STARTING JANUARY 1, 2025:

Use code **J0666** when billing EXPAREL for surgeries across all outpatient settings (1 billable unit = 1 mg).¹

Expanded Medicare reimbursement for qualifying non-opioids, like EXPAREL, across all outpatient settings



This guide can help you make sure your health system is ready for **new reimbursement** in 2025 based on the **NOPAIN Act**, which^{2,3}:

- Mandates that Medicare provide ASP+6% reimbursement for FDA-approved qualifying non-opioid options for the management of postsurgical pain
- Provides reimbursement across HOPD and ASC settings

ASP+6% = reimbursement of 106% of the average sales price.

ASC, ambulatory surgical center; ASP, average sales price; FDA, US Food and Drug Administration; HOPD, hospital outpatient department; NOPAIN, Non-Opioids Prevent Addiction in the Nation.

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.

Important Safety Information

- EXPAREL is contraindicated in obstetrical paracervical block anesthesia.
- 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.





UNDER THE NOPAIN ACT.

EXPAREL is the only covered single-dose therapy approved for both local and regional analgesia across surgeries qualifying for reimbursement²⁻⁴

EXPAREL is a non-opioid treatment proven to be safe and effective for postsurgical pain management^{5,6}

Long-lasting non-opioid option

that eliminates or reduces the need for opioids⁶⁻⁸

Superiority vs bupivacaine HCl

demonstrated in 2 LENB pivotal trials and a phase 4 local infiltration study in TKA*6-8

Broad range of applications

across orthopedics, soft tissue, and pediatrics⁵

2 convenient vial sizes, 10 mL and 20 mL, which offer flexibility based on surgical site and method of administration⁵



Your efforts are crucial for expanding patient access to non-opioids in your health system.

- Reevaluate the utilization of qualifying non-opioids within your system
- In Medicare populations, consider expanding access across surgical procedures within outpatient settings using code J0666

LENB, lower-extremity nerve block; NOPAIN, Non-Opioids Prevent Addiction in the Nation; TKA, total knee arthroplasty.

*EXPAREL showed superiority to bupivacaine in the adductor canal nerve block pivotal trial, the sciatic nerve block in the popliteal fossa pivotal trial, and the phase 4 local infiltration study in TKA.⁶⁻⁸

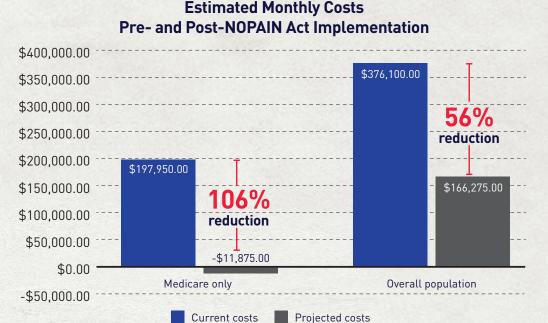
Important Safety Information (cont'd)

- 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.
- 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.





ASP+6% reimbursement via the NOPAIN Act can help reduce costs in the HOPD setting⁹



ASP+6% = reimbursement of 106% of the average sales price.

This example is hypothetical and for illustrative purposes only.

ASC, ambulatory surgical center; HOPD, hospital outpatient department;

NOPAIN, Non-Opioids Prevent Addiction in the Nation.

Assumptions:

- Medicare represents 50% of the population for target surgeries
- System currently conducts 5,000 outpatient surgeries per month in the HOPD setting
- EXPAREL is currently used in 25% of these outpatient surgeries
- EXPAREL usage is split between 20 mL (60%) and 10 mL (40%)
- Commercial reimbursement is based on the assumption that only a small proportion (10%) of payers currently provide separate HOPD reimbursement
- Pricing is based on wholesale acquisition cost and does not include any customer discounts or 340B pricing

With EXPAREL and NOPAIN Act reimbursement, your health system can provide proven postsurgical outcomes for your HOPD and/or ASC patients while reducing your overall net cost

Important Safety Information (cont'd)

- 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.





Five steps to help your health system apply the new NOPAIN Act reimbursement

The NOPAIN Act provides additional ASP+6% reimbursement to expand access to non-opioids like EXPAREL.^{2,3} Consider the following steps to help ensure that your system is ready to implement this new Medicare policy change.







ENSURE

billing and coding teams
thoroughly understand the
key tenets of the NOPAIN
Act, specifically focusing on
additional reimbursement for
non-opioid pain management
options like EXPAREL



Medicare allows you to update claims within 1 year of the date of service, in case your system has not operationalized the NOPAIN Act reimbursement by January 1

CAPTURE

the current utilization of qualifying non-opioid options in postsurgical settings and explore service lines with high outpatient volume or potential for outpatient transition to better understand coding needs



Identifying the need for additional documentation based on service line expansion may help facilitate accurate and timely reimbursement

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HCPCS code J0666 to capture the additional Medicare reimbursement for EXPAREL across all outpatient settings for dates of service on or after January 1, 2025*



Now that the code is available, perform tests to confirm that the HCPCS codes and workflows are correctly integrated and functioning

ASP+6% = reimbursement of 106% of the average sales price.

