REIMBURSEMENT GUIDE
About OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1% / 0.3%

OMIDRIA is the first and only FDA-approved drug that provides continuous intracameral delivery of NSAID and mydriatic/anti-miotic therapy during cataract surgery.

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 for reducing postoperative ocular pain.

Published and presented clinical data and manuscripts in preparation report that in post-launch (i.e., not included in current labeling), prospective and retrospective, double-masked and open-label, cohort and case-controlled, single- and multi-center studies, the use of OMIDRIA statistically significantly:

- Prevents intraoperative floppy iris syndrome (IFIS)
- Prevents iris prolapse

OMIDRIA is reimbursed per mL; therefore, providers should always use 1 mL as the billing unit and bill for 4 units.

OMIDRIA is supplied as a concentrate in a clear, glass, single-patient-use vial containing 4 mL of sterile solution.

OMIDRIA contains a nonsteroidal anti-inflammatory drug (NSAID), ketorolac, to prevent miosis and reduce postoperative pain and an α-adrenergic receptor agonist, phenylephrine, to maintain pupil diameter.

OMIDRIA is easy to integrate into operating procedures:
- Added preoperatively to irrigating solution
- No other preparation required

OMIDRIA is reimbursed per mL; therefore, providers should always use 1 mL as the billing unit and bill for 4 units.

OMIDRIA has a unique permanent J-code

J1097
phenylephrine 10.16 mg/mL and ketorolac 2.88 mg/mL ophthalmic irrigation solution, 1 mL

OMIDRIA is reimbursed per mL; therefore, providers should always use 1 mL as the billing unit and bill for 4 units.

Important reminders
- The OMIDRIAssure® program provides assistance for financially eligible uninsured or government-insured patients and those with insufficient commercial insurance.
- Questions related to a patient’s eligibility for OMIDRIAssure® should be addressed by calling the Live Assistance Reimbursement Hotline at 1-877-OMIDRIA (1-877-664-3742), contacting your OMIDRIA representative, or working directly with your payer provider representative.

INDICATIONS AND USAGE
OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1% / 0.3% is added to ophthalmic 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.

IMPORTANT SAFETY INFORMATION
The most commonly reported adverse reactions at ≥2% are eye irritation, posterior capsule opacification, increased intraocular pressure, and anterior chamber inflammation. You are encouraged to report Suspected Adverse Reactions to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

*Information contained in this guide is provided as a reference for obtaining appropriate and accurate reimbursement for the use of OMIDRIA in eligible patients. Omeros does not guarantee reimbursement. OMIDRIAssure program services are subject to change without notice. Individual plan coverage, payment, policies, and procedures vary and should be confirmed by the facility. Omeros does not guarantee reimbursement.
Pass-through status for OMIDRIA allows ambulatory surgery centers (ASCs) and hospital outpatient departments (HOPDs) to bill Medicare and other payers for OMIDRIA using a HCPCS code unique to OMIDRIA—J1097 phenylephrine 10.16 mg/mL and ketorolac 2.88 mg/mL ophthalmic irrigation solution, 1 mL. The payment is over and above the facility fees paid to ASCs or to HOPDs for cataract surgery.

### Medicare Part B
- OMIDRIA use in cataract and lens replacement surgery for patients with Medicare Part B coverage is separately paid (i.e., in addition to the facility fee) by the Centers for Medicare & Medicaid Services (CMS). This pass-through status for OMIDRIA will remain effective until October 1, 2020. Omeros is in discussions with CMS regarding permanent separate payment for OMIDRIA.
- Pass-through status allows reimbursement for OMIDRIA separate from the packaged Ambulatory Payment Classification (APC) reimbursement for the surgical procedure.
- For pass-through drugs, CMS sets the payment rate at Average Sales Price (ASP) plus 6%—Check the CMS website for current quarterly payment rates in the Hospital OPPS (Addendum B) or ASC Payments (Addendum BB) section.
- Payment rates are updated quarterly by CMS and, during the government sequester, 6% is reduced to 4.3%.
- No co-pay in HOPDs.
- 20% co-pay in ASCs.
- Approximately 90% of Medicare Part B patients have some form of supplemental insurance, which covers co-pays.
- For government-insured patients with an uncovered out-of-pocket expense and who meet certain financial criteria, Omeros has established the Equal Access Patient Assistance Program as part of OMIDRIAssure, which allows patients to receive OMIDRIA at no cost; a free vial is sent to your facility prior to surgery.

