EFFECTIVE JANUARY 1, 2025

Bill J0666 when using EXPAREL across all outpatient settings¹

BILLING AND REIMBURSEMENT GUIDE

The information contained herein is for general reference and informational purposes only. Each healthcare provider is ultimately responsible for determining the appropriate codes, coverage, and payment for individual patients. Pacira does not guarantee third-party coverage or payment for EXPAREL or reimburse for claims that are denied by third-party payers.

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.



The NOPAIN Act Expands Reimbursement for EXPAREL

With Congress's recent passing of the NOPAIN Act, reimbursement continues to expand for EXPAREL.²

The NOPAIN Act—effective as of January 1, 2025—mandates that Medicare provide ASP+6% reimbursement for qualifying non-opioids, like EXPAREL, across all outpatient settings (both ASC and HOPD).^{2,3}

With new reimbursement for qualifying non-opioid options, the NOPAIN Act delivers2:

EXPANDED

reimbursement to the HOPD setting

IMPROVED

choice by removing cost barriers in order to facilitate access to non-opioids

REDUCED

net cost by mitigating financial concerns of non-opioid postsurgical pain management

PROVEN

non-opioids that either replace or reduce opioid consumption

This guide is designed to help your practice with billing and reimbursement for EXPAREL across payer types and settings of care.

Learn more about the NOPAIN Act at NOPAINpact.com



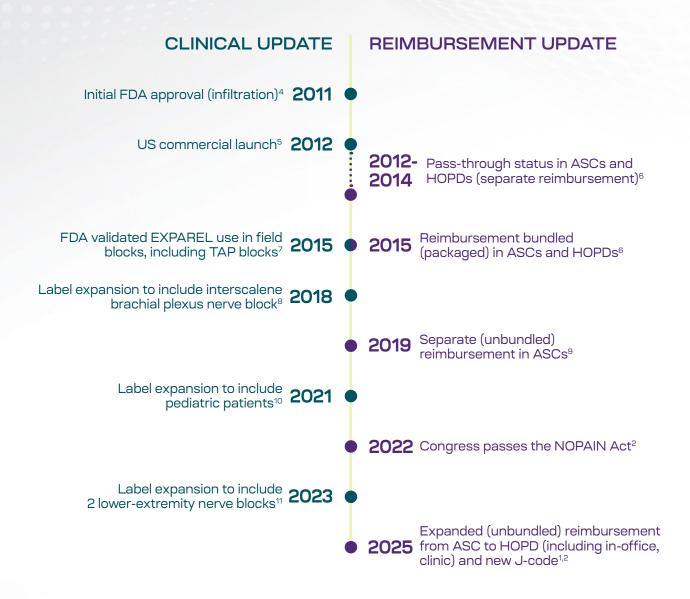
ASP+6% = 106% reimbursement of the average sales price.
ASC, ambulatory surgical center; ASP, average sales price; HOPD, hospital outpatient department; NOPAIN, Non-Opioids Prevent Addiction in the Nation.

IMPORTANT SAFETY INFORMATION (continued)

- 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.



Reimbursement for EXPAREL has continued to improve since commercial launch



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ASC, ambulatory surgical center; FDA, US Food and Drug Administration; HOPD, hospital outpatient department; NOPAIN, Non-Opioids Prevent Addiction in the Nation; TAP, transversus abdominis plane.

IMPORTANT SAFETY INFORMATION (continued)

• 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.



EXPAREL Billing and Reimbursement Summary

EFFECTIVE JANUARY 1, 2025

Bill J0666 when using EXPAREL across all outpatient settings¹

MEDICARE

Since 2019, EXPAREL has separate Medicare reimbursement in the ASC setting, meaning that customers are reimbursed at ASP+6%.^{3,9}

With the NOPAIN Act, outpatient reimbursement is expanded to the HOPD setting starting January 1, 2025, meaning applicable claims will be reimbursed at ASP+6% across both the ASC and HOPD settings.^{2,3}

COMMERCIAL AND MEDICARE ADVANTAGE

Commercial and Medicare Advantage payers will reimburse based on contract terms with specific settings of care, including inpatient hospital, HOPD, or ASC; please contact payers to verify reimbursement

MEDICAID

Each state Medicaid agency and managed Medicaid organization sets its own coverage policies and payment rates

Once you've prepared your system for NOPAIN Act reimbursement, consider leveraging the new ASP+6% reimbursement for Medicare patients in hospital outpatient settings when negotiating contracts with commercial payers

Pacira cannot guarantee reimbursement.

