64430

64430 Injection, anesthetic agent; pudendal nerve

AMA Coding Notes:

Introduction/Injection of Anesthetic Agent (Nerve Block), Diagnostic or Therapeutic (For destruction by neurolytic agent or

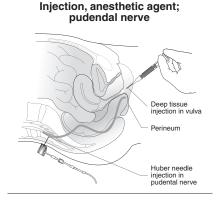
chemodenervation, see 62280-62282, 64600-64681) (For epidural or subarachnoid injection, see

62310-62319)

(64479-64487, 64490-64495 are unilateral procedures. For bilateral procedures, use modifier 50)

Plain English Description

The physician performs a pudendal nerve block by injecting an anesthetic agent into the nerve. Pudendal nerve block is used during the second stage of labor to provide pain relief, for pelvic floor relaxation when forceps delivery is needed, and to provide anesthesia of the perineum for creation or repair of an episiotomy. The block may be administered via a transvaginal or transcutaneous perineal approach. Using a transvaginal approach, the ischial spine on the first side to be injected is palpated. A Huber needle is used to limit the depth of submucosal penetration. The needle is passed through the sacrospinous ligament and advanced about 1 cm. The physician ensures that the needle is in the proper location and that it has not penetrated the pudendal vessels by pulling back on the syringe. If blood is aspirated the needle is reposited. Aspiration is again performed and if no blood is present, the anesthetic is injected. The procedure is repeated on the opposite side. Using a transcutaneous perineal approach, the ischial tuberosity is palpated and the needle introduced slightly medial to the tuberosity. The needle is advanced approximately 2.5 cm. Aspiration is performed to ensure that the needle is not in a blood vessel and then the anesthetic is injected. The needle is withdrawn and directed into the deep superficial tissue of the vulva and anesthetic is again injected to block the ilioinguinal and genitofemoral components of the pudendal nerve. This is repeated on the opposite side.



ICD-9-CM Diagnostic Codes

100-2-0141	Diagnostic coues
185	Malignant neoplasm of prostate of
236.5	Neoplasm of uncertain behavior
	of prostate of
338.11	Acute pain due to trauma
338.18	Other acute postoperative pain
338.19	Other acute pain
338.21	Chronic pain due to trauma
338.28	Other chronic postoperative pain
338.29	Other chronic pain
338.3	Neoplasm related pain (acute) (chronic)
338.4	Chronic pain syndrome
353.1	Lumbosacral plexus lesions
353.4	Lumbosacral root lesions, not elsewhere
	classified
617.3	Endometriosis of pelvic peritoneum $ Q $
618.7	Old laceration of muscles of pelvic floor 9
618.83	Pelvic muscle wasting Q
625.5	Pelvic congestion syndrome $\ Q$
ICD-10-CM	A Diagnostic Codes
C76.3	Malignant neoplasm of pelvis
C79.89	Secondary malignant neoplasm of other
	specified sites

	specified sites
G58.8	Other specified mononeuropathies
G89.11	Acute pain due to trauma
G89.18	Other acute postprocedural pain
G89.21	Chronic pain due to trauma
G89.28	Other chronic postprocedural pain
G89.29	Other chronic pain
G89.3	Neoplasm related pain (acute) (chronic)
G89.4	Chronic pain syndrome
N80.3	Endometriosis of pelvic peritoneum
N80.4	Endometriosis of rectovaginal septum and
	vagina
N94.810	Vulvar vestibulitis
N94.818	Other vulvodynia
N94.819	Vulvodynia, unspecified
N94.89	Other specified conditions associated with
	female genital organs and menstrual cycle
071.89	Other specified obstetric trauma
R10.2	Pelvic and perineal pain
S34.6XX	Injury of peripheral nerve(s) at abdomen,
	Increase la parte parte de la contra

- lower back and pelvis level
 \$34.8XX Injury of other nerves at abdomen, lower back and pelvis level
- S34.9XX Injury of unspecified nerves at abdomen, lower back and pelvis level
- S38.03X Crushing injury of vulva

1

- S39.848 Other specified injuries of external genitals
- S39.94X Unspecified injury of external genitals

ICD-10-CM Coding Notes

Refer to your ICD-10-CM book for a list of all 7th character extensions for codes requiring a 7th digit character. For some procedures, only certain 7th characters will apply. Review the 7th character descriptions and coding guidelines to ensure that the appropriate 7th character is assigned.

CCI Coding Note

See Appendix A for CCI edits.

AMA CPT Assistant

Fall 1993:13, Sep 2004:13

Pub 100

No Pub 100 references apply.

Facility RVUs Global: XXX				
Code	Work	PE Facility	MP	Total Facility
64450	.75	.49	.07	1.31

Non-facility RVUs

Code	Work	PE Non- Facility	MP	Total Non- Facility
64450	.75	1.46	.07	2.28

Modifiers (PAR)

Mod 50	Mod 51	Mod 62	Mod 66	Mod 80
1	2	0	0	1

CPT® Procedural Coding



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What is Perineal Pain?



Perineal pain occurs adjacent to the anus. Typically the pain or discomfort is located in the area between the anus and vagina in women, and between the anus and the scrotum or penis in men. Perineal pain is related to peri-anal pain, and sometimes they are used

interchangeably. Peri-anal pain is more often caused by GI issues such as anal fissures, hemorrhoids, etc.

Perineal pain can vary in severity. Perineal pain can be severe or felt as mild perineal discomfort or soreness.

The common causes of chronic perineal pain in men n are prostatitis / pelvic pain syndrome in men. Perineal pain in women is often related to interstitial cystitis / pelvic pain syndrome in women.

