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
- Best practices for payer contracting

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.
Introduction

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.
EXPARL 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 EXPARL has been captured in the Medicare data as facilities have billed C9290 – Injection, bupivacaine liposome, 1 mg – whenever EXPARL 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 EXPARL 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 EXPARL 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.

EXPARL Billing and Coding With a Miscellaneous or Unclassified Code

Some private payers do not recognize code C9290 for EXPARL 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 EXPARL 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
3. 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:
1. 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.
Billing and Coding for the Surgical Procedure

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:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>64486</td>
<td>Transversus abdominis plane (TAP) BLOCK (abdominal plane block, rectus sheath block) <strong>unilateral</strong>; by injection(s)—includes imaging guidance, when performed</td>
</tr>
<tr>
<td>64487</td>
<td>Transversus abdominis plane (TAP) BLOCK (abdominal plane block, rectus sheath block) <strong>unilateral</strong>; by continuous infusion(s)—includes imaging guidance, when performed</td>
</tr>
<tr>
<td>64488</td>
<td>Transversus abdominis plane (TAP) BLOCK (abdominal plane block, rectus sheath block) <strong>bilateral</strong>; by injection(s)—includes imaging guidance, when performed</td>
</tr>
<tr>
<td>64489</td>
<td>Transversus abdominis plane (TAP) BLOCK (abdominal plane block, rectus sheath block) <strong>bilateral</strong>; by continuous infusion(s)—includes imaging guidance, when performed</td>
</tr>
</tbody>
</table>

CPT® is a registered trademark of the American Medical Association.

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
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](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/](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.
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.

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

<table>
<thead>
<tr>
<th>Category</th>
<th>Example</th>
<th>Location on Paper CMS-1500</th>
<th>Location in 5010 Electronic Claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCPCS code</td>
<td>Confirm with payer</td>
<td>Box 24D</td>
<td>Loop 2400, SV101-2</td>
</tr>
<tr>
<td>CPT code</td>
<td>Varies based on procedure performed</td>
<td>Box 24D</td>
<td>Loop 2400, SV101-2</td>
</tr>
<tr>
<td>Units</td>
<td>If C9290, 266 (for 266 mg of EXPAREL) units administered and wasted may need to be listed separately If J3490, typically 1</td>
<td>Box 24G</td>
<td>Loop 2400, SV104</td>
</tr>
<tr>
<td>ICD-9-CM code</td>
<td>Varies based on patient diagnosis</td>
<td>Box 21</td>
<td>Loop 2300, HI01-2</td>
</tr>
<tr>
<td>Reserved for local use</td>
<td>Payer requirements vary; usual location for additional drug details when billing with J3490</td>
<td>Box 19</td>
<td>Loop 2300, PWK01</td>
</tr>
<tr>
<td>NPI number</td>
<td>Provider-specific</td>
<td>Box 17B</td>
<td>Loop 2310A, NM1</td>
</tr>
<tr>
<td>Prior authorization number</td>
<td>Payer-specific</td>
<td>Box 23</td>
<td>Loop 2300, REF01</td>
</tr>
</tbody>
</table>
**Important Components of the CMS-1500 Paper Form**

- **Enter full description of product by name**
- **Enter appropriate HCPCS pass-through code** (e.g., C9290) or miscellaneous code for EXPAREL® (Bupivacaine Liposome Injectable Suspension)
- **Include appropriate CPT codes describing services rendered to patient during encounter**
- **Enter number of units of product that was administered** (1 mg of EXPAREL = 1 unit)

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

<table>
<thead>
<tr>
<th>Item</th>
<th>Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Include appropriate CPT codes</td>
<td>describing services rendered to patient during encounter</td>
</tr>
<tr>
<td>Enter appropriate HCPCS code</td>
<td>(e.g., C9290) or miscellaneous code for EXPAREL® (Bupivacaine Liposome Injectable Suspension)</td>
</tr>
<tr>
<td>Enter number of units of product that was administered</td>
<td>When billing with C9290, 1 mg of EXPAREL = 1 unit. When billing with J3490, typically 1 vial of EXPAREL = 1 unit.</td>
</tr>
<tr>
<td>Use revenue code 636</td>
<td>for EXPAREL</td>
</tr>
</tbody>
</table>

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.
Other Helpful Resources

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

- Information related to the Medicare appeal process
Important Safety Information

EXPARSEL® (bupivacaine liposome injectable suspension) is contraindicated in obstetrical paracervical block anesthesia.

EXPARSEL 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 EXPARSEL if administered together locally.

The administration of EXPARSEL 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 EXPARSEL.

Monitoring of cardiovascular and neurological status, as well as vital signs should be performed during and after injection of EXPARSEL as with other local anesthetic products. Because amide-type local anesthetics, such as bupivacaine, are metabolized by the liver, EXPARSEL 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 EXPARSEL administration were nausea, constipation, and vomiting.