OMIDRIA®

(phenylephrine and ketorolac intraocular solution) 1% / 0.3%

Billing and Reimbursement Guide

- Codes and guidance on completing claims forms for Medicare Fee-for-Service, Medicare Advantage, and commercial payers
- Billing and reimbursement process information for OMIDRIA
- Guidance for appealing denied claims
- Details on ordering OMIDRIA
- Helpful resources

Rayner

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 an NSAID and a mydriatic agent during cataract surgery.[1]

OMIDRIA is a non-opioid medication added to the irrigating solution used during cataract surgery and lens replacement[1]

Provides direct and continuous intracameral delivery of an NSAID and a mydriatic agent.[1]

FDA-approved OMIDRIA: count on performance that stays ahead of the unexpected

- **Highly effective pupil dilation** and less use of PEDs[1-7]
- **Reduces complications** such as IFIS, CME, and breakthrough iritis[8,9]
- **Improved patient experience** with less pain, greater visual acuity, and fewer drops[2,9]
- **Minimizes the risks and liabilities** of compounded products
- **Easy access** for all your cataract procedures through OMIDRIAssure®

Easy to integrate into routine operating procedures

- Add preoperatively to irrigation solution[1]
  - One 4-mL single-patient-use vial to 500 mL ophthalmic irrigating solution[1]
  - Can be added to irrigation solution in the surgical suite
- No other preparation required

Do not use if the solution is cloudy or contains particulate matter.[1]

CME=cystoid macular edema; IFIS=intraoperative floppy iris syndrome; NSAID=nonsteroidal anti-inflammatory drug; PED=pupil expansion device.

Please see Important Safety Information on page 13 and Full Prescribing Information at omidriahcp.com

OMIDRIA®
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1% / 0.3%

Coding for OMIDRIA*

OMIDRIA has a unique permanent J-code†

J1097 phenylephrine 10.16 mg/mL and ketorolac 2.88 mg/mL ophthalmic irrigation solution, 1 mL[10]

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

Sample CPT® codes[11]	CPT® modifier[12]	NDC number[1]	APC[13]
66984 Uncomplicated cataract surgery **66982**‡ Complex cataract surgery **66983, 66989, 66991, 66988** Related intraocular lens procedures	**RT/LT** Right eye/Left eye	**62225-600-04**	**S9083**

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
- Coverage and payment may vary by payer, contractual agreements, and site of service

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.

CPT is a registered trademark of the American Medical Association.

*Individual plan coverage, payment, policies, and procedures vary and should be confirmed by the facility. Rayner does not guarantee reimbursement.

†Information contained in this guide is provided as a reference for obtaining appropriate and accurate reimbursement for the use of OMIDRIA in eligible patients. Rayner does not guarantee reimbursement. OMIDRIAssure program services are subject to change without notice.

‡If surgery is for complex cataract surgery, physician should note the ICD-10-CM code or reason why the surgery is complex.

APC=Ambulatory Payment Classification; CPT=Current Procedural Terminology; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NDC=National Drug Code.

Please see Important Safety Information on page 13 and Full Prescribing Information at omidriahcp.com

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Sample CMS-1500 Paper Claim Form[14]

For use in Ambulatory Surgery Centers (ASCs)

Enter all applicable patient information

Item 21:
Enter "0" if using ICD-10-CM

Item 21:
Enter the Diagnosis Code(s)

Item 24A:
Enter N4 qualifier and 11-digit NDC code

Item 24B:
"24" indicates an ASC

Item 24D:
Enter applicable procedure code (eg, 66984 for uncomplicated cataract surgery)