Patient Information

0

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Table 2

Cumulative NRS pain scores comparing liposomal bupivacaine versus placebo during the first 72 hours following hemorrhoidectomy

Cumulative pain score (AUC ₀₋₇₂)	Placebo	Liposomal bupivacaine	P value ^a
12 hours	63	29	<.0001
24 hours	103	57	<.0001
36 hours	131	79	<.0001
48 hours	155	99	<.0001
60 hours	179	120	<.0001
72 hours	202	142	<.0001

*Analysis of variance with treatment and site as the main effects

The NRS is an 11-point numeric rating scale for pain intensity (0="no pain" and 10="worst possible pain") that has been validated in the postsurgical setting. In addition to individual NRS scores, this study also included an assessment of the cumulative pain intensity, represented by the area under the curve (AUC) of scores over a 72-hour period. This measure was recommended by FDA as a means of assessing pain control throughout the postsurgical period, rather than at a single designated time point. A lower number indicates less cumulative pain.

Formulary/Source: Refs 26,42

Table 2: Cumulative NRS pain scores comparing liposomal bupivacaine versus placebo during the first 72 hours following hemorrhoidectomy

CLINICAL TRIALS: Hemorrhoidectomy, June 1. 2012

http://formularyjournal.modernmedicine.com

In a pivotal phase 3 trial, a 266 mg/30 mL infiltration dose of liposomal bupivacaine reduced cumulative postsurgical pain by 30% compared with placebo in the 72 hours after hemorrhoid surgery, as measured by the AUC for the numeric rating scale (NRS) scores of pain intensity (P<.0001: Table 2).²⁶ This was a multicenter, randomized, double-blind trial that enrolled 189 patients aged 18 to 86 (mean 48) years across 12 European sites. Patients were randomly assigned at a 1:1 ratio to receive either liposomal bupivacaine or placebo (saline) administered by wound infiltration using a standard block procedure. All patients had a cumulative incision length of ≥3 cm and underwent a 2- or 3-column excisional hemorrhoidectomy under general anesthesia using the Milligan-Morgan technique. Pain intensity was assessed using the NRS (Table 2), and opioid rescue medication was available to both groups. Approximately 3 times the number of patients in the liposomal bupivacaine group as in the placebo group did not require any opioid rescue medication (27.7% vs 9.7% of placebo recipients; P<.0008) in the 72 hours postsurgery. Likewise, consumption of supplemental opioid medication in liposomal bupivacaine recipients was 45% lower than in placebo recipients over the course of 72 hours ($P \le .0006$). The median time to first use of opioid rescue was also significantly delayed by the use of liposomal bupivacaine. Patients in the placebo group first used opioid medication within an hour of surgery whereas the first use of opioids occurred after approximately 14 hours in the liposomal bupivacaine group (P<.0001). Assessment of patient satisfaction using a Likert scale revealed that patients favored the use of liposomal bupivacaine at 24 hours and 72 hours (P=.0007 in both cases). Overall, 95% of patients in the liposomal bupivacaine group versus 73% of those in the placebo group were "extremely satisfied" or "satisfied" with their postsurgical anesthesia.

Liposomal bupivacaine has also been compared with bupivacaine HCl in a phase 2 hemorrhoidectomy study.³¹ In this randomized, double-blind study, 100 patients scheduled to undergo 2- or 3-column excisional hemorrhoidectomy under regional or spinal anesthesia were randomized to 1 of 4 treatment groups: bupivacaine HCl 75 mg or liposomal bupivacaine at a dose of 67 mg, 200 mg, or 266 mg. At a dose of 266 mg, liposomal bupivacaine significantly reduced pain intensity over the first 72 hours by 47% (P<.05), opioid use by 66% (P<.05), and opioid-related side effects by 89% (P<.05), relative to bupivacaine HCl 75 mg over the first 3 postsurgical days. Opioid consumption (in morphine-equivalent doses) was at least 50% lower in the group receiving liposomal bupivacaine than in the bupivacaine HCl group during the 72 hours after surgery (P=.0068). Furthermore, liposomal bupivacaine was associated with significantly lower cumulative pain intensity during the first 96 hours after surgery (P<.05) and a significantly delayed need for rescue opioids compared with bupivacaine HCl; the median time to first opioid use was 19 hours with liposomal bupivacaine HCl group (P<.01).

Reporting Perioperative Peripheral Nerve Blocks



Key elements for documenting regional peripheral block procedures are as follows:

- Name of block performed
- Approach used

4. 8 key statistics on healthcare provider IT budgets

in 2016

2/21/2016

Reporting Perioperative Peripheral Nerve Blocks

- Patient condition
- Indications for block
- Patient position
- Needle design, technique, depth of insertion
- Local anesthetic used
- Dose,
- Monitoring/narrative of event/description of motor response
- Patient vital signs following procedure

Documentation requirements:

• Requirement to document that regional block is separate from the operative anesthetic — In order to bill for any type of block separate from the anesthetic, the reason for performing the block must be for the provision of postoperative pain management. If a different provider provides the regional block than the provider who provides the surgery (anesthesiologist), a documented request must be noted by the surgeon indicating that the intent of the block is for postoperative pain control. This may be documented as a physician order.

 Requirement to document that the regional block is separate from routine postoperative surgical care —An order from the surgeon is required in addition to documentation requesting the regional block that daily analgesia management is planned. This activity must be defined as separate from routine postoperative pain management.

CPT 64400-64520

It is appropriate to report the codes below in conjunction with an operative anesthesia service when a peripheral nerve block injection for post operative pain management is performed.

