ZYNRELEF®
(bupivacaine and meloxicam)
extended-release solution
29.25 mg/mL and 0.88 mg/mL

C9088

- ☑ Product-Specific Code Effective January 1, 2022
- ☑ ASC: Separate Payment Per CMS Rule (Medicare)
- ☑ HOPD: 3-Year Pass-Through Status (Medicare)

REIMBURSEMENT AND BILLING GUIDE

For billing and coding questions, call **Heron Connect®** at **1-844-HERON11 (1-844-437-6611)** 8 AM to 5 PM ET, Monday through Friday.

ZYNRELEF is the first and only extended-release dual-acting local anesthetic (DALA).

INDICATION

ZYNRELEF is indicated in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after foot and ankle, small-to-medium open abdominal, and lower extremity total joint arthroplasty surgical procedures.

Limitations of Use: Safety and efficacy have not been established in highly vascular surgeries, such as intrathoracic, large multilevel spinal, and head and neck procedures.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

- **Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use.**
- **ZYNRELEF is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.**
- **NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.**

See Important Safety Information throughout and full Prescribing Information, including Boxed Warning.

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INTRODUCTION

Heron Therapeutics, Inc, is pleased to provide this reference guide to support patient access to ZYNRELEF.

The coding information contained herein is for informative purposes only and is not a guarantee of coverage or reimbursement for any product or service. This information is not intended to substitute for the physician's independent diagnosis or treatment of each patient.

Coding, coverage, and reimbursement for ZYNRELEF will vary based on the patient's health insurance and the reimbursement status per site of care.

HERON CONNECT

Dedicated Heron Connect Reimbursement Counselors offer customized support for ZYNRELEF benefit verification as well as billing and coding questions. Reimbursement Counselors are available at **1-844-HERON11 (1-844-437-6611)** from 8 AM to 5 PM ET, Monday through Friday.

For more information, visit **HeronConnect.com**

HERON CONNECT®

IMPORTANT SAFETY INFORMATION (CONT)

Contraindications

ZYNRELEF is contraindicated in patients with a known hypersensitivity (eg, anaphylactic reactions and serious skin reactions) to any amide local anesthetic, NSAIDs, or other components of ZYNRELEF; with history of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs (severe, sometimes fatal, anaphylactic reactions to NSAIDS have been reported in such patients); undergoing obstetrical paracervical block anesthesia; or undergoing CABG.

Warnings and Precautions

Dose-Related Toxicity: Monitor cardiovascular and respiratory vital signs and patient's state of consciousness after application of ZYNRELEF. When using ZYNRELEF with other local anesthetics, overall local anesthetic exposure must be considered through 72 hours.

Hepatotoxicity: If abnormal liver tests persist or worsen, perform a clinical evaluation of the patient.

Hypertension: Patients taking some antihypertensive medication may have impaired response to these therapies when taking NSAIDs. Monitor blood pressure.

Heart Failure and Edema: Avoid use of ZYNRELEF in patients with severe heart failure unless benefits are expected to outweigh risk of worsening heart failure.

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ZYNRELEF REIMBURSEMENT AND BILLING SUMMARY

ZYNRELEF should be billed using C9088, the product-specific C-code effective January 1, 2022. The billable unit for C9088 is 1 mg/0.03 mg.

Medicare Billing and Reimbursement

- Separate reimbursement in ASCs at ASP + 6% per CMS rule to reduce incentives for using opioids effective January 1, 2022[1]
- ZYNRELEF was granted 3-year pass-through status effective April 1, 2022
- During the 3-year transitional pass-through status period, ZYNRELEF is separately billable and reimbursed at ASP + 6% in the HOPD setting of care

Commercial Billing and Reimbursement

- Separate payment for ZYNRELEF is available for many commercial patients
- Commercial reimbursement and coding vary by payer and site of care
- Customers should complete a benefit verification to confirm coverage and coding or request one by contacting Heron Connect®

ZYNRELEF Coding Information

HCPCS Code	Description	Billable Unit
C9088	Instillation, bupivacaine and meloxicam	1 mg/0.03 mg

NDC[a]	Bupivacaine/Meloxicam	Billable Units[b]
47426-0301-02	400 mg/12 mg	400
47426-0303-01	200 mg/6 mg	200

[a]11-digit NDCs for billing ZYNRELEF include a 0 before the 3 of the product code.

