

EVIDENCE GENERATION FOR EXPAREL FORMULARY INCLUSION

The Anesthesiologist Perspective

This case study represents the individual experience of one US health system and is intended to demonstrate its experience navigating formulary and operationalization of EXPAREL. Each health system's experience may vary based on, but not limited to, population, location, reimbursement structure, and surgery types.

Pacira BioSciences, Inc. recognizes that there are alternative methodologies for identifying appropriate indications, patient populations, management approaches, and data tracking, and approaches vary by health system.

INDICATION

EXPAREL® (bupivacaine liposome injectable suspension) is indicated to produce postsurgical local analgesia via infiltration in patients aged 6 years and older and regional analgesia in adults via an interscalene brachial plexus nerve block, sciatic nerve block in the popliteal fossa, and an adductor canal block. Safety and efficacy have not been established in other nerve blocks.

SELECT IMPORTANT SAFETY INFORMATION

- EXPAREL is contraindicated in obstetrical paracervical block anesthesia

Please see Important Safety Information on page 4.
Full Prescribing Information is available at www.EXPARELpro.com

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BUPIVACAINE LIPOSOME INJECTABLE SUSPENSION

DATA COLLECTION PRE- AND POST-FORMULARY INCLUSION

System Overview

Major integrated health system operating across 7 states in the Western United States

Strategy Goal

Generate clinical and economic data to support EXPAREL formulary inclusion in a hospital system in an effort to expand non-opioid options

Approach

1

Conducted internal quality improvement study with multidisciplinary support

Clinicians evaluated the cost-benefit profile of non-formulary use of EXPAREL in peripheral nerve blocks in the health system, analyzing opioid use, pain scores, and length-of-stay data pulled from the EMR

2

Recommended EXPAREL be added to formulary

The P&T committee added EXPAREL to formulary for procedures that saw benefits in the internal study (eg, brachial plexus blocks for upper-extremity surgeries, anterior thigh and knee blocks). Exceptions for off-formulary procedures were allowed with appropriate clinical justification

3

Established system-wide use protocols

Anesthesiologists added EXPAREL into the pre-existing, opioid-sparing, multimodal order sets for the approved procedures to promote safe, efficient, and outcome-driven use

4

Monitored patient-reported outcomes

The team collected data about opioid use, pain scores, block effectiveness, and patient satisfaction post-discharge daily through day 5 via nurse calls and digital tools

5

Checked compliance of EXPAREL use

The team conducted quarterly compliance checks to ensure that EXPAREL was used mostly for approved formulary procedures

EMR, electronic medical record; P&T, Pharmacy and Therapeutics.

SELECT IMPORTANT SAFETY INFORMATION (cont'd)

- Adverse reactions reported in adults with an incidence greater than or equal to 10% following EXPAREL administration via infiltration were nausea, constipation, and vomiting; adverse reactions reported in adults with an incidence greater than or equal to 10% following EXPAREL administration via nerve block were nausea, pyrexia, headache, and constipation

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CLINICAL AND ECONOMIC BENEFITS TRACKED THROUGH DATA

Key Considerations

Plan approach for data capture

Preparing data collection before formulary implementation can support appropriate use, identify new use cases, and improve outcomes

Build consensus among key stakeholders

Aligning clinicians, pharmacists, and health system leadership promotes successful formulary addition and proper documentation

Use internal data to drive decisions

Leveraging your health system's data can help identify the most suitable procedure for introducing EXPAREL. Analyze the potential impact on your specific patient population, clinical teams, and system costs, including the effects on opioid use and length of stay

Reported Impact at This Health System



Decreased postoperative opioid use, decreased pain scores, shortened length of stay, decreased system cost, and increased sensory block time with the use of EXPAREL*



Expanded formulary approval for EXPAREL across many procedure types, including new nerve blocks, based on strong outcomes data and high formulary compliance



Ongoing stakeholder partnerships supported continued data generation

For more information on how to establish or expand access to EXPAREL at your health system, contact your Pacira representative or visit [EXPARELpro.com/connect](https://www.EXPARELpro.com/connect)



*Based on data reported by the anesthesiologist interviewed for this case study. These results reflect the experiences of one health system, and results at other health systems may vary.

SELECT IMPORTANT SAFETY INFORMATION (cont'd)

- Adverse reactions with an incidence greater than or equal to 10% following EXPAREL administration via infiltration in pediatric patients six to less than 17 years of age were nausea, vomiting, constipation, hypotension, anemia, muscle twitching, vision blurred, pruritus, and tachycardia

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EXPAREL INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

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IMPORTANT SAFETY INFORMATION

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- Do not admix lidocaine or other non-bupivacaine local anesthetics with EXPAREL. EXPAREL may be administered at least 20 minutes or more following local administration of lidocaine
- EXPAREL is not recommended to be used in the following patient populations: patients <6 years old for infiltration, patients younger than 18 years old for nerve blocks, 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

WARNINGS AND PRECAUTIONS SPECIFIC TO EXPAREL

- Avoid additional use of local anesthetics within 96 hours following administration of EXPAREL
- EXPAREL is not recommended for the following types or routes of administration: epidural, intrathecal, regional nerve blocks **other than interscalene brachial plexus nerve block, sciatic nerve block in the popliteal fossa, and adductor canal block**, or intravascular or intra-articular use
- The potential sensory and/or motor loss with EXPAREL is temporary and varies in degree and duration depending on the site of injection and dosage administered and may last for up to 5 days, as seen in clinical trials

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 paresthesia. 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
- **Methemoglobinemia:** Cases of methemoglobinemia have been reported with local anesthetic use

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For more information, please visit www.EXPARELpro.com or call 1-855-793-9727.