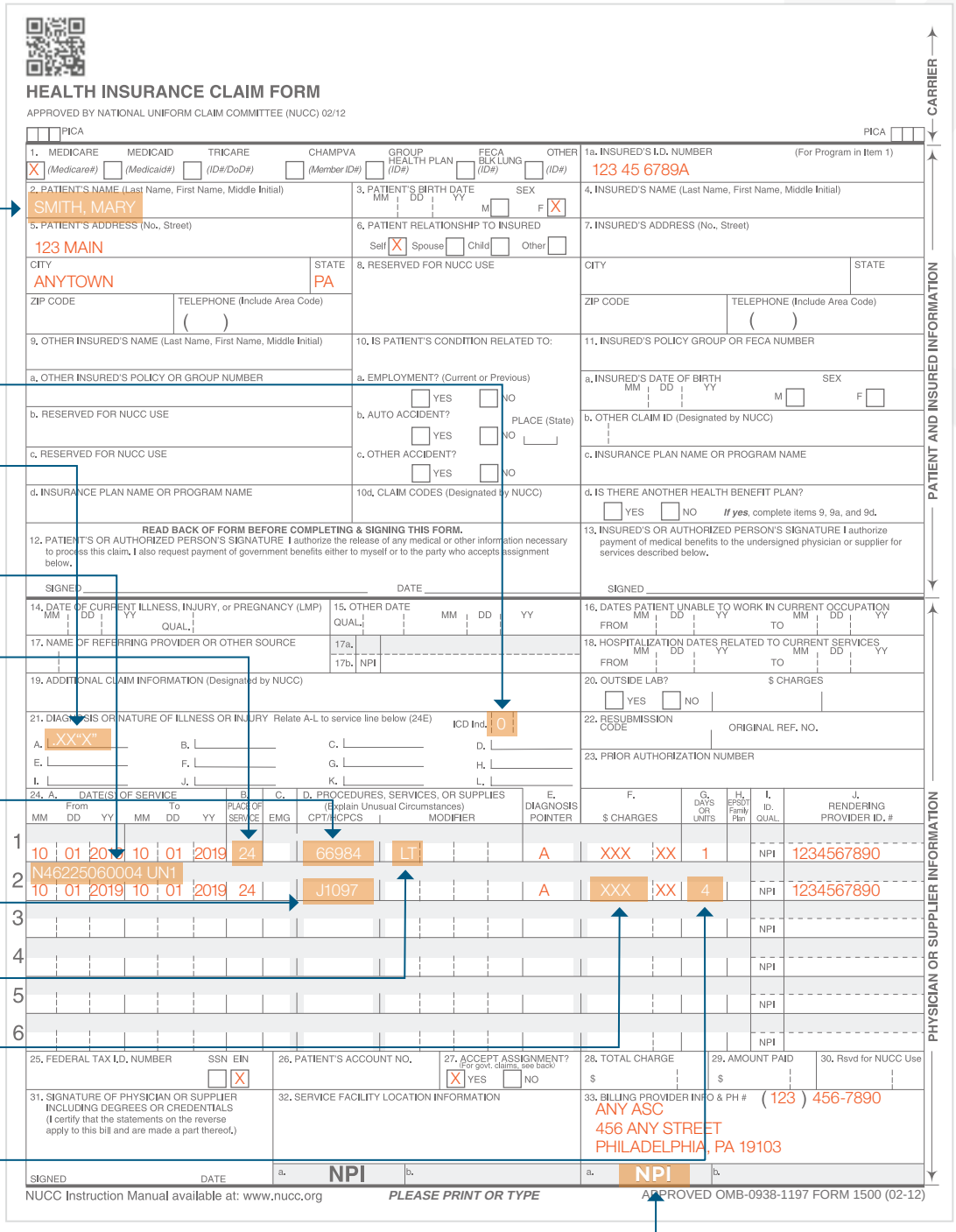
Item 24D:
Enter unique Billing Code for OMIDRIA

Item 24D:
Enter Modifier for left eye (LT) or right eye (RT)

Item 24F:
Enter price for OMIDRIA from price schedule, including all applicable mark-ups