These injections are administered pre, inter, or post- operatively.

СРТ	DESCRIPTION
64415	Injection, anesthetic agent; brachial plexus, single
64416	Injection, anesthetic agent; brachial plexus, continuous infusion by catheter (including catheter placement)
64417	Injection, anesthetic agent; axillary nerve
64418	Injection, anesthetic agent; suprascapular nerve
64445	Injection, anesthetic agent; sciatic nerve, single
64446	Injection, anesthetic agent; sciatic nerve, continuous infusion by catheter (including catheter placement)
64447	Injection, anesthetic agent; femoral nerve, single
64448	Injection, anesthetic agent; femoral nerve, continuous infusion by catheter (including catheter placement)
64449	Injection, anesthetic agent; lumbar plexus, posterior approach, continuous infusion by catheter (including catheter placement)
64450	Injection, anesthetic agent; other peripheral nerve or branch
64520	Injection, anesthetic agent; lumbar or thoracic (paravertebral sympathetic)

Modifiers

The modifiers below are approved modifiers for use with peripheral block procedures. Payment will only be made once

http://www.beckersasc.com/asc-coding-billing-and-collections/reporting-perioperative-peripheral-nerve-blocks.html

5. 2 ASCs adding non-clinical staff members

6. PA demand climbs healthcare job placement rankings? 4 takeaways

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Top 40 Articles from the Past 6 Months

1. How HR outsourcing improves the ASC's bottom line: 5 key areas

2. CMS cuts to colonoscopy reimbursement finalized: 3 things to know

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4. The ASC infection control manifesto: 4 essentials for survey readiness

5. UnitedHealthcare announces updated site of service guidelines for 8 outpatient procedures: 5 things to know

6. Anesthesiologist Dr. Christopher Robert found dead on roadside: 5 things to know

7. The ASC industry won't be the same: 2 significant changes slowly gaining momentum

8. 8 things to know about ASC reimbursement

9. Gastroenterologist Dr. Andrew Chan found stabbed to death; son arrested: 5 things to know

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11. 10 of the biggest GI/endoscopy stories in 2015

12. 18 things to know about anesthesia

13. How Medicare colonoscopy reimbursement cuts could impact GI in 2016 & beyond

14. Rising stars: 63 ASC leaders under 40

15. 100 new outpatient surgery centers in 2015

16. 110 ASC benchmarks I 2015

17. CMS finalizes ASC payment, policy changes: 5 things to know

18. Feeling tired? Stressed? You're not alone - 10 key thoughts on physician burn-out

19. Where is physician ownership headed? Key thoughts from Dr. Blake Curd on POHs, ASCs

20. 5 statistics on ASC administrator, staff salaries

21. The best decision I've made this year: 9 ASC administrators discuss

22. Are independent physicians facing a dependent future?

23. PA salary on the rise - 5 points

24. Possible pay cut for physicians through 2025 - 8 takeaways

2/21/2016

Reporting Perioperative Peripheral Nerve Blocks

during an episode of care. Modifier -59 is required to distinguish the block from the intraoperative anesthetic technique. This is especially important when the same provider performs the nerve block and the intraoperative anesthesia.

Modifier	Description
<mark>-50</mark>	Bilateral procedure
<mark>-59</mark>	Distinct procedural service
-73	Discontinued outpatient/ambulatory surgery center (ASC) procedure prior to the administration of anesthesia
-74	Discontinued outpatient/ambulatory surgery center (ASC) procedure after the administration of anesthesia
-LT	Left side (used to identify procedures performed on the left side of the body)
-RT	Right side (used to identify procedures performed on the right side of the body)

Deficient documentation for pain block procedures occurs when:

- The postoperative pain block is dictated within the operative report and no separate procedure note for the block is provided.
- A postoperative pain procedure report that does not include "postoperative pain management" under indications
- is incomplete
- Statements like "patient was given a femoral block followed by endotracheal anesthesia" are not complete without a physician order (verbal or written) requesting the block for pain management.
- "Anesthesia type regional and general": Documentation must be inclusive of a block procedure report, with clear documentation relating to post operative pain control.

Diagnostic coding

Coding and sequencing for pain are dependent on the physician documentation in the medical record and application of the official coding guidelines for inpatient care.

Postoperative pain can be coded as a secondary diagnosis when the patient develops an "unusual or inordinate amount of postoperative pain" after outpatient surgery. Do not assign a code for the postoperative pain if it is routine or expected after surgery.

Learn more about GENASCIS.

References

CPT Assistant, Volume 7, Issue 2, February 1997

CPT Assistant, Volume 8, Issue 7, July 1998

ICD-9-CM Official Coding Guidelines

NHIC Anesthesia Billing Guide - www.medicarehic.com/providers/pubs/Anesthesia%20Billing%20Guide.pdf

CCI Policy Manual - www.cms.hhs.gov/nationalcorrectcodinited/01_overview.asp

The information provided should be utilized for educational purposes only. Please consult with your billing and coding expert. Facilities are ultimately responsible for verifying the reporting policies of individual commercial and MAC/FI carriers prior to claim submissions.

