SAMPLE Health Plan Letter of Appeal

[Date]
[Payer Name]
[Payer Address]
Attn: [Medical Director]

RE: Appeal of claim denial
Patient: [Patient Name]
Group/Policy Number: [Number]
Date(s) of Service: [Dates]
Claim number: [Number]
Denial date: [Date]
Reference number: [Number]

Dear Medical Reviewer/Appeals Reviewer,

On behalf of [Patient Name], I am requesting an appeal of the decision to deny coverage of the use of OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1% / 0.3% used during cataract surgery. Based on a letter of denial dated [date], OMIDRIA has been denied due to [insert specific reason for denial stated in the denial letter]. In my clinical opinion, the use of OMIDRIA is medically necessary for [Patient Name] during surgery.

Rationale for use of OMIDRIA

- *OMIDRIA is approved for this use by the U.S. Food and Drug Administration.*[1]
  From the Prescribing Information:
  - OMIDRIA is added to an ocular irrigating solution used during cataract surgery or intraocular lens replacement and is indicated for maintaining pupil size by preventing intraoperative miosis and reducing postoperative ocular pain.[1]
- *OMIDRIA has an established efficacy and safety profile*.[1]
  From the Prescribing Information:
  - The efficacy and safety of OMIDRIA were evaluated in two Phase 3, randomized, multicenter, double-masked, placebo-controlled clinical trials in 808 adult patients undergoing cataract surgery or intraocular lens replacement.[1]
  - Furthermore:
    - Mydriasis was maintained in the OMIDRIA-treated groups while the placebo-treated groups experienced progressive constriction.[1]
    - Pain during the initial 10-12 hours postoperatively was statistically significantly less in the OMIDRIA-treated groups than in the placebo-treated groups.[1]
- *OMIDRIA offers benefits beyond phenylephrine or ketorolac alone*.[2]
  From the results of a Phase 2 study published in 2017 in the *Journal of Cataract and Refractive Surgery*:

- Use of OMIDRIA "provided a more-than-additive effect relative to phenylephrine alone and ketorolac alone in preventing intraoperative miosis."[2]

Patient-Specific Rationale for Treatment with OMIDRIA

[Insert information regarding the patient's specific situation, relative risk profile, and other considerations which, based on your medical judgment, support your decision to use OMIDRIA for the patient's procedure.] Based on these points and the above facts about OMIDRIA, treatment of this patient with OMIDRIA during surgery is appropriate.

The attached medical records document [Patient Name]'s clinical condition. I have also attached a Letter of Medical Necessity for treatment with OMIDRIA during [Patient Name]'s surgery.

Reimbursement of OMIDRIA

The Centers for Medicare and Medicaid Services (CMS) considers OMIDRIA a non-opioid pain management drug that functions as a surgical supply.[3] Beginning October 1, 2020, OMIDRIA was excluded from packaging under the ambulatory surgical center (ASC) payment system.[3] The Medicare Claims Processing Manual, Chapter 17, §20.1.2 states the following:

- *"…drugs and biologicals with pass-through status under the OPPS, will be paid based on 106 percent of the ASP [average selling price]."*[4]

Medicare and other third-party payers reimburse facilities for OMIDRIA when used in accordance with the FDA-approved labeling. Use of OMIDRIA in this patient is medically necessary and will follow the FDA-approved labeling.

In Conclusion

I believe treatment of [Patient Name] with OMIDRIA is warranted, appropriate, and medically necessary, and therefore this claim merits reimbursement. On behalf of [Patient Name], please reconsider your previous denial of our claim for use of OMIDRIA.

If you have any further questions regarding this matter or require further documentation, please do not hesitate to call me at [physician telephone number] or email me at [email address]. Thank you for your consideration of this appeal.

Sincerely,

[Physician name], [degree initials] [provider identification number]

Enclosures [attach as appropriate]
[OMIDRIA Prescribing Information]

[Letter of Medical Necessity]

[Medical history for [Patient Name], group/policy number [number]]

[Donnenfeld ED 2017]

CC: [Medical Director, patient, specialty society, insurance]

References: **1.** OMIDRIA [package insert]. Seattle, WA: Omeros Corporation; 2017. **2.** Donnenfeld ED, Whitaker JS, Jackson MA, Wittpenn J. Intracameral ketorolac and phenylephrine effect on intraoperative pupil diameter and postoperative pain in cataract surgery. *J Cataract Refract Surg*. 2017;43:597-605. **3.** US Department of Health and Human Services. Hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs; new categories for hospital outpatient department prior authorization process; clinical laboratory fee schedule: laboratory date of service policy; overall hospital quality star rating methodology; physician-owned hospitals; notice of closure of two teaching hospitals and opportunity to apply for available slots, radiation oncology model; and reporting requirements for hospitals and critical access hospitals (CAHs) to report COVID-19 therapeutic inventory and usage and to report acute respiratory illness during the public health emergency (PHE) for coronavirus disease 2019 (COVID-19). Baltimore, MD: Centers for Medicare & Medicaid Services (CMS), US Department of Health and Human Services; 2020. **4.** Center for Medicare and Medicaid Services. Drugs and biologicals. In: *Medicare Claims Processing Manual*; 2020:chap 17. Updated August 8, 2020. Accessed June 29, 2021. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf

The information contained in this template letter is provided by Omeros for informational purposes for patients who have been prescribed OMIDRIA. This template letter is not meant to substitute for a prescriber's independent medical decision-making.