Sample Letter of Medical Appeal

[PRACTICE LETTERHEAD]

[Date]

[Dr/Mr/Ms] [Medical Director Name] [Name of Health Insurance Company] [Insurer Address] [City], [State] [Zip Code]

Re:

[Patient Name]
Patient Policy Number: []
Group Number: []
Date(s) of Service: []
Claim Number: []

Dear [Dr/Mr/Ms] [Contact Name]:

This letter serves as a request for reconsideration of payment for a denied claim for ZYNRELEF® (bupivacaine and meloxicam) extended-release solution, a non-opioid local anesthetic used in the [Surgical Procedure] for [Patient Name] on [Date of Procedure]. Reimbursement was denied because of [Reason for Denial From EOB]. I am writing to request a review of this denial.

Based on the typical pain associated with [*Surgical Procedure*], ZYNRELEF was used because of its clinical effectiveness, its length of postoperative pain reduction, and its superior efficacy compared to standard-of-care bupivacaine HCl solution.¹⁻⁴ ZYNRELEF is indicated in adults for instillation to produce postsurgical analgesia for up to 72 hours after soft tissue and orthopedic procedures including foot and ankle, and other procedures in which direct exposure to articular cartilage is avoided. <u>Limitations of Use</u>: Safety and efficacy have not been established in highly vascular surgeries, such as intrathoracic, large 4 or more level spinal, and head and neck procedures.

Using ZYNRELEF was an important part of [**Patient Name**]'s postoperative pain management plan after [**Surgical Procedure**], as ZYNRELEF was intended to reduce pain and minimize the need for opioids.

Summary of patient's history:

[Note: Consider including the information below. Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

- [Patient's diagnosis, condition, and history/treatment]
- [Patient's postsurgical procedure condition]

Please refer to the enclosed Prescribing Information, including Boxed Warning, which provides the approved clinical information for ZYNRELEF.

Based on the patient's medical need, I am confident you will agree that ZYNRELEF was medically necessary and the appropriate option to use during the patient's procedure. As a non-opioid alternative, ZYNRELEF provided an option to minimize this patient's exposure to opioids without sacrificing adequate pain relief. We appreciate your reconsideration of this claim denial and believe it is important that this treatment is covered and reimbursed.

Please contact me at [*Telephone Number*] if you require additional information.

Sincerely,

[Physician Name] [NPI Number] [Phone Number] [Fax Number]

Enclosures: [List and attach the original claim form, denial/explanation of benefits, ZYNRELEF Prescribing Information, and additional supporting documentation.]

Please see full <u>Prescribing Information</u>, including Boxed Warning.

References: 1. ZYNRELEF [package insert]. San Diego, CA: Heron Therapeutics Inc; 2021. **2.** Viscusi E, Gimbel JS, Pollack RA, Hu J, Lee G-C. HTX-011 reduced pain intensity and opioid consumption versus bupivacaine HCl in bunionectomy: Phase III results from the randomized EPOCH 1 study. *Reg Anesth Pain Med.* 2019;44(7):700-706. doi:10.1136/rapm-2019-100531. **3.** Viscusi E, Minkowitz H, Winkle P, Ramamoorthy S, Hu J, Singla N. HTX-011 reduced pain intensity and opioid consumption versus bupivacaine HCl in herniorrhaphy: results from the Phase 3 EPOCH 2 study. *Hernia.* 2019;23(6):1071-1080. doi:10.1007/s10029-019-02023-6. **4.** Lachiewicz PF, Lee G-C, Pollak R, Leiman D, Hu J, Sah A. HTX-011 reduced pain and opioid use after primary total knee arthroplasty: results of a randomized Phase 2b trial. *J Arthroplasty.* 2020;35(10):2843-2851. doi:10.1016/j.arth.2020.05.044.