25. 21 gastroenterologists leading osteopathic fellowship programs

26. California ASCs to settle out-of-network class action with United Health: 5 key notes

27. A surprising uptick: More physicians not selling practices

28. The heart of ASCs — 5 key qualities for successful nurse leaders

29. Healthcare is barreling toward integration -5 key thoughts on where ASCs fit

30. 10 statistics on GI physician salary & bonus

31. Borland-Groover Clinic to drop Blue Cross & Blue Shield contract due to proposed 50% reimbursement cut: 5 things to know

32. Anesthesiologist salary & bonus: 10 statistics

33. ICD-10 troubleshooting: Ounce of prevention worth a pound of cure

34. 15 things to know about gastroenterology for ASCs

35. The biggest challenges for GI in 2016: 3 gastroenterologists weigh in

36. 10 things for physicians to know about PAs, RNs & APNs

37. Dr. George Winch sues hospital over revoked privileges after hospital acquires ASC: 5 key notes

38. 164 ASC industry physician leaders to know – 2016

39. The state of the ASC industry: Key thoughts from Surgical Care Affiliates CEO Andrew Hayek

40. ASC quality data in Q1 2015: 7 statistics



EXPAREL® (bupivacaine liposome injectable suspension) PATIENT-FOCUSED PAIN CONTROL REIMBURSEMENT GUIDE

This Reimbursement Guide guide is made available by Pacira Pharmaceuticals, Inc. ("Pacira") for educational purposes only. You should note that rules concerning International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) diagnosis codes, Current Procedural Terminology (CPT®) procedure codes, and Healthcare Common Procedure Coding System (HCPCS) Level II product codes and other billing and identification codes change from time to time and you are responsible for determining whether the use described in this Reimbursement Guide is consistent with current rules and regulations. Pacira disclaims responsibility for any liability attributable to end use of the Reimbursement Guide and makes no warranty, express or implied, regarding the contents of this Instructional Manual. Pacira will not be liable for any claims attributable to any errors, omissions, or other inaccuracies in the information or material contained in the Reimbursement Guide. In no event shall Pacira be liable for direct, indirect, special, incidental, or consequential damages arising out of the use of such information or material.

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Indication

EXPAREL is indicated for single-dose administration into the surgical site to produce postsurgical analgesia.

Important Safety Information

EXPAREL is contraindicated in obstetrical paracervical block anesthesia.

EXPAREL has not been studied for use in patients younger than 18 years of age.

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.

Other formulations of bupivacaine should not be administered within 96 hours following administration of EXPAREL.

Monitoring of cardiovascular and neurological status, as well as vital signs should be performed during and after injection of EXPAREL as with other local anesthetic products. 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.

In clinical trials, the most common adverse reactions (incidence ≥10%) following EXPAREL administration were nausea, constipation, and vomiting.

Pacira understands that appropriate and accurate reimbursement for treatment is a critical aspect of meeting healthcare needs.

This reimbursement guide is intended to provide general coding, coverage, and payment information applicable to EXPAREL and can be used to assist providers and clarify frequently asked reimbursement questions. If you still have questions about how to complete a claim for services that include EXPAREL after reviewing this guide, you can also contact the payer directly for guidance.

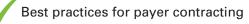
This guide contains:

Billing and coding information for EXPAREL, including various codes that may be used to report EXPAREL

Guidance on claims submission, including sample claims and help with electronic claims completion



Resources like sample letters of medical necessity and appeals



To use this guide, refer to the relevant section for content of interest, paying special attention to both the site of service where EXPAREL is being administered and the payer responsible for covering the services provided to the patient. Coding, coverage, and payment can all vary substantially by payer and site of service, so it is important to confirm this information to ensure that you are referencing the most appropriate information related to EXPAREL reimbursement information.

It is always the provider's responsibility to determine and submit appropriate codes, modifiers, and claims for rendered services in accordance with all applicable federal and state laws. Every effort is made to ensure the information contained herein is accurate at the time of publication and is in no way a guarantee of coverage or payment.

Purpose

The benefits of proper billing and coding for medical procedures are two-fold – facilitating timely reimbursement by standardizing claim submission and ensuring appropriate reimbursement based on previously agreed upon rates. Payers may accept billing for EXPAREL® (bupivacaine liposome injectable suspension) using either the currently assigned C-code, C9290 – Injection, bupivacaine liposome, 1mg, (Note: 1 vial of EXPAREL is 266mg and is billed in units of 1mg, so if one full vial is used, it would be 266 units) or miscellaneous J-codes which may require additional steps be fulfilled for adequate claim submission. Because different payers have different standards for billing it is important to be aware of appropriate options, understand contractual requirements, and confirm specific guidelines.

General Coverage Information

EXPAREL is a local analgesic that uses bupivacaine in combination with the delivery platform, DepoFoam[®], and is administered as an intraoperative injection to treat pain at the source. (Pacira Pharmaceuticals, Inc.) Coding, coverage, and payment for EXPAREL depend on the payer type and whether EXPAREL is administered in the inpatient or outpatient setting.

For Medicare beneficiaries, Medicare Part A covers treatment performed in the hospital inpatient setting and sets per discharge payment rates for 751-severity-adjusted Medicare severity diagnosis related groups (MS-DRGs), which are based on patients' clinical conditions and treatment strategies (Medicare Payment Advisory Commission (MedPAC) 2013). Payment is bundled and based on the patient's diagnosis. *In instances where EXPAREL is used during treatment of a Medicare patient during an inpatient stay, EXPAREL is a covered service, but not paid separately, although the product and associated procedures may be listed as line items on the claim.*

Medicare Part B covers treatments performed in the physician office, hospital outpatient, or ambulatory surgery center (ASC) setting when deemed medically necessary. Coverage and coding requirements differ based on treatment setting. In instances where EXPAREL is used during treatment of a Medicare patient during a surgery performed in a hospital outpatient department or an Ambulatory Surgical Center, EXPAREL is a covered drug, but not paid separately, although the product and associated procedures, using C9290, should be listed as line items on the claim.

