posimir®
(bupivacaine solution)
for infiltration use

# ASC REIMBURSEMENT AND BILLING GUIDE

**Use C-9144 when billing for POSIMIR**

**POSIMIR** | The **FIRST** and **ONLY** non-opioid, locally administered, bupivacaine solution that delivers consistent rapid-acting and long-lasting pain relief for up to 72 hours following arthroscopic subacromial decompression[1]

## INDICATIONS AND USAGE

POSIMIR is a bupivacaine solution indicated in adults for administration into the subacromial space under direct arthroscopic visualization to produce post-surgical analgesia for up to 72 hours following arthroscopic subacromial decompression.

### LIMITATIONS OF USE

Safety and effectiveness have not been established in other surgical procedures, including soft tissue surgical procedures, other orthopedic procedures, including for intra-articular administration, and boney procedures, or when used for neuraxial or peripheral nerve blockade.

## IMPORTANT SAFETY INFORMATION

**BOXED WARNING: RISK OF POTENTIAL ADVERSE EMBOLIC EFFECTS RESULTING FROM INADVERTENT INTRAVASCULAR INJECTION. Inadvertent intravascular injection could cause POSIMIR droplets to be deposited in the pulmonary and other capillary beds. Administer POSIMIR into the subacromial space at the end of arthroscopic shoulder surgery. Direct arthroscopic visualization must be used to confirm proper placement of the needle tip before injecting POSIMIR.**

**Please see complete Important Safety Information on the back cover, and accompanying full Prescribing Information, including BOXED WARNING.**

# ORDERING AND BILLING POSIMIR FOR YOUR FACILITY WITH HCPCS CODE C-9144

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## PRICING AND ORDERING INFORMATION

POSIMIR can be ordered using standard ordering procedures through your wholesaler for next-day delivery.

| NDC # | POSIMIR Dose | Configuration | WAC Price |
|---|---|---|---|
| 51715-660-10 | 660 mg | Carton of 10 units | $3,190 |

| Wholesaler | Customer Support |
|---|---|
| AmerisourceBergen Corporation | (844) 222-2273 |
| Cardinal Health | (800) 926-3161 |
| Cardinal Health Specialty Distribution | (866) 677-4844 |
| McKesson Customer Support for Hospitals | (855) 625-7385 |
| McKesson Med-Surge | (855) 571-2100 |

## MEDICARE REIMBURSEMENT INFORMATION

- For Medicare patients, POSIMIR is eligible for separate reimbursement in both the hospital outpatient and ambulatory surgical center (ASC) settings when using the ***product-specific billing code of C-9144***
- The Medicare reimbursement amount for POSIMIR will be the Average Sales Price (ASP) plus 6%, subject to any CMS adjustments, when utilizing the ***product-specific billing code of C-9144*** in certified Medicare ASCs
- Should you have questions related to Medicare billing and reimbursement for POSIMIR under this policy, please contact the Medicare Administrative Contractor (MAC) for your region

## BILLING INFORMATION

- When POSIMIR is used, document usage in the operative note in the medical record
- For Medicare, bill unused and discarded drug amounts as a separate line item using "JW" modifier, and record the discarded amounts in the patient's medical record. Beginning July 1, 2023, the "JZ" modifier will also be required on claims for single-dose vial or container drugs (on the claim line with the administered amount) when there are no discarded amounts
- Additional claim modifiers may also apply based on CMS or MAC guidance. Separate payment for POSIMIR may be available for Commercial patients. However, Commercial reimbursement, billing rules, and policies related to use of C-9144 may vary by payer and site of care
- Check your ASC contracts and payer provider manuals to verify the reimbursement amount if your commercial contract reimburses at a percentage of the Medicare payment rate. Contact your payer's Provider Network Representative to confirm any billing or reimbursement questions
- If your ASC successfully negotiates reimbursement for POSIMIR with any of its commercial payers, it is important that your insurance verification process is updated to include POSIMIR
- It is important to provide surgeons, anesthesiologists, and their office staff with a list of payers and the applicable benefit plan that will reimburse POSIMIR in an ASC setting



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# SAMPLE CLAIM FORM CMS-1500: ASC (MEDICARE) AND PHYSICIAN OFFICE

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CMS requires ASCs to submit a CMS-1500 claim form when billing a MAC. Many commercial plans require a CMS-1450 (UB-04) claim form. Please use the claim form that you are currently utilizing when submitting to a commercial plan. Physician office billing requires the submission of the CMS-1500 claim form for all plans.