[b]Use the JW modifier to separately bill unused and discarded drug amounts.

Note: ZYNRELEF is supplied as a kit consisting of a single-dose nonsterile glass vial (containing sterile active ingredients) and the following sterile components: Luer lock syringe(s), a vented vial spike, Luer lock cone-shaped applicator(s), and syringe tip cap(s). ZYNRELEF should only be prepared and administered with the components provided in the ZYNRELEF kit.

Modifier	Description
JW	Drug amount discarded/not administered to any patient (indicate quantity discarded)

IMPORTANT SAFETY INFORMATION (CONT)

Warnings and Precautions (cont)

Renal Toxicity: Monitor renal function in patients with renal or hepatic impairment, heart failure, dehydration, or hypovolemia. Avoid use of ZYNRELEF in patients with advanced renal disease unless benefits are expected to outweigh risk of worsening renal failure.

Anaphylactic Reactions: Seek emergency help if an anaphylactic reaction occurs.

Chondrolysis: Limit exposure to articular cartilage due to the potential risk of chondrolysis.

Methemoglobinemia: Cases have been reported with local anesthetic use.

Serious Skin Reactions: NSAIDs, including meloxicam, can cause serious skin adverse reactions. If symptoms present, evaluate clinically.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): If symptoms are present, evaluate clinically.

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ASC COVERAGE AND BILLING FOR ZYNRELEF

Coverage for ZYNRELEF varies by health insurance plan and site of care. The table below summarizes the coverage and payment type for ASCs.

ZYNRELEF Coverage and Reimbursement Policy in ASCs

Medicare	To reduce incentives for using opioids, CMS established separate reimbursement in ASCs for ZYNRELEF at **ASP + 6%** starting January 1, 2022, utilizing C9088.[1]
Medicaid[a]	Each State Medicaid Agency sets its own coverage policies and payment rates.
Private Commercial Payer[a]	Separate payment for ZYNRELEF is available for many commercial patients. Commercial reimbursement and coding vary by payer and site of care. **Customers should complete a benefit verification to confirm coverage and coding or request one by contacting Heron Connect®.**

[a]Please contact Heron Connect to understand coverage for specific health plans. Heron Connect provides guidance on completing claim forms, benefit verification, review of claims before submission, assistance with appeals in the event of a denial, and more.

IMPORTANT SAFETY INFORMATION (CONT)

Warnings and Precautions (cont)

Fetal Toxicity: Due to the risk of oligohydramnios/fetal renal dysfunction and premature closure of the ductus arteriosus with NSAIDS, limit use of ZYNRELEF between about 20 to 30 weeks gestation, and avoid use after about 30 weeks.

Hematologic Toxicity: Monitor hemoglobin and hematocrit in patients with any signs or symptoms of anemia.

Drug Interactions

Drugs That Interfere with Hemostasis: Monitor patients for bleeding who are using ZYNRELEF with drugs that interfere with hemostasis (eg, warfarin, aspirin, SSRIs/SNRIs).

ACE Inhibitors, Angiotensin Receptor Blockers (ARBs), or Beta-Blockers: Use with ZYNRELEF may diminish the antihypertensive effect of these drugs. Monitor blood pressure.

ACE Inhibitors and ARBs: Use with ZYNRELEF in elderly, volume-depleted, or those with renal impairment may result in deterioration of renal function. In such high-risk patients, monitor for signs of worsening renal function.

Diuretics: NSAIDs can reduce natriuretic effect of furosemide and thiazide diuretics. Monitor patients to assure diuretic efficacy including antihypertensive effects.

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ACUTE CARE (HOSPITAL INPATIENT DEPARTMENT, ED[a], AND HOPD) COVERAGE AND BILLING FOR ZYNRELEF

Coverage for ZYNRELEF varies by health insurance plan and site of care. Reimbursement of ZYNRELEF in a surgical procedure occurring during a hospital inpatient admission would be included in the diagnosis-related group (DRG) payment.