Private payer coverage and coding requirements can vary greatly by plan, so providers are encouraged to confirm reimbursement prior to treatment.

State Medicaid programs do not currently pay separately for EXPAREL in any site of care.

General Overview

Payers require providers to use standard coding systems to bill for EXPAREL® (bupivacaine liposome injectable suspension) on claims for payment in procedures where it is used. The International Classification of Disease, 9th edition, Clinical Modification (ICD-9-CM) diagnosis codes, Current Procedural Terminology (CPT®) procedure codes, and Healthcare Common Procedure Coding System (HCPCS) Level II product codes are recognized as national standards and are typically required when submitting claims for EXPAREL. This reimbursement guide reviews use of these codes as they are required for Medicare and most private payers. Some payers may require use of alternate codes or additional details, and providers should verify the correct coding nomenclature accordingly.

Coding and payment methodologies for EXPAREL itself most commonly use the HCPCS Level II codes, either C9290 when used in a hospital outpatient department or ASC for a Medicare patient or possibly the unclassified Jcode, J3490, for private insurance.



EXPAREL Billing and Coding With a C-Code

In 2014, the Centers for Medicare and Medicaid Services finalized a policy change such that all drugs and biologicals that function as a supply during a surgical procedure – i.e. are used in conjunction with or at the time of the surgical procedure - now have their reimbursement included in the reimbursement for the surgical procedure.

Over the last two years, the cost for EXPAREL has been captured in the Medicare data as facilities have billed C9290 - Injection, bupivacaine liposome, 1 mg - whenever EXPAREL was injected during a surgical procedure for a Medicare beneficiary allowing for these costs to be calibrated into the base payment for the surgical procedure where EXPARAL may be used.

Hospital outpatient departments and free standing ambulatory surgery centers should continue to bill C9290 - Injection, bupivacaine liposome, 1 mg - whenever EXPAREL is injected during a surgical procedure for a Medicare beneficiary in 2015.

C-code C9290 (Injection, bupivacaine liposome, 1 mg) may be accepted by other payers in various sites of service. One single-use vial of EXPAREL contains 266 units (or milligrams), which may be reported in two separate line items on a single claim, once with the number of units administered to the patient, and once with the number of units wasted. When billing wastage, the second line item should include the modifier –JW appended to C9290 with the number of corresponding units reported.

EXPAREL Billing and Coding With a Miscellaneous or Unclassified Code

Some private payers do not recognize code C9290 for EXPAREL and may require use of the miscellaneous or unclassified code J3490 (Unclassified drugs) instead. In these instances, payers typically will need additional information included with the claim to appropriately process reimbursement. If the J3490 code is used, payers typically require one or a combination of the following to be included in box 19 of the CMS-1500 form, field 80 (Remarks) of the UB-04 form, or the electronic 837P equivalent:

- Drug name/generic name
- Drug strength
- Dosage administered (because J3490 is not specific to EXPAREL and dosage administered is included separately, most payers require that the number of units billed be defaulted to 1)
- Route of administration
- National Drug Code (NDC)

Some payers also require additional documentation such as one or a combination of the following to accompany the claim for processing:

- Prescribing information
- FDA approval letter
- Purchase invoice
- · Relevant documentation to support medical necessity (eg, letter of medical necessity, chart or laboratory notes)

Depending on the level of detail in the information requested, claims submitted with miscellaneous or unclassified HCPCS codes may trigger manual review by the payer, resulting in potentially longer processing times for payment. Because payers may have different acceptable supplemental documentation requirements or reporting syntax for NDC or drug name, providers should carefully review payer contracts and miscellaneous or unclassified HCPCS code claim requirements prior to claim submission to avoid unnecessary delay or claim denials.

Payment Mechanisms for EXPAREL® (bupivacaine liposome injectable suspension)

ASC and hospital outpatient department reimbursement rates are housed on the CMS web site. Private payer reimbursement may be calculated using different methodology based on the Average Wholesale Price (AWP), Wholesale Acquisition Cost (WAC), or other pricing mechanisms. Providers should review their payer contracts to confirm reimbursement.

To find the most current ASC reimbursement rates, follow these steps:

- 1. Access www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment
- 2. Click on "Addenda Updates" in the left-hand navigation window
- Click on the quarterly "ASC Approved HCPCS Codes and Payment Rates" file in the Downloads section
- 4. Open the compressed file labeled "ASC_BB"
- 5. Search for the CPT code of the surgical procedure performed to find the reimbursement rate that includes reimbursement for EXPAREL

To find the most current ASP pricing file, follow these steps:

- Access www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/ McrPartBDrugAvgSalesPrice/index.html
- 2. Click on the current year's "ASP Drug Pricing Files" link in the left-hand navigation window
- 3. Click on the "ASP Pricing File" in the Related Links section

Current, published AWP or WAC may be found in the major drug compendia.

CPT® Billing and Coding

CPT[®] codes are the standard codes used when documenting drug administration and surgical procedures. Surgical procedures involving EXPAREL[®] (bupivacaine liposome injectable suspension) are commonly bundled within an APC when they are performed in the hospital outpatient or ASC setting. While hospitals are required to submit CPT[®] codes for packaged services, ASCs do not report individual CPT[®] codes for packaged services reimbursed under an APC.

Modifiers are required by Medicare, as well as by many private payers, when appropriate to document specific information about procedures such as the areas of the body treated.