ASP+6% = 106% reimbursement of the average sales price.
ASC, ambulatory surgical center; ASP, average sale price; HOPD, hospital outpatient department; NOPAIN, Non-Opioids Prevent Addiction in the Nation.

IMPORTANT SAFETY INFORMATION (continued)

 Because amide-type local anesthetics, such as bupivacaine, are metabolized by the liver, EXPAREL should be used cautiously in patients with hepatic disease.



EXPAREL Coding Information

National Drug Codes (NDCs) for EXPAREL

| NDC# (on package label) | EXPAREL dose/ vial size | Configuration | NDC# (for billing) |
|----------------------------|----------------------------|------------------|-----------------------|
| 65250-133-10 | 133 mg/10 mL | Single-dose vial | 65250-0133-10 |
| 65250-266-20 | 266 mg/20 mL | Single-dose vial | 65250-0266-20 |

Contact the patient's individual payer to confirm.

10-digit NDC numbers should always be converted into appropriate 11-digit NDC numbers when billing for reimbursement.

Dose and vial size varies based on administration and surgery type



133 mg

Small areas: Rotator cuff repair (RCR), foot/ankle, hand/wrist, anterior cruciate ligament repair, oral surgery, ISBPNB, adductor canal block, sciatic nerve block in the popliteal fossa

266 mg

Large areas: Transversus abdominis plane (TAP) blocks, total knee arthroplasty, total hip arthroplasty, colorectal, spine, breast reconstruction, C-section

ISBPNB, interscalene brachial plexus nerve block.

IMPORTANT SAFETY INFORMATION (continued)

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.



HCPCS Codes for EXPAREL

EFFECTIVE JANUARY 1, 2025

Bill J0666 when using EXPAREL across all outpatient settings¹

| HCPCS Code | Description | Billable Unit | Details |
|---------------------|--|---|---|
| J0666¹ | Injection, bupivacaine liposome, 1 mg | 1 billable unit = 1 mg (eg, 133 mg = 133 units, 266 mg = 266 units) | For dates of service on or after January 1, 2025, across outpatient settings |
| C9290 ¹ | Injection, bupivacaine liposome, 1 mg | 1 billable unit = 1 mg (eg, 133 mg = 133 units, 266 mg = 266 units) | For dates of service before January 1, 2025, in ASCs |
| J3490 ¹² | Unclassified drugs | 1 unit | For dates of service before January 1, 2025, for commercial payers who do not accept the C-code |

When billing for EXPAREL, be sure to bill as milligram (mg) dosage for the number of units (eg, 133 mg = 133 units, 266 mg = 266 units), not vials or mL¹

ASC, ambulatory surgical center; HCPCS, Healthcare Common Procedure Coding System.

IMPORTANT SAFETY INFORMATION (continued)

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.



HCPCS Modifier Codes for EXPAREL

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The HCPCS modifiers are used to provide additional billing information, such as when denoting product wastage (or lack thereof).

| HCPCS Modifiers ¹² | Description |
|-------------------------------|---|
| JZ | Zero drug amount discarded/not administered to any patient |
| JW | Drug amount discarded/not administered to any patient (indicate quantity discarded) |

Additional Codes

| Code Type | Description |
|-----------|--|
| Revenue | Use designated revenue code as instructed by your facility or contract |
| ICD | Use appropriate diagnosis code based on the patient's diagnosis and surgery type |
| CPT | Use the appropriate CPT code based on the type of surgery and product administration |

CPT, current procedural terminology; HCPCS, Healthcare Common Procedure Coding System; ICD, International Classification of Diseases.