Item 24G:
Enter 4 units

Item 33a:
Entry of NPI number is required



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

CARRIER

PATIENT AND INSURED INFORMATION

1. MEDICARE X (Medicare#) — MEDICAID (Medicaid#) — TRICARE (ID#/DoD#) — CHAMPVA (Member ID#) — GROUP HEALTH PLAN (ID#) — FECA BLK LUNG (ID#) — OTHER (ID#)

1a. INSURED'S I.D. NUMBER: 123 45 6789A (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial): SMITH, MARY

3. PATIENT'S BIRTH DATE MM DD YY — SEX: M ☐ F X

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street): 123 MAIN

6. PATIENT RELATIONSHIP TO INSURED: Self X Spouse ☐ Child ☐ Other ☐

7. INSURED'S ADDRESS (No., Street)

CITY: ANYTOWN — STATE: PA

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 ☐ NO

a. INSURED'S DATE OF BIRTH MM DD YY — SEX: M ☐ F ☐

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? ☐ YES ☐ NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? ☐ YES ☐ NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? ☐ YES ☐ NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

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.

SIGNED _____ DATE _____

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 _____

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM — MM DD YY TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM — MM DD YY TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? ☐ YES ☐ NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0

A. XX"X" B. C. D.

E. F. G. H.

I. J. K. L.

22. RESUBMISSION CODE — ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

PHYSICIAN OR SUPPLIER INFORMATION

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 10 01 20	10 01 2019	24		66984	LT	A	XXX	XX 1		NPI	1234567890
2 N46225060004 UN1 10 01 2019	10 01 2019	24		J1097		A	XXX	XX 4		NPI	1234567890
3										NPI	
4										NPI	
5										NPI	
6										NPI	

25. FEDERAL TAX I.D. NUMBER — SSN ☐ EIN X

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) X YES ☐ NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd 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.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # (123) 456-7890

ANY ASC
456 ANY STREET
PHILADELPHIA, PA 19103

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org — *PLEASE PRINT OR TYPE* — APPROVED OMB-0938-1197 FORM 1500 (02-12)

Information contained herein is provided as a reference for obtaining appropriate and accurate reimbursement. This content is for informational purposes only. Rayner 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.

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NDC=National Drug Code; NPI=National Provider Identifier.

Please see Important Safety Information on page 13 and Full Prescribing Information at omidriahcp.com

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Sample UB-04 Paper Claim Form[15]

For use in hospital outpatient departments (HOPD)

Form Locator 4:
Enter 4-digit code that specifies place of service and submission type. For example, for HOPD, the first 3 digits are 013. The final digit is usually a "1," meaning one claim for the event

Enter all applicable patient information

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 Revenue Code

Form Locator 43:
Enter OMIDRIA NDC

Form Locator 44:
Enter unique Billing Code for OMIDRIA

Form Locator 44:
Enter Procedure Code(s)