Additional information about CPT[®] codes and their modifiers is available from the American Medical Association at http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt.page

According to the American Society of Regional Anesthesia and Pain Medicine (ASRA), effective January 1, 2015 there are four new CPT codes to use in reporting TAP block procedures. These four codes are:

Code	Description
64486	Transversus abdominis plane (TAP) BLOCK (abdominal plane block, rectus sheath block) unilateral ; by injection(s)—includes imaging guidance, when performed
64487	Transversus abdominis plane (TAP) BLOCK (abdominal plane block, rectus sheath block) unilateral ; by continuous infusion(s)—includes imaging guidance, when performed
64488	Transversus abdominis plane (TAP) BLOCK (abdominal plane block, rectus sheath block) bilateral ; by injection(s)—includes imaging guidance, when performed
64489	Transversus abdominis plane (TAP) BLOCK (abdominal plane block, rectus sheath block) bilateral ; by continuous infusion(s)—includes imaging guidance, when performed

 $\ensuremath{\mathsf{CPT}}^{\ensuremath{\$}}$ is a registered trademark of the American Medical Assocation.

For additional information regarding the use of these codes, please contact the following professional societies:

- American Society of Regional Anesthesia and Pain Medicine (ASRA): http://www.asra.com
- American Society of Interventional Pain Physicians (ASIPP): http://www.asipp.org
- American Association of Professional Coders (AAPC): https://www.aapc.com

Payment for the Surgical Procedure

For Medicare, when surgery reimbursement is bundled within an APC group in an ASC or hospital setting, the payment rate depends on the APC category that includes the CPT[®] code billed. In both the hospital outpatient and ASC setting, any ultrasonic guidance for needle replacement or imaging is also included in the APC bundle and separate reimbursement is not available. To find which APC category includes which CPT[®] codes and the current payment rate, review the addendum updates available on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

When surgery is performed in the physician office setting or hospital outpatient setting where payment is not bundled within an APC group, Medicare payment is based on the actual CPT[®] code(s) billed. When multiple CPT[®] codes are billed for the same procedure, reimbursement is subject to Multiple Procedure Payment Reduction (MPPR) – the code resulting in the highest payment is paid based on 100% of the allowed amount, and subsequent codes are reimbursed 50% of the amount listed in the Medicare Physician Fee Schedule. Payment is calculated by multiplying the relative value units (RVUs) associated with a CPT[®] code by the current conversion factor and geographic adjustments. To find the reimbursement rate for a particular CPT[®] code, review the physician fee schedule on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html?redirect=/PhysicianFeeSched/.

Similar to payment for the drug, private payer payments for procedures may depend on different methodologies for the administration. Providers should review their payer contracts to confirm expected payment dynamics.

Claim Submission \, 🧮

Electronic data interchange (EDI) allows providers to submit claims electronically to payers and results in more efficient claims processing. Medicare requires all providers to submit claims electronically, with few exceptions. Claims are submitted via ANSI X12N 837 business transactions and may be sent either directly, using vendor software, or through a clearinghouse. To learn more about EDI transactions and to access the most recent references, including the HIPAA implementation guide, providers can visit the CMS support website: http://www.cms.gov/Medicare/Billing/ElectronicBillingEDITrans/EDISupport.html.

Some EDI systems and payers do not allow electronic submission of claims associated with miscellaneous J-codes. Providers are encouraged to review payer rules and EDI system capabilities prior to claim submission.

Electronic and Paper Billing and Coding for EXPAREL® (bupivacaine liposome injectable suspension) in the Hospital Outpatient or Ambulatory Surgical Center Setting

Table 1 provides claims information when billing for EXPAREL when administered in the hospital outpatient or ASC setting and where these codes are reported within your electronic claims software.

Category	Example	Location on Paper UB-04 Form	Location in 5010 Electronic Claim
HCPCS code	C9290 for Medicare J3490 may be required by other payers	Field 44	Loop 2400, SV202-2
CPT code	Varies based on procedure performed	Field 44	Loop 2400, SV202-2
Units	266 (for 266 mg of EXPAREL); units administered and wasted may need to be listed separately	Field 46	Loop 2400, SV205
ICD-9-CM code	Varies based on patient diagnosis	Field 66	Loop 2300, HI01-2
Revenue code	0636 for Medicare; may vary by other payers	Field 42	Loop 2400, SV201
NPI number	Provider-specific	Field 56	Loop 2310A, NM1

Table 1. Hospital Outpatient or ASC Claims – Paper and Electronic Claims Coding Information

Electronic and Paper Billing and Coding for EXPAREL® (bupivacaine liposome injectable suspension) in the Physician Office

Table 2 provides examples of relevant codes when billing for EXPAREL when it is administered in the physician office setting and where these codes are reported within your electronic claims software.

Table 2. Physician Office Claims (sometimes used by ASCs) Paper and Electronic Claims Coding Information

Category	Example	Location on Paper CMS-1500	Location in 5010 Electronic Claim
HCPCS code	Confirm with payer	Box 24D	Loop 2400, SV101-2
CPT code	Varies based on procedure performed	Box 24D	Loop 2400, SV101-2
Units	If C9290, 266 (for 266 mg of EXPAREL) units administered and wasted may need to be listed separately If J3490, typically 1	Box 24G	Loop 2400, SV104
ICD-9-CM code	Varies based on patient diagnosis	Box 21	Loop 2300, HI01-2
Reserved for local use	usual location for		Loop 2300, PWK01
NPI number	Provider-specific	Box 17B	Loop 2310A, NM1
Prior authorization number	Payer-specific	Box 23	Loop 2300, REF01

Important Components of the CMS-1500 Paper Form



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNFORM CLAIM COMMITTEE (NUCC) 02/12

For use in Ambulatory Surgery Center or Physician Office settings for non-Medicare beneficiary after payer confirmation.

