EXPAREL®
(bupivacaine liposome injectable suspension)

OPIOID FREE

C9290
GENERAL FACT SHEET

EFFECTIVE JANUARY 1, 2019

EXPAREL APPROVED BY CMS FOR REIMBURSEMENT IN ASCs

On November 2, 2018, the Centers for Medicare & Medicaid Services (CMS) published the final ambulatory surgery center (ASC) Medicare rules and regulations for 2019.

Under the new rules, the Healthcare Common Procedure Coding System (HCPCS) code **C9290** that is assigned to EXPAREL was assigned a payment status of "allowed" when used in a surgical procedure on Medicare patients in Medicare-certified ASCs.

- —The "allowed" payment status enables EXPAREL to be reimbursed separately by Medicare and, potentially, other commercial payors
- —In 2015, the payment status for **C9290** was defined as "packaged," which meant that EXPAREL was considered packaged into the pricing of the surgical procedure and, therefore, NOT eligible for separate reimbursement. The new rule changes the payment status from "packaged" to "allowed" in the ASC
- —Effective January 1, 2019, EXPAREL will be priced at $1.20/mg and should be billed using HCPCS code **C9290**
  - –For the 20 mL (266 mg) dose, the allowed amount* for reimbursement is $319.20
  - –For the 10 mL (133 mg) dose, the allowed amount* for reimbursement is $159.60
- —Acute care hospitals, hospital outpatient departments (HOPDs), and hospital-based same-day surgery centers are NOT included in the rule; therefore, will not be reimbursed separately for EXPAREL

As a result of the new payment status for **C9290**, which has been approved as "allowed", ASCs can provide greater patient access to EXPAREL, an opioid-free option for postsurgical pain management.

Why is this so important?

Within the past 5 years, >90% of the Medicare population was reported to be in good health.[1] Advanced age is considered a risk factor when undergoing surgical procedures; 1 in 10 people who have surgery are aged ≥65 years.[2] Opioid-based postsurgical pain management may cause significant side effects.[3]

In 1 study of elderly patients undergoing low-risk surgical procedures, 10% of patients were still taking opioids 1 year later.[4] Minimizing exposure to opioids and providing long-lasting pain control are key elements of a multimodal postsurgical pain management protocol.[5] EXPAREL, a non-opiod, provides significant long-lasting pain control while reducing opioid use.†

The table below provides an example of surgical procedures performed in the HOPD and ASC settings in 2014 and 2016 on Medicare patients.

- The table highlights Medicare ASC procedural trends, including the shift in site of service
- Postsurgical pain management is a key consideration when choosing surgical procedures performed in an ambulatory setting. EXPAREL has a broad indication for infiltration across surgical procedures and as an interscalene brachial plexus nerve block for rotator cuff repair and shoulder arthroplasty

**The allowed amount for reimbursement is based on the full dose being used for the surgical procedure.*
†The clinical benefit of the decrease in opioid consumption was not demonstrated in the pivotal trials.

	HOPD utilization‡		ASC utilization§	
MEDICARE PROCEDURE	2014	2016	2014	2016
Spine	46,248	82,824	137	2869
Rotator cuff/shoulder repair‖	64,867	55,196	34,835	37,386
Hernia repair	37,644	50,336	2575	3299
Breast reconstruction	55,812	37,376	3631	4279
Bunionectomy¶	17,559	9939	3010	2431
Joint replacement (eg, TKA)	6827	9664	853	1331
Hemorrhoidectomy	8121	7607	422	290

CPT, Current Procedural Terminology; OPPS, Outpatient Prospective Payment System; TKA, total knee arthroplasty.
‡HOPD utilization from OPPS CPT cost statistics files.
§ASC utilization from Medicare provider utilization and payment public use files for physician and other suppliers where provider type is an ACS.
‖Rotator cuff includes CPT codes 23412 and 29827; shoulder repair includes CPT codes 23130, 23410, 23420, 29807, and 29824.
¶Bunionectomy includes CPT codes 28292, 28296, 28297, 28298, and 29299.

Please see Indication and Important Safety Information on reverse and refer to accompanying full Prescribing Information.

With the "allowed" payment status for **C9290** and thus, separate reimbursement for EXPAREL, financial considerations or supply cost concerns to use EXPAREL on Medicare patients in an ASC are now eliminated. It also provides the necessary momentum for commercial payors to follow CMS policy, which is aimed at supporting the use of non-opioid–based postsurgical pain management in an ASC for Medicare patients.

For details and guidance on how to access Medicare reimbursement and engage your commercial payors, please visit **www.EXPAREL.com/reimbursement**.

For additional information about reimbursement for EXPAREL, please contact **1-855-RX-EXPAREL (1-855-793-9727)** or **reimbursement@pacira.com**.

Indication

EXPAREL is indicated for single-dose infiltration in adults to produce postsurgical local analgesia and as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia. 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 with an incidence greater than or equal to 10% following EXPAREL administration via infiltration were nausea, constipation, and vomiting; adverse reactions reported with an incidence greater than or equal to 10% following EXPAREL administration via interscalene brachial plexus nerve block were nausea, pyrexia, and constipation.

If EXPAREL and other non-bupivacaine local anesthetics, including lidocaine, are administered at the same site, there may be an immediate release of bupivacaine from EXPAREL. Therefore, EXPAREL may be administered to the same site 20 minutes after injecting lidocaine.

EXPAREL is not recommended to be used in the following patient population: patients <18 years old 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**, 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.

Please refer to accompanying full Prescribing Information.

For more information, please visit www.EXPAREL.com or call 1-855-RX-EXPAREL (793-9727).

References: 1. Medicare Payment Advisory Commission. *Health Care Spending and the Medicare Program*. http://www.medpac.gov/docs/default-source/data-book/jun18_databookentirereport_sec.pdf?sfvrsn=0. Published June 2018. Accessed November 7, 2018. **2.** Risks: age. American Society of Anesthesiologists website. https://www.asahq.org/whensecondscount/preparing-for-surgery/risks/age/. Accessed November 7, 2018. **3.** Pain medications after surgery. Mayo Clinic website. https://www.mayoclinic.org/pain-medications/art-20046452. Updated June 30, 2017. Accessed November 7, 2018. **4.** Alam A, Gomes T, Zheng H, Mamdani MM, Juurlink DN, Bell CM. Long-term analgesic use after low-risk surgery: a retrospective cohort study. *Arch Intern Med*. 2012;172(5):425-430. **5.** Beck DE, Margolin DA, Babin SF, Russo CT. Benefits of a multimodal regimen for postsurgical pain management in colorectal surgery. *Ochsner J*. 2015;15(4):408-412.

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