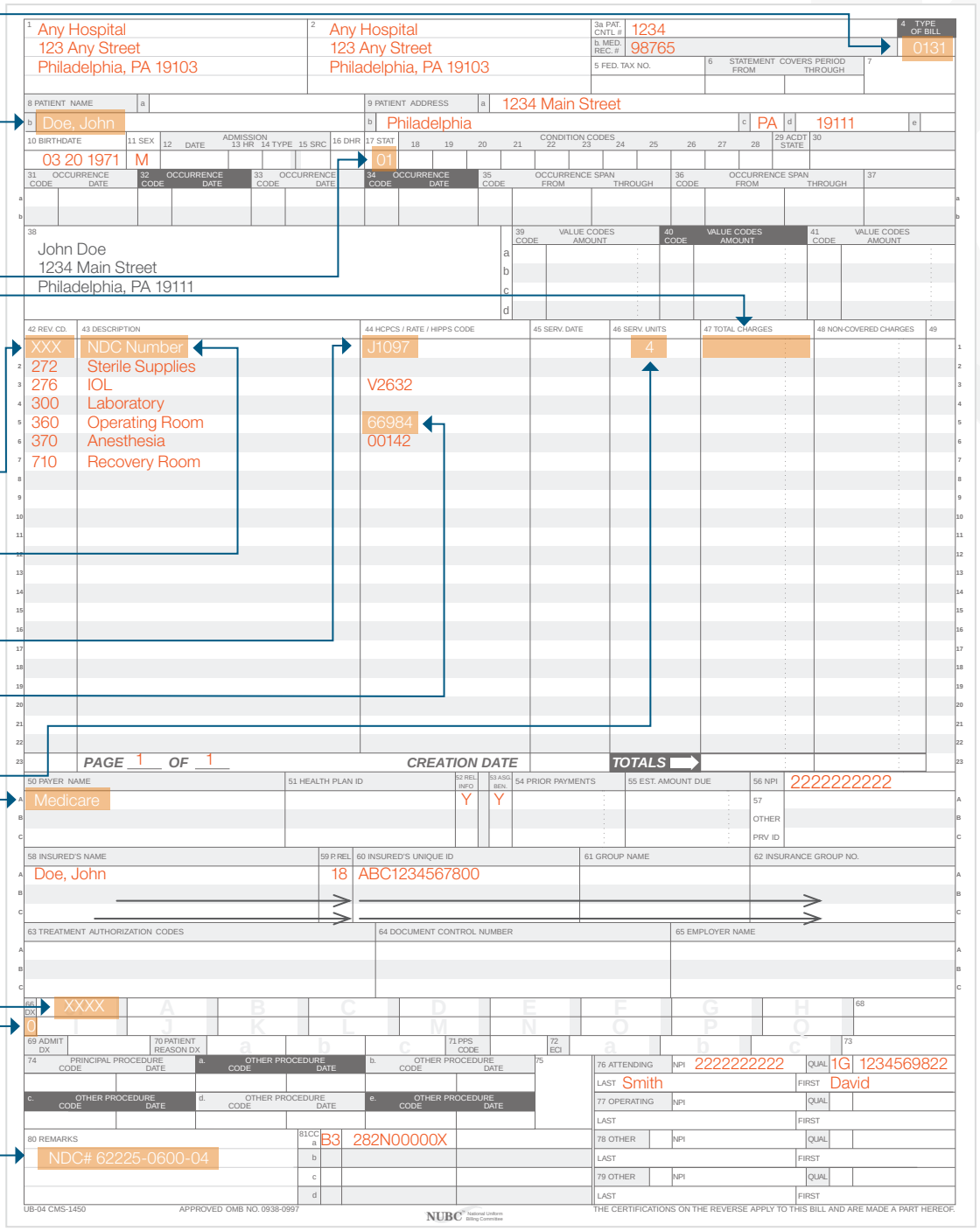
Form Locator 46:
Enter 4 units

Form Locator 50A:
If Medicare is the primary payer, enter "Medicare" on line A

Form Locator 67:
Enter primary Diagnosis Code

Form Locator 66:
Enter "0" if using ICD-10-CM

Form Locator 80:
This is where the NDC number should be placed if an NOC code is required or for drugs purchased through the Medicaid 340B Drug Pricing Program



***Note: For hospitals and ASCs using UB-04 form, it is a best practice to confirm the correct revenue code with the payer to ensure reimbursement.**

Information contained herein is provided as a reference for obtaining appropriate and accurate reimbursement. This content is for informational purposes only. Rayner 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.

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; IOL=intraocular lens; NDC=National Drug Code; NOC=not otherwise classified.