*For dates of service prior to January 1, 2025, Medicare reimbursement is available in ASCs when billing with C9290. For commercial or Medicare Advantage plans, please confirm with the individual payer.

ASC, ambulatory surgical center; CMS, Centers for Medicare & Medicaid Services; HCPCS, Healthcare Common Procedure Coding System; NOPAIN, Non-Opioids Prevent Addiction in the Nation.

Important Safety Information (cont'd) 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.





Five steps to help your health system apply the new NOPAIN Act reimbursement (cont'd)



INFORM

financial, clinical, and operational stakeholders to ensure system-wide readiness. Educate stakeholders on the importance of accurate documentation to support billing and coding



TRACK

claims submissions and key outcomes to monitor reimbursement and impact of implementation



Relevant stakeholders may include but are not limited to:

- Revenue Cycle Management/Billing & Coding
- Director of Pharmacy, Clinical Pharmacists
- Health System Leaders (Chief Pharmacy/Operations/Medical/Officer)
- Orthopedic Surgeons, General Surgeons, Anesthesiologists

P&T, Pharmacy and Therapeutics.



Gathering data can aid in leadership discussions and help address P&T Committee queries

Make the pact today and commit to bringing the NOPAIN Act to your health system, starting January 1, 2025

Important Safety Information (cont'd)

Warnings and Precautions Specific to EXPAREL (cont'd)

 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.





Indication and Important Safety Information

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.

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- 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.
- 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.







Indication and Important Safety Information (cont'd)

Warnings and Precautions Specific to EXPAREL

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- 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.

Full Prescribing Information is available at <u>www.EXPARELpro.com</u>. For more information, please visit <u>www.EXPARELpro.com</u> or call 1-855-793-9727.



Key tips to help you prepare your health system

- ✓ Reevaluate the utilization of qualifying non-opioids within your health system
- Identifying the need for additional documentation based on service line expansion may help facilitate accurate and timely reimbursement
- Perform tests to confirm that the codes and workflows are correctly integrated and functioning
- ✓ Educate relevant stakeholders on the importance of accurate documentation to support billing and coding
- ✓ Medicare allows you to update claims within 1 year of the date of service, in case your system has not operationalized NOPAIN Act reimbursement by January 1
- ✓ Gathering data can aid in leadership discussions and help address P&T Committee queries
- ✓ Once you've implemented NOPAIN Act reimbursement for your Medicare patients, consider leveraging this new ASP+6% CMS reimbursement in the HOPD when negotiating contracts with commercial payers

For reimbursement support or questions:







Helpline **1-855-793-9727**

reimbursement@pacira.com

EXPARELpro.com/reimbursement

Scan the QR code on the right to contact a Pacira representative or learn more about the NOPAIN Act



ASP+6% = reimbursement of 106% of the average sales price.

CMS, Centers for Medicare & Medicaid Services; HOPD, hospital outpatient department; NOPAIN, Non-Opioids Prevent Addiction in the Nation; P&T, pharmacy and therapeutics.

References: 1. CMS.gov. Published October 10, 2024. Accessed October 4, 2024. https://www.cms.gov/files/document/2024-hcpcs-application-summary-quarter-3-2024-drugs-and-biologicals-posted-10-02-2024.pdf 2. Consolidated Appropriations Act 2023. Accessed June 5, 2024. https://www.congress.gov/117/bills/hr2617/BILLS-117hr2617enr.pdf 3. CMS.gov. 2024. Accessed June 4, 2024. https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price 4. Federal Register. Accessed August 15, 2024. https://federalreg-ister.gov/d/2024-15087 5. EXPAREL. Prescribing Information. San Diego, CA, Pacira Pharmaceuticals, Inc. November 2023. 6. Schwartz G, et al. *J Clin Anesth*. 2024;94:111402. doi:10.1016/j.jclinane.2024.111402 7. Gadsden J, et al. Poster presented at: 48th Annual Regional Anesthesiology and Acute Pain Medicine Meeting; April 20, 2023; Hollywood, FL. Poster 4381. 8. Mont MA, et al. *J Arthroplasty*. 2018;33(1):90-96. doi:10.1016/j.arth.2017.07.024 9. Merative Micromedex. *RED BOOK*. Accessed June 24, 2024. https://micromedexsolutions.com