IMPORTANT SAFETY INFORMATION (continued)

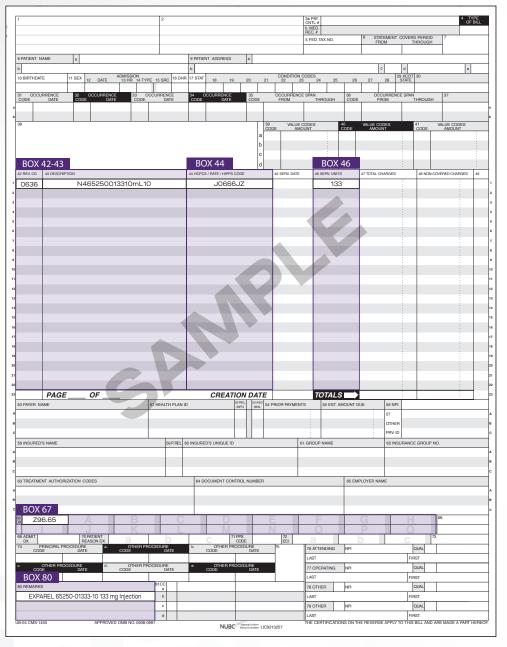
Warnings and Precautions for Bupivacaine-Containing Products

 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.



Sample CMS-1450 Claim Form for Outpatient Settings (HOPD)

Providers administering EXPAREL in an institutional setting, such as a hospital outpatient department, should use the CMS-1450 claim form (also known as UB-04) when billing and coding. Be sure to include the following information when filling out a CMS-1450 claim form.



This document is provided for your guidance only. Check with the patient's individual payer regarding the appropriate claim form and process to bill for EXPAREL.

Box 42

Enter the appropriate revenue codes corresponding to the HCPCS code in Box 44 (eg, 0636 revenue code for drugs requiring detailed coding); use designated revenue code as instructed by your facility or contract¹³

Box 43

When required, include qualifier N4 immediately followed by the 11-digit NDC. Next, enter the appropriate qualifier for the correct dispensing unit of measure (eg, mL [milliliter]), followed by the quantity (up to 3 decimal places)

• Note: Consult payer policies for NDC and unit of measure reporting requirements

Box 44

Enter the appropriate HCPCS/CPT code for EXPAREL, J0666.1

Indicate modifier as appropriate¹²:

- JZ on the same claim line if no drug wasted
- JW on a separate claim line if any drug wasted, with the amount wasted listed in Box 80

Box 46

Specify the number of units administered. For EXPAREL, 1 billable unit = 1 mg when billing with J0666. Be sure to bill as milligram (mg) dosage for the number of units, not vials or mL¹

- When using J0666, 133 billable units = 133 mg of EXPAREL; 266 billable units = 266 mg of EXPAREL
- When billing with a miscellaneous code (eg, J3490), bill 1 unit

Box 67

Enter the appropriate ICD-10-CM diagnosis code(s) corresponding to the patient's diagnosis. Use the highest level of specificity. List the primary diagnosis code first

Box 80

Include the drug name, NDC, strength, dosage administered, amount wasted, and route of administration

Please see Important Safety Information throughout and on page 14. Full Prescribing Information is available at www.EXPARELpro.com.

ASC, ambulatory surgical center; CMS, Centers for Medicare & Medicaid Services; CPT, current procedural terminology; HCPCS, Healthcare Common Procedure Coding System; HOPD, hospital outpatient department; ICD-10-CM, International Classification of Diseases, Tenth Revision; NDC, National Drug Code; UB, Uniform Billing.



Sample CMS-1500 Claim Form for Billing in the Physician Office and Freestanding ASC

Practices and ASCs that administer EXPAREL to patients should submit claims on the CMS-1500 claim form or its electronic equivalent. Be sure to include the following information when filling out a CMS-1500 claim form.

| HEALTH INSUF | | | | | | | | | | | |
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| CITY | | STATE | 8, RESERVED F | OH NUCC USE | | CIIY | | | | SIAIE | |
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| to process this claim. I als below. | o request payment of govern | ment benefits either | to myself or to the | party who accepts a | ssignment | services described | below. | | | | |
| SIGNED | | | DATE | | | SIGNED | | | | | |
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This document is provided for your guidance only. Check with the patient's individual payer regarding the appropriate claim form and process to bill for EXPAREL.