PICA		PICA	
	- HEALTH PLAN - BLK LUNG -	1a. INSURED'S LD. NUMBER (For Program in Item 1)	
	(ID#) (ID#) (ID#)		
2. PATIENT'S NAME (Last Name, First Name, Middle Initial) Consister Tarland	3. PATIENT'S BIRTH DATE SEX	4. INSURED'S NAME (Last Name, First Name, Middle Initial)	
Smith, John 5. PATIENT'S ADDRESS (No., Street)	6, PATIENT RELATIONSHIP TO INSURED	Smith, John 7. INSURED'S ADDRESS (No., Street)	
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	STATE 8. RESERVED FOR NUCC USE	CITY STATE Z	
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ZIP CODE TELEPHONE (Include Area Code)	a)	ZIP CODE TELEPHONE (Induae Avea Code)	
45678 ()		45678 ()	
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)	 IS PATIENT'S CONDITION RELATED TO: 	11. INSURED'S POLICY GROUP OR FECA NUMBER	
& OTHER INSURED'S POLICY OR GROUP NUMBER	a, EMPLOYMENT? (Current or Previous)		
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b, RESERVED FOR NUCC USE	6. AUTO ACCIDENT? PLACE (State)	b. OTHER CLAIM ID (Deelgralied by NUCC)	
	YES NO	NA NA	
6. RESERVED FOR NUCC USE	C OTHER ACCIDENT?		
	YES NO	E, INSURANCE PLAN NAME OR PROGRAM NAME	
& INSURANCE PLAN NAME OR PROGRAM NAME	10d. CLAIM CODES (Designated by NJCC)	4. IS THERE ANOTHER HEALTH BENEFIT PLAN?	
		YES NO If yes, complete items 9, 9a, and 9d.	
READ BACK OF FORM BEFORE CO 12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE 1 to process this claim, also request payment of government be	Enter full description of	13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE authorize payment of medical benefits to the undersigned physician or supplier for	
to process this claim, I also request payment of government be below,	product by name	services described below.	
SIGNED Signature on File	product by name	SIGNED	
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17. NAME OF REFERRING PROVIDER OR OTHER SOURCE	code (eq. C	9290) or miscellaneous	
	Th, NPI	XPAREL [®] (Bupivacaine	
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describing ser	rvices rendered		
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XX-XXXXXXX X	YES NO	\$	
31. SIGNATURE OF PHYSICIAN OR SUPPLIER 32. SERV INCLUDING DEGREES OR CREDENTIALS	CE FACILITY LOCATION INFORMATION	33. BILLING PROVIDER INFO & PH # ()	
() certify that the statements on the reverse apply to this bill and are made a part thereof.)		1234 Healthcare St	
		Anytown, IL 45678-1234	
-	MIR) b.		
SIGNED DATE			

For complete information related to EXPAREL, please call 1-855-RX-EXPAREL or visit www.EXPAREL.com

Important Components of the UB-04 Paper Form

For use in Ambulatory Surgery Center or Physician Office settings for non-Medicare beneficiary after payer confirmation.

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For complete information related to EXPAREL, please call 1-855-RX-EXPAREL or visit www.EXPAREL.com

Letters of Medical Necessity

Letters of medical necessity may be included as additional documentation when securing prior authorization for treatment or submitting claims to the payer for reimbursement. Letters of medical necessity should include the reason for the treatment and the patient's medical history, where applicable. Below is a sample letter of medical necessity that may be tailored to meet your specific practice's or patient's needs.

Re: Coverage of EXPAREL (bupivacaine liposome injectable suspension) Subscriber's First and Last Name Patient's First and Last Name Policy #/Patient ID Group # Patient Date of Birth Patient Age Patient Sex

Dear [Name of Payer], Medical Director:

I am writing **[to obtain prior authorization, to support coverage]** on behalf of **[patient's name, policy number]** for treatment with EXPAREL* (bupivacaine liposome injectable suspension) provided on **[date of service]**. EXPAREL can be reported on the claim form using code **[J3490 "Unclassified drugs", C9290 "Injection, bupivacaine liposome, 1 mg"]** and the surgical procedure is reported using **[insert relevant code and descriptor with appropriate modifier]**.

Mr./Mrs./Ms. [patient's last name]'s medical history is as follows:

• [Describe the patient's history, diagnosis, and comorbidities that make him/her a candidate for EXPAREL]

In my clinical opinion, Mr./Mrs./Ms. [patient's last name] should receive EXPAREL for the following reasons:

• [List reasons for treatment with EXPAREL]

EXPAREL is a liposome injection of bupivacaine, an amide local anesthetic, indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia. The full prescribing information for EXPAREL can be accessed at http://www.exparel.com/pdf/EXPAREL_Prescribing_Information.pdf.

Sincerely,

[Your name] [Your signature]

Appealing Denied Claims

Accurate billing and coding is the best way to prevent claim denial or underpayment. Claims are often denied due to incorrect or transposed patient information; invalid or unrecognized codes; missing information; and/or omission of special coding requirements, such as the use of a modifier. As such, it is important to accurately confirm the reason for claim denial or underpayment prior to appeal.

There may be instances when a claim is denied due to the service not being deemed medically necessary. Many payers have automatic edits built into their claims-processing systems to review claims, so it is important to verify coverage policies prior to treatment. If a claim is denied due to clinical reasons and there are no claim submission errors, providers and patients can often appeal successfully when the treatment is medically necessary. Thorough and accurate documentation of the patient's treatment, along with a letter of medical necessity, can help with the appeal process. Below is a sample letter of medical necessity specifically designed for appeals that may be tailored to meet your practice's or patient's needs.