### Medicare Part C (Medicare Advantage)
- Like traditional Medicare Part B, Medicare Advantage plans will cover OMIDRIA, but the payment rate may differ from traditional Part B or be subject to payer-specific facility contractual limitations.
- Omeros does not guarantee payment by any payer.
- For a Medicare Advantage patient, the specific Medicare Advantage payer should be contacted in advance to determine the level of reimbursement for OMIDRIA.

### HCPCS and APC codes for OMIDRIA

<table>
<thead>
<tr>
<th>HCPCS code</th>
<th>Long descriptor</th>
<th>APC</th>
</tr>
</thead>
<tbody>
<tr>
<td>J1097</td>
<td>Phenylephrine 10.16 mg/mL and ketorolac 2.88 mg/mL ophthalmic irrigation solution, 1 mL</td>
<td>9324</td>
</tr>
</tbody>
</table>

1 billing unit = 1 mL; one standard 4-mL vial = 4 units

### About Medicare Billing and Reimbursement

**Equal Access Patient Assistance Program**
- Assistance for financially eligible uninsured or government-insured patients
  - Eligible patients will receive OMIDRIA at no cost.
  - Free vial will be sent to your facility prior to surgery.
  - Application for free vial must be submitted at least 5 days prior to date of surgery.

- Please contact your OMIDRIA representative for more details.
- For personalized help, call the Live Assistance Reimbursement Hotline at 1-877-OMIDRIA (1-877-664-3742), 9 AM-5 PM ET, Monday-Friday.

*Based on currently available information and subject to change without notice. Individual plan coverage, payment, policies, and procedures vary and should be confirmed by the facility. Omeros does not guarantee reimbursement.

1To be eligible for the Equal Access Patient Assistance Program, patients must be enrolled prior to surgery. Program is subject to change without notice. For any patient eligible for the Equal Access Patient Assistance Program, (1) the facility reserves a free vial of OMIDRIA prior to surgery; and (2) the patient’s insurance carrier(s) should not be billed for OMIDRIA.

1Benefit verifications may not address contracted payer payment rates.
WE PAY THE DIFFERENCE
PATIENT REIMBURSEMENT PROGRAM
Assistance for patients with insufficient commercial insurance

- Omeros will pay your facility, on behalf of your patient, the difference between your facility’s acquisition cost for Omidria and the amount covered by your patient’s insurance*
- The benefits apply even if the annual commercial deductible obligation has not yet been met
- Visit www.omidria.com/resources/ to download the We Pay The Difference Claims Submission Form, OmidriaSure Flashcard, and other available resources
- Please contact your Omidria representative for more details
- For personalized help, call the Live Assistance Reimbursement Hotline at 1-877-Omidria (1-877-664-3742), 9 am-5 pm ET, Monday-Friday

Payer Contracts: Best Practices for Medicare Advantage and Commercial Payers

- Check if your facility-specific payer contracts allow for separate payment of drugs, new technologies, and pass-through drugs
- Confirm and verify payer payment/fee schedules for Omidria
- Verify acceptance of J-code and payer-specific use of appropriate revenue code
- Cultivate relationship with payer-provider network representative
- Utilize payer-provider portal for specific medical benefit coverage of Omidria

Patient insurance benefits are typically comprised of primary and additional coverage that determine billable status

- Work with your Omeros Reimbursement Specialist to determine billable status for your payers*

Step 1: Primary Insurance
- Medicare B (FFS or Legacy Medicare)
- Medicare Supplemental (Medigap)
- Secondary
- Medicaid
- Other

Step 2: Additional Insurance
- Medicare C (Replacement or Advantage)
- Commercial
- Other Government
- Secondary
- Medicare Part A/B
- Medicaid
- Tricare/DOD
- Veterans Health Administration