Please see Important Safety Information on page 13 and Full Prescribing Information at omidriahcp.com

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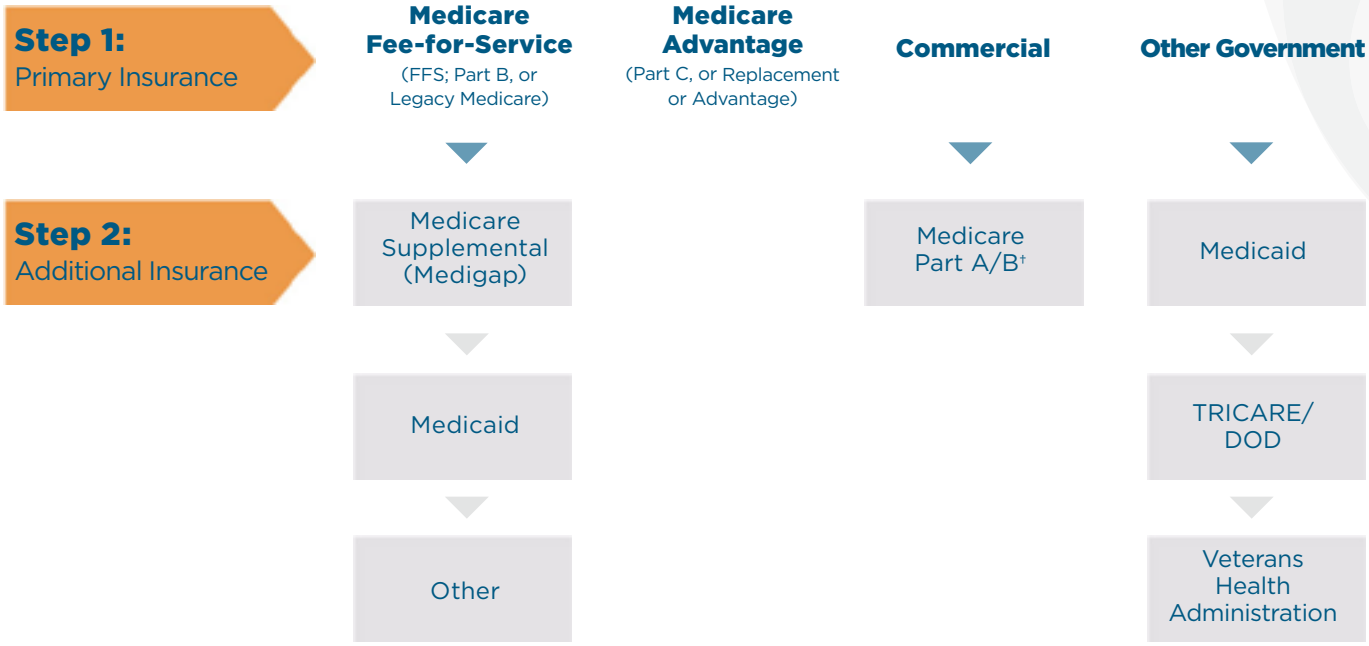
Understanding Billable Status for Patients Receiving OMIDRIA

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

Work with your OMIDRIA Field Reimbursement Manager to determine billable status for your payers*



*Individual plan coverage, payment, policies, and procedures vary and should be confirmed by the facility. Rayner does not guarantee reimbursement.

†Patients with Medicare Part B secondary insurance will not be eligible for company programs for commercial patients.

DOD=Department of Defense; FFS=Fee-for-Service.

Please see Important Safety Information on page 13 and Full Prescribing Information at omidriahcp.com

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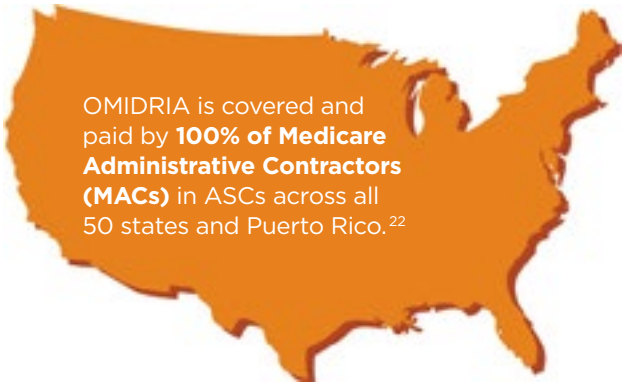
Medicare Fee-for-Service Billing and Reimbursement