The table below summarizes the coverage and payment type for HOPDs.

ZYNRELEF Coverage and Reimbursement Policy in HOPDs

Medicare	**Separate reimbursement at ASP + 6%** under 3-year transitional pass-through status effective April 1, 2022.[b]
Medicaid[c]	Each State Medicaid Agency sets its own coverage policies and payment rates.
Private Commercial Payer[c]	Separate payment for ZYNRELEF is available for many commercial patients. Commercial reimbursement and coding vary by payer and site of care. **Customers should complete a benefit verification to confirm coverage and coding or request one by contacting Heron Connect®.**

[a]For patients covered by Medicare, when the surgery occurs in the ED, reimbursement is the same as in a HOPD; however, if a patient is admitted, inpatient reimbursement rules apply.

[b]When pass-through status expires, ZYNRELEF will be reimbursed as part of the packaged rate for each surgical procedure.

[c]Please contact Heron Connect to understand coverage for specific health plans. Heron Connect provides guidance on completing claim forms, benefit verification, review of claims before submission, assistance with appeals in the event of a denial, and more.

IMPORTANT SAFETY INFORMATION (CONT)

Use in Specific Populations

Infertility: NSAIDs are associated with reversible infertility. Consider avoidance of ZYNRELEF in women who have difficulties conceiving.

Severe Hepatic Impairment: Only use if benefits are expected to outweigh risks; monitor for signs of worsening liver function.

Severe Renal Impairment: Not recommended.

Adverse Reactions

Most common adverse reactions (incidence ≥10%) in controlled clinical trials with ZYNRELEF are constipation, vomiting, and headache.

Report side effects to Heron at 1-844-437-6611 or to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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SAMPLE CLAIM FORM CMS-1450 (UB-04): HOPD, ASC (NON-MEDICARE PAYERS; CONFIRM WITH PAYER)

For commercial payers, complete a **benefit verification** to confirm coverage and coding or request one by contacting Heron Connect® at 1-844-HERON11 (1-844-437-6611).

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

Field 43:
Include the required additional information (eg, product name and NDC).

Example:

- **For 400 mg/12 mg (14 mL) kit:** ZYNRELEF, 47426-0301-02
- **For 200 mg/6 mg (7 mL) kit:** ZYNRELEF, 47426-0303-01