Helpful Hints: Best Practices for Claim Submissions in General

- Make sure submissions are timely and accurate
- Double-check codes and units
- Verify
  - Diagnosis codes and procedure codes
  - CPT, HCPCS, and revenue codes
  - NDC (depending on claim form)
- Stay up to date on payer coverage as well as billing and coding trends
- Pay close attention and double-check your work when creating claims
- Follow up with payers after claims are submitted
- If any claim is denied, seek out appeal process and utilize letter of medical necessity

*OMidriaSure program services are subject to change without notice. The We Pay The Differences Patient Reimbursement Program patient benefit is not available for patients with any government insurance. Omeros does not guarantee reimbursement. Facility acquisition cost is determined after application of any volume-based discount. Claims must be submitted within one year of date of surgery. To be eligible for the Equal Access Patient Assistance Program, patients must be enrolled prior to surgery.

*Individual plan coverage, payment, policies, and procedures vary and should be confirmed by the facility. Omeros does not guarantee reimbursement.
Information contained herein is provided as a reference for obtaining appropriate and accurate reimbursement. This content is for informational purposes only. Omeros does not guarantee that the use of the recommended codes will result in reimbursement. Providers should always contact the payer directly with reimbursement or billing questions. Contact 1-844-OMEROS1 (1-844-663-7671) for more information about how to submit for OMIDRIA reimbursement.

OMIDRIA reimbursement.

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Sample UB-04 Paper Claim Form

**Form Locator 4:** Enter the 4-digit code that specifies place of service and submission type. For example, for HOPD, the first 3 digits are 018. The first digit is usually a “1” meaning one claim for the event.

**Form Locator 17:** Enter Patient Status

**Form Locator 47:** Enter price for OMIDRIA from price schedule, including all applicable mark-ups

**Form Locator 42:** Enter the Revenue Code

**Form Locator 44:** Enter the unique Billing Code for OMIDRIA

**Form Locator 44:** Enter the Procedure Code(s)

**Form Locator 46:** Enter the number of Units (mL)

**Form Locator 50A:** If Medicare is the primary payer, enter “Medicare” on line A

**Form Locator 67:** Enter the primary Diagnosis Code

**Form Locator 66:** Enter “0” if using CPT-10 CM

**Form Locator 80:** This is where NDC number should be placed if NDC code required or if Medicaid for 340B rebate reimbursement

*Note: For hospitals and ASCs using UB04 form, it is a best practice to confirm the correct revenue code with the payer to ensure reimbursement.

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CPT is a registered trademark of the American Medical Association.


Please see the Full Prescribing Information for OMIDRIA on pages 10-11 and Important Safety Information on the back cover.
INDICATIONS AND USAGE
Omidria® is an intraocular solution containing 10.16 mg/mL (1% w/v) of phenylephrine and 2.88 mg/mL of the nonsteroidal anti-inflammatory ketorolac tromethamine, for addition to ocular irrigating solution used during cataract surgery or intraocular lens replacement.

DOSAGE AND ADMINISTRATION
Omidria must be diluted prior to intraocular use. For administration to patients undergoing cataract surgery or intraocular lens replacement, 4 mL of Omidria is diluted in 500 mL of ocular irrigating solution. Intragraft solution is to be used for the surgical procedure for a single patient only. The storage period for the diluted solution is not more than 4 hours at room temperature or 24 hours under refrigerated conditions. Do not use if the solution is cloudy or if it contains particulate matter.

DOSAGE FORMS AND STRENGTHS
Omidria is a sterile aqueous solution containing 10.16 mg/mL (1% w/v) of phenylephrine and 2.88 mg/mL of ketorolac tromethamine.

CONTRAINDICATIONS
Hypersensitivity to aspirin/NSAIDs or a past medical history of asthma. Therefore, use Omidria with caution in patients with a history of allergy to any component of this product (4).

WARNINGS AND PRECAUTIONS
Phenylephrine is a sympathomimetic agent that causes vasoconstriction. Phenylephrine, like other sympathomimetics, can produce adverse cardiovascular effects, such as myocardial ischemia and infarction, angina, and myocardial infarction (4).