HCPCS and APC codes for OMIDRIA

HCPCS code[10]	Long descriptor[10]	APC[13]
J1097	Phenylephrine 10.16 mg/mL and ketorolac 2.88 mg/mL ophthalmic irrigation solution, 1 mL	S9083

Reimbursed with separate payment

- OMIDRIA use in cataract and lens replacement surgery for patients with Medicare Fee-for-Service coverage is separately paid (ie, in addition to the facility fee) by the Centers for Medicare & Medicaid Services (CMS) in the ASC setting[16]
  - CMS confirmed ongoing separate payment in ASCs in the Medicare outpatient prospective payment system 2021 final rule[17]
- For OMIDRIA reimbursement in the ASC setting, CMS sets the payment rate at ASP plus 6%, minus a set amount due to sequestration[18,19]
  - Check the CMS website for current quarterly payment rates in the ASC Payments (Addendum BB) or Hospital OPPS (Addendum B) section
- Medicare will pay the ASC 80% of the ASP + 6% (minus sequestration)[20]
  - The ASC is responsible for 20% of the cost, which they may recoup from patients as a co-payment[20]
  - Approximately 83% of Medicare Fee-for-Service patients have some form of supplemental insurance, which covers co-pays[21]



For personalized help, call the Live Assistance Reimbursement Hotline at 1-877-OMIDRIA (1-877-664-3742), 9 AM-5 PM ET, Monday-Friday*

*Benefit verifications may not address contracted payer payment rates.

APC=Ambulatory Payment Classification; ASC=Ambulatory Surgery Center; ASP=average sales price; HCPCS=Healthcare Common Procedure Coding System; OPPS=Outpatient Prospective Payment System.

Please see Important Safety Information on page 13 and Full Prescribing Information at omidriahcp.com

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Medicare Advantage Billing and Reimbursement

May or may not reimburse with separate payment

- Medicare Advantage plans may bundle payment for OMIDRIA with that for the cataract surgery procedure

May or may not use Medicare FFS payment rate as a benchmark

- Like traditional Medicare FFS, Medicare Advantage plans should cover OMIDRIA, but the payment rate may differ from traditional FFS or be subject to payer-specific facility contractual limitations*
- For a Medicare Advantage patient, the specific Medicare Advantage payer should be contacted in advance to determine its reimbursement process as well as the level of reimbursement for OMIDRIA

Best practices for dealing with Medicare Advantage plans

- Before surgery, verify if patient has a Medicare Advantage plan
- Check if your facility-specific payer contracts allow for separate payment of drugs, including OMIDRIA
- If the plan bundles payment for OMIDRIA, share the CMS announcement regarding separate billable status

You can look up a patient's Medicare plan by entering the patient's name and date of birth in any of the following databases, among others:

- Secure Provider Online Tool (SPOT), provided by First Coast MAC
- Availity (for BCBS, Aetna, Humana)
- Palmetto e-services
- Noridian Medicare Portal

You do not need to pay a subscription fee to access these databases

EQUAL ACCESS

PATIENT ASSISTANCE PROGRAM

Assistance for financially eligible uninsured or government-insured patients

For government-insured patients with an uncovered out-of-pocket expense and who meet certain financial criteria, Rayner has established the Equal Access Patient Assistance Program as part of OMIDRIAssure.†

- 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 completed and approved at least 5 days prior to date of surgery

*Rayner does not guarantee payment by any payer.

†To 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 receives a free vial of OMIDRIA prior to surgery, and (2) the patient's insurance carrier(s) should not be billed for OMIDRIA.

