

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 decompression¹

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



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

This information is provided as a courtesy for educational purposes only. The coding, pricing, and billing information in this reimbursement guide is not a guarantee of coverage or reimbursement for any product or service. It is also not a substitute for a physician's independent diagnosis or treatment of a patient. Payer policies are subject to frequent change, including the rules governing Medicare coverage and reimbursement. Innocoll does not guarantee or warrant that the information provided herein is or will remain applicable. Physicians and other healthcare professionals are solely responsible for accurate completion of all reimbursement and coverage related documentation.

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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										PICA							
1. MEDICARE <input type="checkbox"/> (Medicare#) MEDICAID <input type="checkbox"/> (Medicaid#) TRICARE <input type="checkbox"/> (ID#/DoD#) CHAMPVA <input type="checkbox"/> (Member ID#) GROUP HEALTH PLAN <input type="checkbox"/> (ID#) FECA (LUNG) <input type="checkbox"/> (ID#) OTHER <input type="checkbox"/> (ID#)										1a. INSURED'S I.D. NUMBER (For Program in Item 1)							
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)					3. PATIENT'S BIRTH DATE MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/>			4. INSURED'S NAME (Last Name, First Name, Middle Initial)									
5. PATIENT'S ADDRESS (No., Street)					6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>			7. INSURED'S ADDRESS (No., Street)									
CITY STATE					8. RESERVED FOR NUCC USE			CITY STATE									
ZIP CODE TELEPHONE (Include Area Code)								ZIP CODE TELEPHONE (Include Area Code)									
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)					10. IS PATIENT'S CONDITION RELATED TO:			11. INSURED'S POLICY GROUP OR FECA NUMBER									
a. OTHER INSURED'S POLICY OR GROUP NUMBER					a. EMPLOYMENT? (Current or Previous) YES <input type="checkbox"/> NO <input type="checkbox"/>			a. INSURED'S DATE OF BIRTH MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/>									
b. RESERVED FOR NUCC USE					b. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> PLACE (State)			b. OTHER CLAIM ID (Designated by NUCC)									
c. RESERVED FOR NUCC USE					c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/>			c. INSURANCE PLAN NAME OR PROGRAM NAME									
d. INSURANCE PLAN NAME OR PROGRAM NAME					10c. CLAIM CODES (Designated by NUCC)			d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES <input type="checkbox"/> NO <input type="checkbox"/> If yes, complete items 9, 9a, and 9d.									
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim, I also request payment of government benefits either to myself or to the party who accepts assignment below.										13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.							
SIGNED DATE					SIGNED												
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.					15. OTHER DATE MM DD YY					16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY							
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE					17a. NPI		18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY										
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)					20. OUTSIDE LAB? YES <input type="checkbox"/> NO <input type="checkbox"/> \$ CHARGES												
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.					22. RESUBMISSION CODE ORIGINAL REF. NO.												
A. _____ B. _____ C. _____ D. _____					23. PRIOR AUTHORIZATION NUMBER												
E. _____ F. _____ G. _____ H. _____																	
I. _____ J. _____ K. _____ L. _____																	
24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY		B. PLACE OF SERVICE XX		C. PROCEDURE, SERVICE, OR SUPPLIES CPT/HCPCS MODIFIER		E. DIAGNOSIS POINTER		F. \$ CHARGES		G. DAYS OR UNITS		H. Special Family Plan		I. ID. QUAL.		J. RENDERING PROVIDER ID. #	
1 MM DD YY		2 MM DD YY		3 XXXX		4 A		5 XXXX XX		6 1		7 NPI		8 XXXXXXXXXXXX			
1 MM DD YY		2 MM DD YY		3 C-9144		4 A		5 XXXX XX		6 660		7 NPI		8 XXXXXXXXXXXX			
3		4		5		6		7		8		9		10			
4		5		6		7		8		9		10		11			
5		6		7		8		9		10		11		12			
6		7		8		9		10		11		12		13			
25. FEDERAL TAX I.D. NUMBER		SSN EIN		26. PATIENT'S ACCOUNT NO.		27. ACCEPT ASSIGNMENT? (If group, assigner, or biller) YES <input type="checkbox"/> NO <input type="checkbox"/>		28. TOTAL CHARGE \$		29. AMOUNT PAID \$		30. Rsvfd for NUCC Use					
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)					32. SERVICE FACILITY LOCATION INFORMATION					33. BILLING PROVIDER INFO & PH # ()							
SIGNED DATE					a. NPI b.					a. NPI b.							

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

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

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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

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