ADVERSE REACTIONS
The most common reported adverse reactions (≥2%) are eye irritation, posterior capsule opacification, and mydriasis. 3

REFERENCES
1. Clinical Laboratory Experience
2. Dosage and Administration
3. Contraindications
4. Warnings and Precautions
5. Adverse Reactions
6. Us and Specific Populations
7. Pregnancy
8. Lactation
9. Pediatric Use
10. Overdosage

FULL PRESCRIBING INFORMATION: CONTENTS*
1 INDICATIONS AND USAGE
Omidria® is an intraocular solution containing 10.16 mg/mL (1% w/v) of phenylephrine and 2.88 mg/mL of injectable NSAIDs. Ketorolac plasma concentrations are detectable following ocular Omidria administration. In animal studies, ketorolac decreased eye pressure and was well tolerated at low (100 μL) and high (200 μL) doses, resulting in a decrease in intraocular pressure (IOP) in all animal species. In a 3-4 month canine study, ketorolac at doses of 100 μL and 200 μL produced significant reductions in IOP. In addition, ketorolac demonstrated a doserelated anti-inflammatory effect as measured by reductions in cyclooxygenase (COX) activity.

11 DESCRIPTION
Omidria is a sterile, clear, colorless solution containing 10.16 mg/mL (1% w/v) of phenylephrine and 2.88 mg/mL of ketorolac tromethamine, for addition to ocular irrigating solution. Omidria is a sterile aqueous solution, containing the mydriatic and anesthetic agents. Pupil diameter was measured throughout the surgical procedure. Phenylephrine is an α1-adrenergic receptor agonist and nonselective (phenoxyethanol) indicated for the treatment of hypertension. It is a sympathomimetic agent that causes vasoconstriction. Phenylephrine, like other sympathomimetics, can produce adverse cardiovascular effects, such as myocardial ischemia and infarction, angina, and myocardial infarction (4).

12.1 Mechanism of Action
Omidria is a colorless, slightly yellow, sterile solution containing 10.16 mg/mL (1% w/v) of phenylephrine and 2.88 mg/mL of ketorolac tromethamine.

12.2 Pharmacokinetics
Omidria is a sterile, clear, colorless solution containing 10.16 mg/mL (1% w/v) of phenylephrine and 2.88 mg/mL of ketorolac tromethamine, for addition to ocular irrigating solution. Omidria is a sterile aqueous solution, containing the mydriatic and anesthetic agents. Pupil diameter was measured throughout the surgical procedure. Phenylephrine is an α1-adrenergic receptor agonist and nonselective (phenoxyethanol) indicated for the treatment of hypertension. It is a sympathomimetic agent that causes vasoconstriction. Phenylephrine, like other sympathomimetics, can produce adverse cardiovascular effects, such as myocardial ischemia and infarction, angina, and myocardial infarction (4).

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IMPORTANT SAFETY INFORMATION
OMIDRIA must be added to irrigating solution prior to intraocular use.

OMIDRIA is contraindicated in patients with a known hypersensitivity to any of its ingredients. Systemic exposure of phenylephrine may cause elevations in blood pressure.

Use OMIDRIA with caution in individuals who have previously exhibited sensitivities to acetylsalicylic acid, phenylacetic acid derivatives, and other nonsteroidal anti-inflammatory drugs (NSAIDs), or have a past medical history of asthma.

The most commonly reported adverse reactions at ≥2% are eye irritation, posterior capsule opacification, increased intraocular pressure, and anterior chamber inflammation.

Please see the Full Prescribing Information for OMIDRIA at www.omidria.com/prescribinginformation.

You are encouraged to report Suspected Adverse Reactions to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Visit www.omidria.com to learn more.

References:
3. Visco D, et al. Study to evaluate patient outcomes following cataract surgery when using OMIDRIA with postoperative topical NSAID administration versus a standard regimen of postoperative topical NSAIDs and steroids. Presented at: 28th Annual Meeting of the American College of Eye Surgeons (ACES), the American Board of Eye Surgery (ABES), and the Society for Excellence in Eyecare (SEE), Caribbean Eye Meeting. February 1-5, 2019; Cancun, Mexico.

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