Complete the information needed to bill for the procedure. **POSIMIR must be billed using a separate line.**

**Field 24 (Shaded Area):** Include the required additional information (eg, product name and NDC).

*Example:*

**POSIMIR, 517175-660-10**

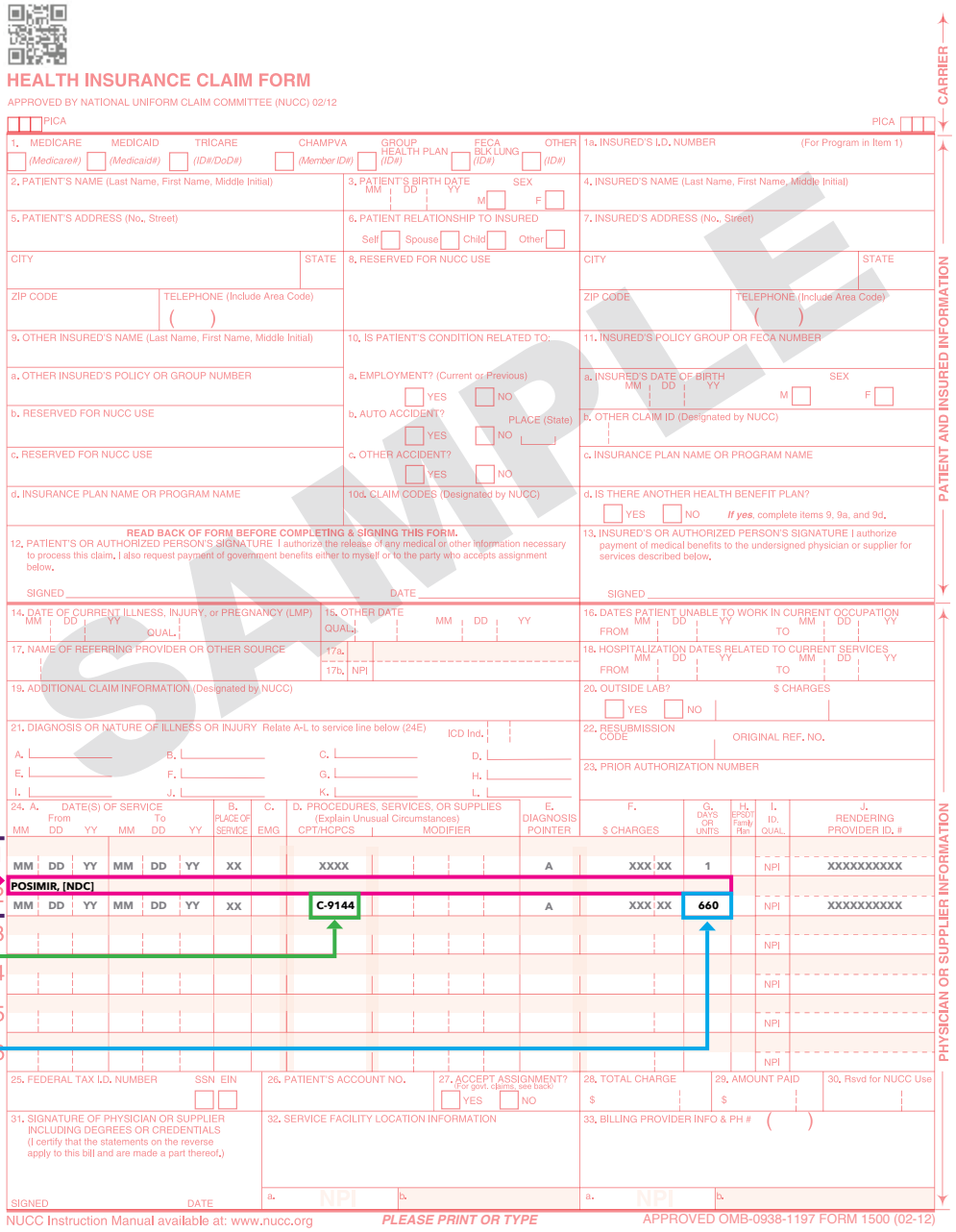
*Payer NDC requirements and placement may vary; confirm with payer.*

**Field 24D:** Specify appropriate HCPCS code. For dates of service on or after January 1, 2023, ASC can use **C-9144** for Medicare claims.

For Medicare, units that are discarded or wasted are reported as a separate line item using the "JW" modifier.

*Additional modifiers may be required; please confirm with your local MAC, commercial plan, or other payer.*

**Field 24G:** Specify the number of units administered. **The billable unit for C-9144 is 1 mg.** The FDA-approved, POSIMIR dose is 660 mg, which corresponds to 660 billable units.



HEALTH INSURANCE CLAIM FORM

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

PICA

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

SAMPLE

| 24. A. DATE(S) OF SERVICE From To | B. PLACE OF SERVICE | C. EMG | D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS | MODIFIER | E. DIAGNOSIS POINTER | F. $ CHARGES | G. DAYS OR UNITS | H. EPSDT Family Plan | I. ID. QUAL. | J. RENDERING PROVIDER ID. # |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 MM DD YY MM DD YY | XX | | XXXX | | A | XXX XX | 1 | | NPI | XXXXXXXXXX |
| 2 POSIMIR, [NDC] | | | | | | | | | | |
| 2 MM DD YY MM DD YY | XX | | C-9144 | | A | XXX XX | 660 | | NPI | XXXXXXXXXX |
| 3 | | | | | | | | | NPI | |
| 4 | | | | | | | | | NPI | |
| 5 | | | | | | | | | NPI | |
| 6 | | | | | | | | | NPI | |

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

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## INDICATIONS AND USAGE

POSIMIR is a bupivacaine solution indicated in adults for administration into the subacromial space under direct arthroscopic visualization to produce post-surgical analgesia for up to 72 hours following arthroscopic subacromial decompression.

