

EXPAREL CODING GUIDE IN OMFS

Many payers will reimburse the use of EXPAREL (**D9613**) when used in certain oral surgeries and procedures

Definition of D9613

- Infiltration of sustained-release therapeutic drug, per quadrant
 - Infiltration of a sustained-release pharmacologic agent for long-acting surgical site pain control (not for local anesthesia purposes)

Commonly Used Codes

Dental	
D7240	Removal of impacted tooth - completely bony
D7230	Removal of impacted tooth - partially bony
D7220	Removal of impacted tooth - soft tissue
D7241	Removal of impacted tooth - completely bony, with unusual surgical complications
D7251	Coronectomy - intentional partial tooth removal

Medical	
21025	Excision of bone (eg, osteomyelitis or bone abscess); mandible if the excision of bone is in conjunction with removal of an impacted third molar
41899	Unlisted procedure, dentoalveolar structures, if the unlisted procedure is removal of an impacted third molar

Please contact the individual payer for specific reimbursement information

Coverage amounts

- The maximum allowed amount for EXPAREL is subject to plan design, including co-pay, co-insurance, maximum, and deductible
- It is recommended that practices contact individual payers prior to surgery to confirm coverage or to address a coverage dispute

OMFS=oral and maxillofacial surgery.

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

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

NON-OPIOID
EXPAREL[®]
(bupivacaine liposome injectable suspension)

D9613
OMFS CODING

UNDERSTANDING THE USE OF EXPAREL

What is EXPAREL?

EXPAREL is a long-lasting, non-opioid option for postsurgical pain control. EXPAREL works locally at the surgical site and uses the proprietary multivesicular liposome (pMVL) technology, which encapsulates bupivacaine in a suspension of multivesicular liposomes. After injection, bupivacaine is released over time.^{1,2}

Can EXPAREL be used with pediatric patients?

EXPAREL is the first and only FDA-approved long-acting local analgesic for ages 6 and above.⁴

Which oral surgeries are appropriate for EXPAREL?

EXPAREL is indicated for single-dose infiltration in patients aged 6 years and older to produce postsurgical local analgesia and in adults as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia. Safety and efficacy have not been established in other nerve blocks. The indication encompasses use for postsurgical analgesia when administered as local infiltration at the site of oral surgery procedures, including tooth extraction. The indication also includes use as a local anesthetic deposited near a terminal branch of the maxillary or mandibular branch of the trigeminal nerve (periapical injections). EXPAREL is also indicated as an interscalene brachial plexus nerve block in adults to produce postsurgical regional analgesia. Safety and efficacy have not been established in other nerve blocks.

Has EXPAREL been studied in oral surgery?

Phase 3 clinical study—INNOVATE: The safety, efficacy, and pharmacokinetics of EXPAREL were evaluated in a multicenter, Phase 3, randomized, double-blind, placebo-controlled study of local administration of EXPAREL for prolonged postsurgical analgesia in patients undergoing bilateral third-molar extraction. EXPAREL was shown to be safe in the safety population (EXPAREL, n=105; placebo, n=57). Significant reduction in mean AUC of NRS through 48 hours in the per-protocol analysis population (120.8 vs 183.3, P=0.023). Significant reduction in cumulative pain scores at 24, 72, and 96 hours after surgery in the per-protocol analysis population (P<0.05).^{5*}

Retrospective study: A retrospective cross-sectional study of 600 patients undergoing thirdmolar extraction (≥1 partial bony or full bony impacted mandibular third molar) and receiving EXPAREL 133 mg (n=300) were prescribed significantly fewer opioids than patients who did not (n=300), with a lower opioid prescription refill rate.⁶ 59% fewer prescribed MMEs than the non-EXPAREL group (47.1 MME vs 113.8 MME, P<0.0001). Significantly lower opioid prescription refill rate (3.3% vs 7.7%, P=0.028).⁶

How is EXPAREL administered?

EXPAREL should be injected with a 25-gauge or larger-bore needle. EXPAREL is best administered using a series of injections to effectively cover the surgical area, as it does not diffuse throughout tissues in the same manner as traditional bupivacaine.

How do I order EXPAREL?

EXPAREL can be ordered directly from Pacira BioSciences, Inc., the manufacturer of EXPAREL, or through authorized distributors. You must have an account with Pacira to make direct orders. To open an account, please visit www.EXPAREL.com/ordering to fill out a Letter of Affiliation form.[†]

What does my office staff need to know about EXPAREL?

It is important that the office manager, treatment coordinators, surgical staff, and surgeons are fully knowledgeable about how to use EXPAREL. The office should educate OMFS patients and caregivers about the role EXPAREL plays in the practice's commitment to a culture of opioid reduction.[‡] Pacira has developed some easy-to-use reference materials for customers and staff members to support patient education. Please contact your EXPAREL representative or go to <https://www.exparel.com/hcp/specialty/oral-maxillofacial> for any materials.

*Due to extensive protocol violations the INNOVATE trial did not meet its primary endpoint. However, in a per protocol population analysis EXPAREL patients demonstrated statistically significant difference in pain scores out to 96 hours.

†If you are practicing in the state of Florida, you will also need to fill out and submit the Health Care Clinic Establishment form.

‡The clinical benefit of the decrease in opioid consumption was not demonstrated in the pivotal trials.

For reimbursement support or questions, please call 1-855-793-9727, email reimbursement@pacira.com, or visit www.EXPAREL.com/reimbursement.

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Indication

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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 interscalene brachial plexus nerve block were nausea, pyrexia, 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.

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 populations: patients <6 years old for infiltration, patients younger than 18 years old for interscalene brachial plexus nerve block, 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 1-855-793-9727.

References: **1.** Malik O, Kaye AD, Kaye A, Belani K, Urman RD. Emerging roles of liposomal bupivacaine in anesthesia practice. *J Anaesthesiol Clin Pharmacol.* 2017;33(2):151-156. **2.** Portillo J, Kamar N, Melibary S, Quevedo E, Bergese S. Safety of liposome extended-release bupivacaine for postoperative pain control. *Front Pharmacol.* 2014;5:90. **3.** Pacira BioSciences. Pacira announces FDA approval of supplemental new drug application for EXPAREL® (bupivacaine liposome injectable suspension) in pediatric patients [press release]. Pacira website. <https://investor.pacira.com/news-releases/news-release-details/pacira-announces-fda-approval-supplemental-new-drug-o>. Published March 22, 2021. Accessed February 14, 2022. **4.** Lieblich, S. E., Misiek, D., Olczak, J., Fleck, H., & Waterman, F. (2021). A retrospective cross-sectional study of the effect of liposomal bupivacaine on postoperative opioid prescribing after third molar extraction. *Journal of Oral and Maxillofacial Surgery*, 79(7). <https://doi.org/10.1016/j.joms.2021.02.012>. **5.** Lieblich SE, Misiek D, Olczak J, Fleck H, Waterman F. A retrospective cross-sectional study of the effect of liposomal bupivacaine on postoperative opioid prescribing after third molar extraction. *J Oral Maxillofac Surg.* Published.