Box 19

Include the drug name, NDC, strength, dosage administered, amount wasted, and route of administration

Box 21

Enter the appropriate ICD-10-CM diagnosis code(s) corresponding to the patient's diagnosis. Use the highest level of specificity. Line A—primary diagnosis code

Box 24A

When required, include qualifier N4 immediately followed by the 11-digit NDC. Next, enter the appropriate qualifier for the correct dispensing unit of measure (eg, mL [milliliter]) followed by the quantity (up to 3 decimal places)

• Note: Consult payer policies for NDC and unit of measure reporting requirements

Box 24D

Enter the appropriate HCPCS/CPT code for EXPAREL, J06661

Indicate modifier as appropriate¹²:

- JZ on the same claim line if no drug wasted
- JW on a separate claim line if any drug wasted with the amount wasted listed in Box 24G

Box 24E

Specify the diagnosis letter from Box 21 relating to each CPT/HCPCS code listed in Box 24D

Box 24G

Specify the number of units administered. For EXPAREL, 1 billable unit = 1 mg when billing with J0666. Be sure to bill as milligram (mg) dosage for the number of units, not vials or mL¹

- When using J0666, 133 billable units = 133 mg of EXPAREL; 266 billable units = 266 mg of EXPAREL
- When billing with a miscellaneous code (eg, J3490), bill 1 unit

ASC, ambulatory surgical center; CMS, Centers for Medicare & Medicaid Services; CPT, Current
Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; HOPD, hospital
outpatient department; ICD-10-CM, International Classification of Diseases, Tenth Revision;
NDC, National Drug Code.

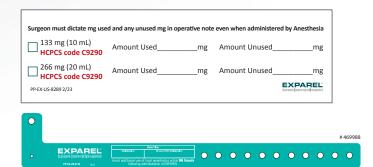


Billing and Reimbursement Tips and Reminders



DOCUMENTATION

- The amount of EXPAREL used in a surgery case is to be documented in the patient's medical record
- A best practice is for the surgeon to dictate the amount of EXPAREL used or unused in milligrams (mg) even when administered by anesthesia
- Your Pacira representative can provide your system with chart stickers and wrist bands to help your teams document the amount of EXPAREL administered





REIMBURSEMENT

- Medicare reimburses for EXPAREL in the 2 vial sizes that are available: 266 mg/20 mL and 133 mg/10 mL
- Medicare Advantage plans may also reimburse EXPAREL when billed with HCPCS code J0666. Check with the patient's individual payer to confirm¹
- For commercial plans, check your HOPD/ASC contracts or contact the patient's individual payer to verify the reimbursement amount
 - Please notify the payer that you would like to pursue contractual options, including reimbursement for EXPAREL
 - If your HOPD/ASC successfully negotiates reimbursement for EXPAREL with any
 of its commercial payers, it is crucial to notify your teams to raise awareness of the
 available reimbursement
 - For questions on how to navigate payer challenges, contact your Pacira representative
- Your Pacira representative can provide your team with a list of local payers who reimburse for EXPAREL use in the HOPD and ASC settings for you to help notify your teams

ASC, ambulatory surgical center; HCPCS, Healthcare Common Procedure Coding System; HOPD, hospital outpatient department.



Billing and Reimbursement Tips and Reminders (continued)

EFFECTIVE JANUARY 1, 2025

Bill J0666 when using EXPAREL across all outpatient settings¹



BILLING

- Bill with HCPCS code J0666 whenever EXPAREL is used, unless it is contractually prohibited1
- Be sure to review your contracts to determine if there are any provisions that do not allow the HOPD/ASC to bill for drugs and/or HCPCS code J06661
- Keep in mind that payer contract policies sometimes include provisions that allow for a drug, such as EXPAREL, to be covered even if it is not included in the HOPD/ASC fee schedule
- · Check with the patient's individual payer to understand the appropriate policies
- Consistent billing of EXPAREL regardless of reimbursement can provide the payer with the
 necessary information to ensure that payers understand the types of procedures that could
 benefit from EXPAREL, increasing the likelihood of securing reimbursement

Remember, payers may not know that EXPAREL was used or is in demand unless it is billed. Consistent billing of EXPAREL may increase opportunities for payers to add EXPAREL to their approved HOPD/ASC list and/or your contract

ASC, ambulatory surgical center; HCPCS, Healthcare Common Procedure Coding System; HOPD, hospital outpatient department.



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.
- 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.

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.