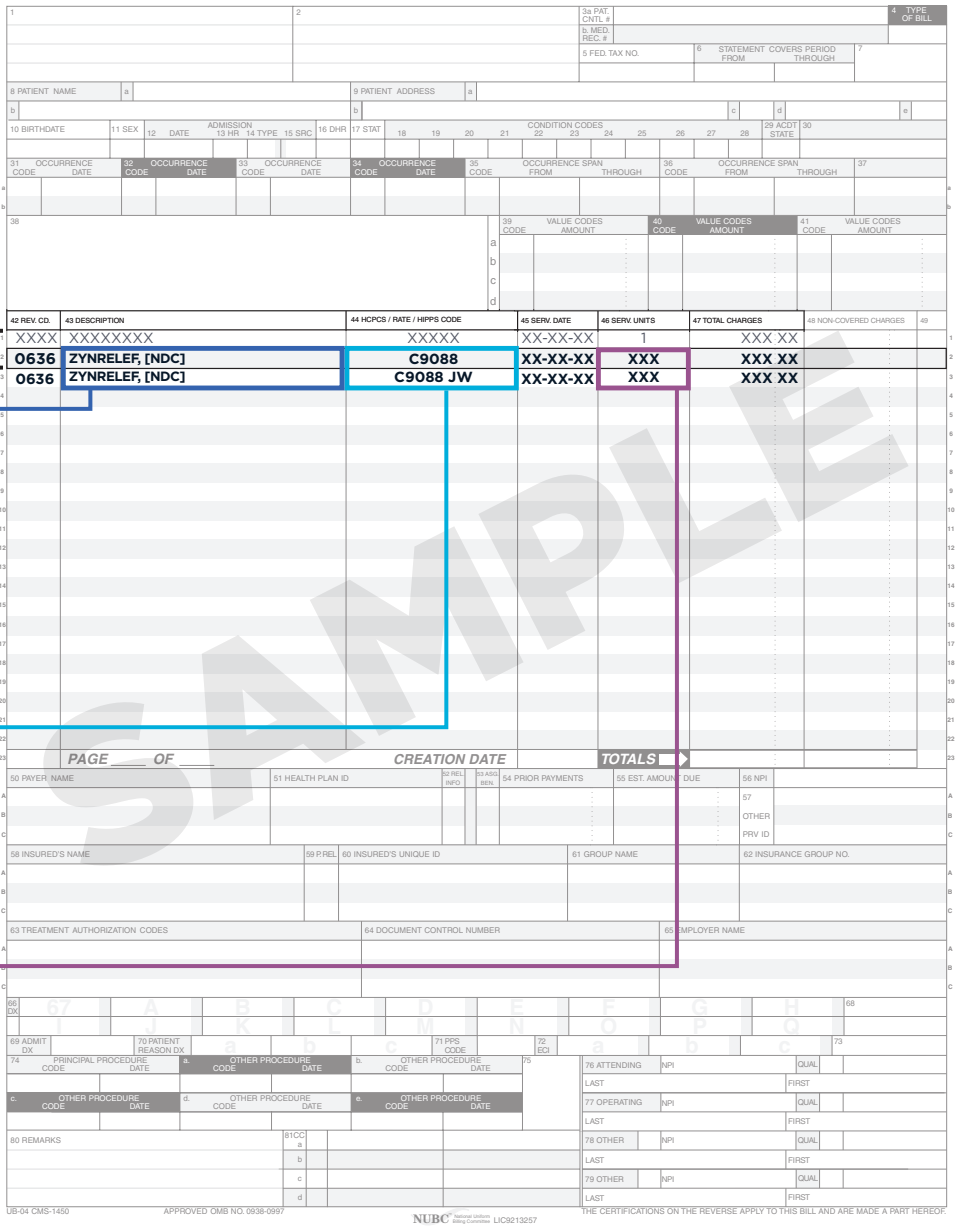
Payer NDC requirements and placement may vary; confirm with payer or Heron Connect.

Field 44:
Specify appropriate HCPCS code. For dates of service on or after January 1, 2022, use **C9088**.

Commercial: Confirm coding with payers by completing a benefit verification or requesting one through Heron Connect.

Field 46:
Specify the number of units administered. **The billable unit for C9088 is 1 mg/0.03 mg.** For example, 300 mg/9 mg (10.5 mL) corresponds to 300 billable units.

If a portion of the single-use vial was discarded, document it on a **separate line** using the HCPCS modifier JW. For example, if 100 mg/3 mg (3.5 mL) was discarded, enter 100 billable units.



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

CMS requires ASCs to submit a CMS-1500 claim form when billing a Medicare Administrative Contractor (MAC). Most commercial plans require a CMS-1450 (UB-04) claim form (see page 6 for an example). 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. **ZYNRELEF must be billed using a separate line**.

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

Example:

- **For 400 mg/12 mg (14 mL) kit:** ZYNRELEF, 47426-0301-02
- **For 200 mg/6 mg (7 mL) kit:** ZYNRELEF, 47426-0303-01