BCBS=Blue Cross Blue Shield; CMS=Centers for Medicare & Medicaid Services; FFS=Fee-for-Service.

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Commercial Insurance Billing and Reimbursement

May reimburse with bundled payment

- Of all insurance types, commercial payers are the most likely to bundle payment for OMIDRIA with that for the cataract surgery procedure

Payment rate will vary by plan

- The amount commercial payers will reimburse for use of OMIDRIA may be dependent on the terms in the contract between your ASC and the payer
- Work with your OMIDRIA Field Reimbursement Manager to determine billable status for your payers*

May or may not use Medicare FFS payment rate as a benchmark

- Like traditional Medicare FFS, commercial plans should cover OMIDRIA, but the payment rate may differ from traditional FFS or be subject to payer-specific facility contractual limitations*
- For a commercial patient, the specific payer should be contacted in advance to determine its reimbursement process as well as the level of reimbursement for OMIDRIA

Best practices for commercial payers

- Check if your facility-specific payer contracts allow for separate payment of drugs, new technologies, and pass-through drugs, including OMIDRIA
- Confirm and verify payer payment/fee schedules for OMIDRIA
- Verify payer-specific use of appropriate revenue code
- Cultivate relationship with payer-provider network representative

WE PAY THE DIFFERENCE

PATIENT REIMBURSEMENT PROGRAM

Assistance for patients with insufficient commercial insurance

- Rayner 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 commercially insured patient's insurance†
- The benefits apply even if the annual commercial deductible obligation has not yet been met
- Visit https://www.omidriahcp.com/resources to download the We Pay the Difference Submission Form, OMIDRIAssure Flashcard, and other available resources

* Individual plan coverage, payment, policies, and procedures vary and should be confirmed by the facility. Rayner does not guarantee reimbursement.

† OMIDRIAssure program services are subject to change without notice. The We Pay the Difference Patient Reimbursement Program patient benefit is not available for patients with any government insurance. Rayner does not guarantee reimbursement. Facility acquisition cost is determined after application of any volume-based discount. Claims must be submitted within 1 year of date of surgery. Rayner does not guarantee coverage or reimbursement.

ASC=Ambulatory Surgery Center; FFS=Fee-for-Service.

Please see Important Safety Information on page 13 and Full Prescribing Information at omidriahcp.com

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Physician Billing for Procedures Performed in an ASC

Physicians are required to report the place of service (POS) on all health insurance claims they submit to Medicare Part B contractors

- An ASC is any distinct entity that operates exclusively for providing surgical services to patients not requiring hospitalization, and in which the expected duration of services would not exceed 24 hours following admission
- The entity must have an agreement with CMS to participate in Medicare as an ASC, and must meet the conditions in the CMS Publication 100-04, Medicare Claims Processing Manual, Chapter 14

Some physicians/practitioners performing services in Medicare-participating ASCs are reporting an incorrect POS code

- Services billed with the incorrect POS could result in a claim denial/rejection
- **The correct POS for physicians/practitioners who perform services in Medicare-participating ASCs is 24 (freestanding facility, other than a physician's office, where surgical and diagnostic services are provided on an ambulatory basis)**
  - Do **not** report POS 11 (office) unless the physician has an office at the same physical location as the ASC that meets all other requirements including the "distinct entity" criteria in the CMS Publication 100-07, State Operations Manual, Appendix L. This precludes the ASC and an adjacent physician office from being open at the same time

Under the Medicare physician fee schedule, some procedures have separate rates for physicians' services when provided in facility and non-facility settings

- The ASC payment does not include the professional services of the physician; the physician bills separately
- Physician services include the services of anesthesiologists:
  - Administration of anesthesia, or
  - Supervising the administration of anesthesia

ASC=Ambulatory Surgery Center; CMS=Centers for Medicare & Medicaid Services.