References: 1. CMS.gov. Published October 10, 2024. Accessed October 4, 2024. https://www.cms.gov/files/document/2024-hcpcs-application-summaryquarter-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/partb-drugs/average-drug-sales-price; 4. Pacira Pharmaceuticals, Inc. announces U.S. FDA approval of EXPAREL™ for postsurgical pain management. News release. Pacira Pharmaceuticals. Published October 31, 2011. Accessed October 25, 2024. https://investor.pacira.com/news-releases/news-release-details/ pacira-pharmaceuticals-inc-announces-us-fda-approval-expareltm; 5. Pacira Pharmaceuticals, Inc. announces commercial availability of EXPAREL®. News release. Pacira Pharmaceuticals. Published April 9, 2012. Accessed October 25, 2024. https://investor.pacira.com/news-releases/news-release-details/ pacira-pharmaceuticals-inc-announces-commercial-availability; 6. Federal Register. Medicare program: changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and quality reporting programs; revisions of organ procurement organizations conditions of coverage; prior authorization process and requirements for certain covered outpatient department services; potential changes to the laboratory date of service policy; changes to grandfathered children's hospitals-within-hospitals; notice of closure of two teaching hospitals and opportunity to apply for available slots. Published November 12, 2019. Accessed October 25, 2024. https://www.govinfo.gov/content/pkg/FR-2019-11-12/pdf/2019-24138.pdf; 7. Food and Drug Administration. Published December 14, 2015. Accessed October 25, 2024. https://media.corporate-ir.net/media_files/IROL/22/220759/The_Warning_Letter_Withdrawal_ Letter.pdf; 8. Pacira announces FDA approval of supplemental new drug application for EXPAREL® as a nerve block to produce regional analgesia. News release. Pacira Pharmaceuticals. Published April 6, 2018. Accessed October 25, 2024. https://investor.pacira.com/news-releases/news-release-details/pacira-announcesfda-approval-supplemental-new-drug-application; 9. Centers for Medicare and Medicaid Services and American Dental Association establish new reimbursement for EXPAREL. News release. Pacira Pharmaceuticals. Published November 2, 2018. Accessed October 25, 2024. https://investor.pacira.com/news-releases/newsrelease-details/centers-medicare-and-medicaid-services-and-american-dental; 10. Pacira announces FDA approval of supplemental new drug application for EXPAREL® (bupivacaine liposome injectable suspension) in pediatric patients. News release. Pacira Pharmaceuticals. Published March 22, 2021. Accessed October 25, 2024. https://investor.pacira.com/news-releases/news-release-details/pacira-announces-fda-approval-supplemental-new-drug-0; 11. Pacira announces FDA approval of expanded EXPAREL label to include two additional nerve block indications. News release. Pacira Pharmaceuticals. Published November 10, 2023. Accessed October 25, 2024. https://investor.pacira.com/news-releases/news-release-details/pacira-announces-fda-approval-expanded-exparel-labelinclude-two; 12. Centers for Medicare & Medicaid Services. HCPCS Quarterly Update (October 2024). Updated September 11, 2024. Accessed October 25, 2024. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update; 13. CMS.gov. Billing and coding: hospital outpatient drugs and biologicals under the Outpatient Prospective Payment System (OPPS) (A55913). Updated April 23, 2020. Accessed October 25, 2024. https://www.cms.gov/ medicare-coverage-database/view/article.aspx?articleId=55913



Claim Submission Checklist

- ✓ Confirm with your patient's individual payer to verify reimbursement
 - If Medicare, reimbursement is available across the ASC and HOPD settings
 - If commercial or Medicare Advantage, contact payers to verify
- ✓ Include the HCPCS code for EXPAREL: J0666¹
- ✓ Be sure to bill as milligram (mg) dosage for the number of units (eg, 1 billable unit = 1 mg), not vials or mL, when using J0666¹
- ✓ Utilize the appropriate modifier to document that the entire single-dose vial of EXPAREL was used (JZ) or to document that a portion of the vial was discarded (JW)¹²
- ✓ Include the drug name and the 11-digit NDC to support utilization of J0666
- ✓ Ensure that the revenue code(s) align(s) to the patient's individual payer's policy

For reimbursement support or questions:



Reimbursement Helpline: 1-855-793-9727



reimbursement@pacira.com



www.EXPARELpro.com/reimbursement

ASC, ambulatory surgical center; HCPCS, Healthcare Common Procedure Coding System; HOPD, hospital outpatient department; NDC, National Drug Code.