Re: Claim Denial of EXPAREL* (bupivacaine liposome injectable suspension) Subscriber's First and Last Name Patient's First and Last Name Policy #/Patient ID Group # Patient Date of Birth Patient Age Patient Sex

Dear [Name of Payer], Director of Claims:

I am writing to request a review of a denied claim for **[patient's name, claim number]**. Your company has denied this claim for the following reason(s), listed on the Explanation of Benefits (EOB):

• [List reason(s) from EOB]

Mr./Mrs./Ms. **[patient's last name]** was treated with EXPAREL (bupivacaine liposome injectable suspension) to produce postsurgical analgesia due to the following reasons:

• [List reasons for treatment with EXPAREL]

The full prescribing information for EXPAREL can be accessed at http://www.exparel.com/pdf/EXPAREL_Prescribing_Information.pdf.

Treatment with EXPAREL was a necessary therapy for this patient's medical condition, and it is my clinical opinion and assessment that **[patient's name]** has benefited from EXPAREL. I trust that the enclosed information, along with my medical recommendations, will establish the medical necessity for payment of this claim.

Sincerely,

[Your name] [Your signature]

In addition to understanding the appeal process, providers may also wish to consider patient's rights in the appeal process. Information related to the Medicare appeal process may be found on the CMS website at http://www.medicare.gov/claims-and-appeals/file-an-appeal/appeals.html.

Because private payer contracts can vary greatly, providers are encouraged to review their contracts regularly and carefully. At a minimum, providers and their practice staff should know where their contracts are physically located within the facility, be familiar with their payer representatives, and understand how to escalate coverage or reimbursement concerns as appropriate. In addition, practices may wish to review the following best practices when negotiating contracts to ensure adequate reimbursement:

- **Understand the market:** Run reports to identify commonly billed codes for your practice and compare reimbursement methodologies across payer contracts to assess areas of financial impact.
- **Simplify processes:** Claims can be incorrectly denied when a payer is not familiar with a certain product or procedure. To help streamline reimbursement, providers may wish to agree on mutually beneficial practices that will help payers' claim processing staff easily spot recurring charges.
- **Participate in incentive programs:** Providers may offer to adopt best practices early, such as electronic claims submission when negotiating contracts with private payers, in order to realize incentives.

The following resources may be helpful for providers in assessing correct coding, coverage, and payment for EXPAREL[®] (bupivacaine liposome injectable suspension) and related procedures.

- ASC payment rates and updates http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment
- EDI transactions and references http://www.cms.gov/Medicare/Billing/ElectronicBillingEDITrans/EDISupport.html.
- Information related to the Medicare appeal process http://www.medicare.gov/claims-and-appeals/file-an-appeal/appeals.html

Important Safety Information

EXPAREL[®] (bupivacaine liposome injectable suspension) is contraindicated in obstetrical paracervical block anesthesia.

EXPAREL has not been studied for use in patients younger than 18 years of age.

Non-bupivacaine-based local anesthetics, including lidocaine, may cause an immediate release of bupivacaine from EXPAREL if administered together locally.

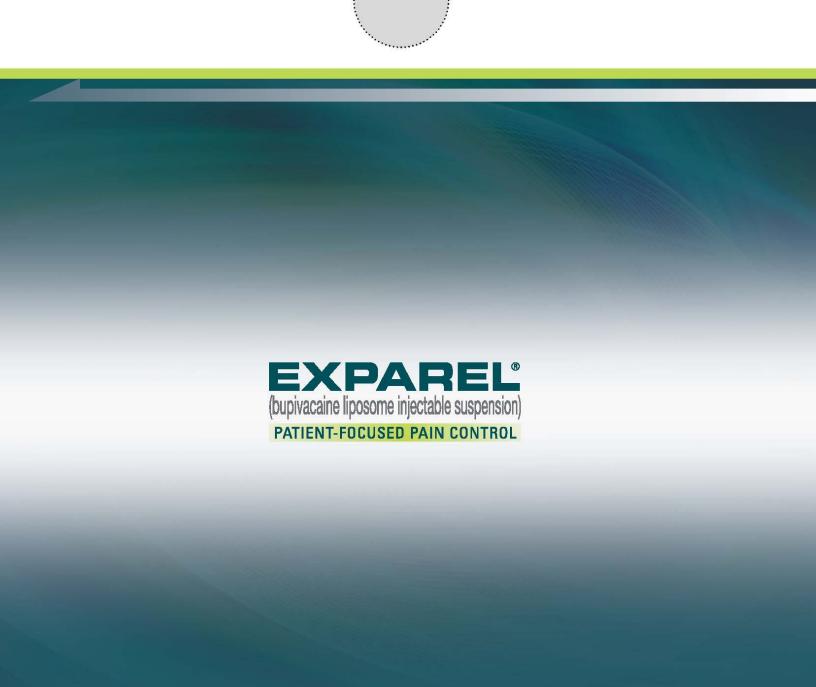
The administration of EXPAREL may follow the administration of lidocaine after a delay of 20 minutes or more.

Other formulations of bupivacaine should not be administered within 96 hours following administration of EXPAREL.

Monitoring of cardiovascular and neurological status, as well as vital signs should be performed during and after injection of EXPAREL as with other local anesthetic products. 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.

In clinical trials, the most common adverse reactions (incidence \geq 10%) following EXPAREL administration were nausea, constipation, and vomiting.

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PP-EX-US-0636

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