### LIMITATIONS OF USE

Safety and effectiveness have not been established in other surgical procedures, including soft tissue surgical procedures, other orthopedic procedures, including for intra-articular administration, and boney procedures, or when used for neuraxial or peripheral nerve blockade.

## IMPORTANT SAFETY INFORMATION

**BOXED WARNING: RISK OF POTENTIAL ADVERSE EMBOLIC EFFECTS RESULTING FROM INADVERTENT INTRAVASCULAR INJECTION.**
**Inadvertent intravascular injection could cause POSIMIR droplets to be deposited in the pulmonary and other capillary beds. Administer POSIMIR into the subacromial space at the end of arthroscopic shoulder surgery. Direct arthroscopic visualization must be used to confirm proper placement of the needle tip before injecting POSIMIR.**

### CONTRAINDICATIONS

POSIMIR is contraindicated in patients with a known hypersensitivity to any amide local anesthetic or to other components of POSIMIR, and in patients undergoing obstetrical paracervical block anesthesia.

### WARNINGS AND PRECAUTIONS

**Risk of Potential Adverse Embolic Effects Resulting From Inadvertent Intravascular Injection:** Inadvertent intravascular injection could cause POSIMIR droplets to be deposited in the pulmonary and other capillary beds. Direct arthroscopic visualization must be used to confirm proper placement of the needle tip in the subacromial space before injecting POSIMIR.

**Risk of Joint Cartilage Necrosis With Unapproved Intra-articular Use:** The safety and effectiveness of POSIMIR in surgical procedures other than subacromial decompression have not been established, and POSIMIR is not approved for use via intra-articular injection. A study of POSIMIR in dogs following an intra-articular administration demonstrated joint cartilage necrosis.

**Risk of Systemic Toxicity:** Unintended intravascular injection of POSIMIR may be associated with systemic toxicities, including CNS or cardiorespiratory depression and coma, progressing ultimately to respiratory arrest.

Careful and constant monitoring of cardiovascular and respiratory (adequacy of ventilation) vital signs and the patient's state of consciousness should be performed after injection of bupivacaine. Possible early warning signs of central nervous system (CNS) toxicity are restlessness, anxiety, incoherent speech, lightheadedness, numbness and tingling of the mouth and lips, metallic taste, tinnitus, dizziness, blurred vision, tremors, twitching, CNS depression, or drowsiness.

Avoid additional use of local anesthetics within 168 hours following administration of POSIMIR. Consider increased monitoring for systemic toxicity in debilitated, elderly, or acutely ill patients.

**Methemoglobinemia:** Cases of methemoglobinemia have been reported in association with local anesthetic use. If local anesthetics must be used in patients known to be more susceptible to methemoglobinemia, close monitoring for symptoms and signs of methemoglobinemia is recommended.

**Chondrolysis With Intra-Articular Infusion of Local Anesthetics:** There have been reports of chondrolysis (mostly in the shoulder joint) following intra-articular infusion of local anesthetics (including bupivacaine), which is an unapproved use. Do not inject POSIMIR intra-articularly.

**Risk of Toxicity in Patients With Hepatic Impairment:** Consider reduced dosing and increased monitoring for bupivacaine systemic toxicity in patients with moderate to severe hepatic impairment.

**Risk of Use in Patients With Impaired Cardiovascular Function:** Care should be taken when considering the use of POSIMIR in patients with impaired cardiovascular function (eg, hypotension, heartblock). Consider reduced dosing. Monitor patients closely for blood pressure, heart rate, and ECG changes.

### ADVERSE REACTIONS

Adverse events reported with an incidence greater than or equal to 10% and greater than control following POSIMIR administration in shoulder surgery were dizziness, dysgeusia, dysuria, headache, hypoesthesia, paresthesia, tinnitus, and vomiting.

Adverse events reported with an incidence greater than or equal to 10% and greater than control following POSIMIR administration in soft tissue surgical procedures were anemia, bradycardia, constipation, C-reactive protein increased, diarrhea, dizziness, dysgeusia, headache, nausea, post-procedural contusion (bruising), procedural pain, pruritus, pyrexia, somnolence, surgical site bleeding, visible bruising, and vomiting.

### DRUG INTERACTIONS

Do not dilute or mix POSIMIR with local anesthetics or other drugs or diluents.

### SPECIAL POPULATIONS

**Hepatic Impairment:** Consider reduced dosing and increased monitoring for bupivacaine toxicity in patients with moderate to severe hepatic impairment.

**Renal Impairment:** Consider increased monitoring for local anesthetic systemic toxicity when administering POSIMIR to patients with impaired renal function.

**To report SUSPECTED ADVERSE REACTIONS, contact Innocoll at 1-833-606-1421 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch**

**For additional safety information, please see accompanying full Prescribing Information, including BOXED WARNING.**

**Reference: 1.** Data on File. Innocoll Pharmaceuticals Limited.

innocoll