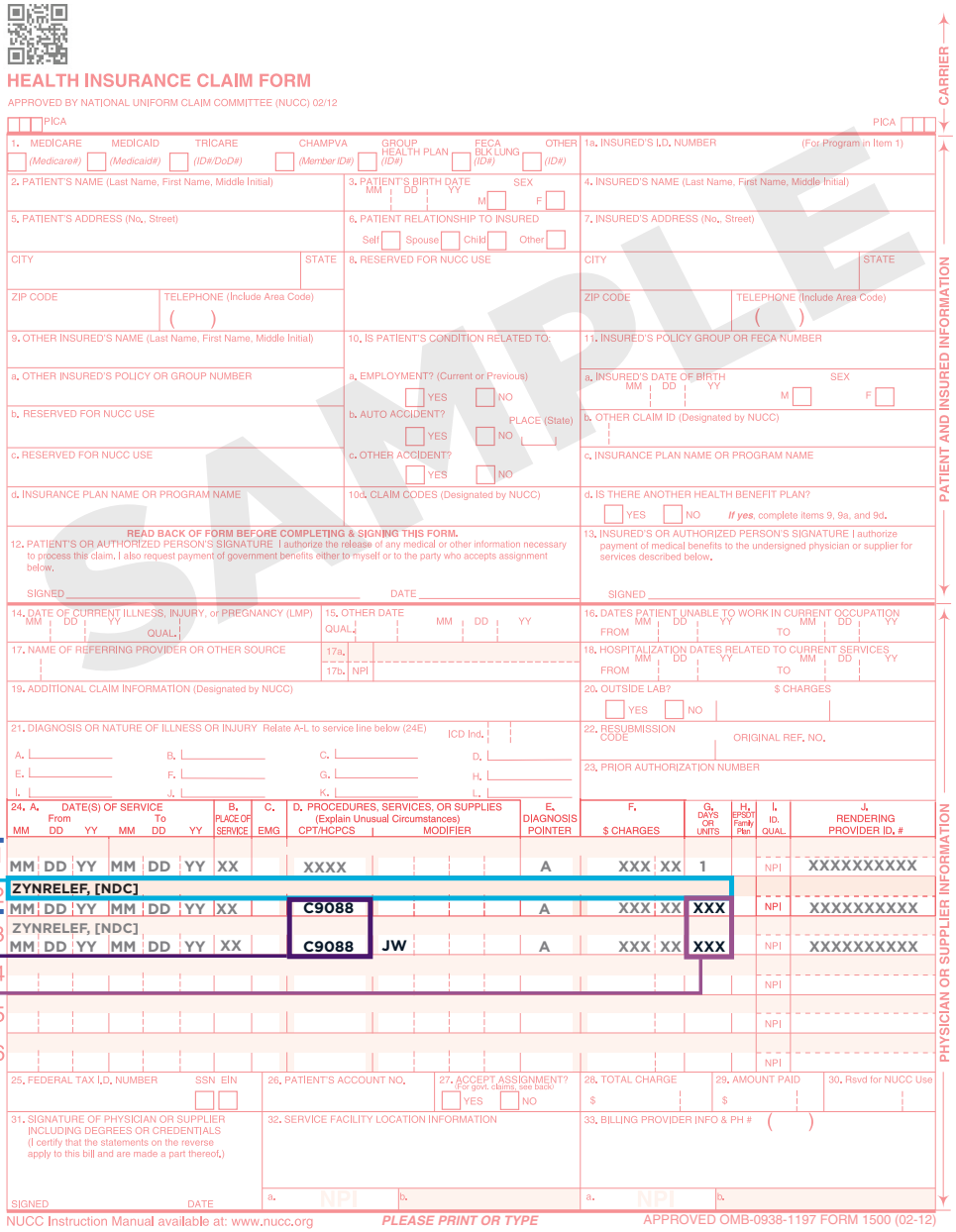
Payer NDC requirements and placement may vary; confirm with payer or Heron Connect®.

Field 24D:
Specify appropriate HCPCS code. For dates of service on or after January 1, 2022, use **C9088**.

Additional modifiers may be required; please confirm with commercial plans.

Field 24G:
Specify the number of units administered. **The billable unit for C9088 is 1 mg/0.03 mg.** For example, 300 mg/9 mg (10.5 mL) corresponds to 300 billable units.

If a portion of the single-use vial was discarded, document it on a **separate line** using the HCPCS modifier JW. For example, if 100 mg/3 mg (3.5 mL) was discarded, enter 100 billable units.



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CLAIM SUBMISSION CHECKLIST

Have you included the HCPCS code for ZYNRELEF?

☐ C9088

Have you included the following information to support utilization of C9088?

☐ Drug name ☐ NDC

Have you documented any unused and discarded drug amounts with the JW modifier on a separate line?

☐ Yes

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Please see full Prescribing Information, including Boxed Warning.

References: 1. Centers for Medicare & Medicaid Services. CY 2022 OPPS/ASC Payment System Final Rule. *Fed Regist*. 2021;86(147):63458-63998.

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