>$169</td>
<td>$163</td>
<td>$183</td>
<td>$9,030</td>
<td>$1,275</td>
<td>$176</td>
<td>$11,239</td>
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<tr>
<td>Continuous nerve block using elastomeric pump</td>
<td>$272</td>
<td>$412</td>
<td>$244</td>
<td>$163</td>
<td>$789</td>
<td>$7,308</td>
<td>$1,275</td>
<td>$142</td>
<td>$10,605</td>
</tr>
<tr>
<td>Continuous wound infiltration using elastomeric pump</td>
<td>$135</td>
<td>$215</td>
<td>$217</td>
<td>$162</td>
<td>$656</td>
<td>$7,671</td>
<td>$1,275</td>
<td>$142</td>
<td>$10,473</td>
</tr>
<tr>
<td>Continuous epidural using PCA device</td>
<td>$109</td>
<td>$128</td>
<td>$339</td>
<td>$163</td>
<td>$25</td>
<td>$9,030</td>
<td>$1,275</td>
<td>$176</td>
<td>$11,246</td>
</tr>
<tr>
<td>Liposomal bupivacaine</td>
<td>$336</td>
<td>$7</td>
<td>$58</td>
<td>$82</td>
<td>$0</td>
<td>$6,090</td>
<td>$727</td>
<td>$65</td>
<td>$7,365</td>
</tr>
</tbody>
</table>
Pharma Reps Aren’t in the Operating Room

• Training and Education
  – Dosing; expanding the volume
  – Administration technique
  – Drug-to-drug interactions
  – Variability by surgical site (size, vascularity)

• Multimodal Programs
  – Require changes to existing protocols
  – Crossfunctional team

• Access
Surgeons Don’t Understand P&T
Getting your value message to the right people:
Start high, you can always go down but can’t always go up.
Consider...

• What problem does my product solve? Get on customer’s agenda
• Consider Value Based Contract
• Who is high enough to have an overall view of cost, patient care, impact on the system?
• What is the reporting structure of the hospital/system?
• Use your network and LinkedIn
Who Is the Customer of My Customer?

- Hospitals who own a health plan
- Health Plans
- Employers
- Unions
- State and city governments
How Employers Can Tackle the Opioid Epidemic in Their Workplace

Monday, May 8, 2017

By Janet Poppe, Senior Director, Payer and Employer Relations, Pacira Pharmaceuticals, Inc.

With recent CDC reports indicating 91 Americans die per day from an opioid overdose, it's evident that our nation's struggle with opioid abuse and addiction has reached epidemic proportions. The effects of this crisis have placed unparalleled social and economic stress on communities across the country, state and federal legislatures, and our healthcare system at large. Now, a new tool can help employers understand the impact on their businesses, as well.

Called the Substance Use Cost Calculator, the online tool allows employers to quantify the cost of substance abuse in their workplace by entering information about their organization's size, location, and specialty. A 250-person Florida-based communications company, for example, can incur up to $56,802 in expenses related to healthcare costs. Lost time, job...
A Non-Opioid Option for Postsurgical Pain Management

Janet Poppe
Senior Director, Payer and Employer Relations
Pacira Pharmaceuticals
FLHCC Affiliate Partner
Complimentary Webinar Presentation:

Strategies to Address the Opioid Crisis- Insights from a National Summit

In April there was a Summit of over twenty Healthcare Professionals, Academics, Payers, Employers, Unions, Providers, Advocacy, and Pharmacists to discuss the scope of the opioid burden and opioid-sparing and enhanced recovery initiatives to determine ways for payers and employers to take action against the abuse, misuse, and diversion of prescription opioids. This webinar will share best practices from across the country that positively impact the opioid epidemic and ways that employers can embrace their role in addressing the opioid crisis.

Speakers

Neil Goldfarb
President & CEO
Greater Philadelphia Business Coalition on Health

Javier D. Lasala, M.D.
MD Anderson Cancer Center

Janet Poppe
Senior Director
Pacira Exparel

Karen van Cauill
President & CEO
Florida Health Care Coalition

REGISTER NOW

After registering, you will receive a confirmation email containing information about joining the webinar.

This webinar is open to your members and affiliates. We look forward to your participation in this event!
Call to Action

– Educate employees  [www.PlanAgainstPain.com](http://www.PlanAgainstPain.com)
– Ask provider networks what they are doing to reduce opioids post surgery
– Change benefit design to steer employees to surgeons and facilities using alternatives to opioids
– Include opioid reduction in quality metrics
– Work with TPA vendors to advance Bundled Payment models- both inpatient and moving cases to Ambulatory Surgery Centers.

*We can, and must, do better!*
What Is *Choices Matter*?
www.PlanAgainstPain.com

- **National patient education campaign** aimed at:
  - **Empowering patients** to seek out non-opioid options—and the clinicians and institutions that offer those options—for their postsurgical recovery
  - **Enhancing patient/surgeon communications** around available options for postsurgical pain management
  - **Driving patient involvement** in the decision making process as it relates to their postsurgical recovery

- Launched Aug 1, 2016 by **Pacira, ASER** (American Society of Enhanced Recovery), and professional athlete and recent TKA patient **Gabrielle Reece** (campaign spokesperson)
ACS will develop **Opioids and Surgery Consensus Recommendations: Use, Abuse and Alternatives** (Opioids and Surgery)
EXPAREL® (bupivacaine liposome injectable suspension)
Important Safety Information

• EXPAREL is contraindicated in obstetrical paracervical block anesthesia
• In clinical trials, the most common adverse reactions (incidence ≥10%) following EXPAREL administration were nausea, constipation, and vomiting
• EXPAREL is not recommended to be used in the following patient population: patients <18 years old and/or pregnant patients
• Because amide-type local anesthetics, such as bupivacaine, are metabolized by the liver, EXPAREL should be used cautiously in patients with hepatic disease. Patients with severe hepatic disease, because of their inability to metabolize local anesthetics normally, are at a greater risk of developing toxic plasma concentrations

Warnings and Precautions Specific to EXPAREL
• EXPAREL is not recommended for the following types or routes of administration: epidural, intrathecal, regional nerve blocks, or intravascular or intra-articular use
• Non-bupivacaine-based local anesthetics, including lidocaine, may cause an immediate release of bupivacaine from EXPAREL if administered together locally. The administration of EXPAREL may follow the administration of lidocaine after a delay of 20 minutes or more. Formulations of bupivacaine other than EXPAREL should not be administered within 96 hours following administration of EXPAREL

Full Prescribing Information is available at www.EXPAREL.com.
EXPAREL® (bupivacaine liposome injectable suspension)
Important Safety Information (cont)

Warnings and Precautions for Bupivacaine-Containing Products
• Central Nervous System (CNS) Reactions: There have been reports of adverse neurologic reactions with the use of local anesthetics. These include persistent anesthesia and paresthesias. CNS reactions are characterized by excitation and/or depression
• Cardiovascular System Reactions: Toxic blood concentrations depress cardiac conductivity and excitability which may lead to dysrhythmias sometimes leading to death
• Allergic Reactions: Allergic-type reactions (eg, anaphylaxis and angioedema) are rare and may occur as a result of hypersensitivity to the local anesthetic or to other formulation ingredients
• Chondrolysis: There have been reports of chondrolysis (mostly in the shoulder joint) following intra-articular infusion of local anesthetics, which is an unapproved use

Full Prescribing Information is available at www.EXPAREL.com.
THANK YOU

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www.EXPAREL.com