Appealing Denied Claims

Appealing claims

When a payer denies a claim for OMIDRIA, the first step in appealing the decision is to understand why the claim was denied

Payers may deny claims for a number of reasons:

- Claim forms are incomplete
- Codes in use may not meet the payer's specific requirements
- Payer does not reimburse for use of OMIDRIA
- Patient has supplemental insurance that will reimburse for OMIDRIA

In the case of incomplete or incorrect forms, new claims can be submitted to rectify the problem

If the payer has denied the claim based on medical information:

- Utilize the payer-provider portal to review specific medical benefit coverage of OMIDRIA
- Access sample Letters of Appeal and Medical Necessity at www.omidriahcp.com/resources to use in your claims appeal process

Best practices for claim submissions

- Consider submitting claims to all payers—even those who have denied reimbursement in the past
  - Some offices have been successful with this proactive approach
- Make sure submissions are timely and accurate
- Double-check that codes and units match payer requirements
- Check your payer contract
- 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

CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code.

Ordering OMIDRIA for Your Facility

How to order OMIDRIA

NDC#[1]	PRODUCT[1]	UNIT QUANTITY[1]	CASE QUANTITY
62225-600-04	OMIDRIA is supplied in a clear, 5-mL glass, single-patient-use vial containing 4 mL of sterile solution. The smallest sellable unit is a carton, which contains four (4) single-patient-use vials.	One (1) carton contains four (4) single-patient-use vials.	One (1) case contains thirty (30) cartons (120 total vials).

One (1) carton is the minimum order. OMIDRIA is sold only in carton quantities. OMIDRIA is not sold in individual vial quantities.

OMIDRIA is available through specialty distributors

DISTRIBUTOR	ITEM ORDER NUMBER	CONTACT PHONE NUMBER
McKesson Specialty Distribution*	5005028	1-800-482-6700
McKesson Plasma and Biologics*	3507175	1-877-625-2566
Cardinal Health Specialty Distribution†	5071410	1-855-855-0708
Besse Medical	44567	1-888-767-7123
AmerisourceBergen Specialty Distribution‡	44567	1-800-746-6273
FFF Enterprises, Inc.	OMI060004	1-800-843-7477

*For customers of McKesson full-line wholesaler division, OMIDRIA is available for purchase through McKesson Plasma and Biologics and McKesson Specialty Distribution.

†For customers of Cardinal full-line wholesaler division, OMIDRIA is available for purchase through Cardinal Health Specialty Distribution.

‡For customers of AmerisourceBergen Corporations full-line wholesale division, OMIDRIA is available through AmerisourceBergen specialty distribution and can be ordered using the Passport ordering platform through AmerisourceBergen.

NDC=National Drug Code.

Please see Important Safety Information on page 13 and Full Prescribing Information at omidriahcp.com

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HELPFUL RESOURCES*

www.cms.gov

- ASC (Addendum BB) and HOPD (Addendum B) Payment Rates and Updates
- CMS ASP Drug Pricing Files
- CMS Quarterly Update
- MLN Matters Articles

www.omidriahcp.com/resources

- OMIDRIAssure Flashcard
- We Pay the Difference Submission Form
- OMIDRIAssure Patient Certification Form
- Letter of Appeal
- Letter of Medical Necessity

*Rayner does not guarantee the accuracy, completeness, or current status of information provided on third-party websites.

ASC=Ambulatory Surgery Center; ASP=average sales price; CMS=Centers for Medicare & Medicaid Services; HOPD=hospital outpatient department; MLN=Medicare Learning Network®.

INDICATIONS AND USAGE

OMIDRIA® 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

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.

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

References: 1. OMIDRIA [package insert]. Seattle, WA: Omeros Corporation; 2017. **2.** Rosenberg ED, Nattis AS, Alevi D, et al. Visual outcomes, efficacy, and surgical complications associated with intracameral phenylephrine 1.0%/ketorolac 0.3% administered during cataract surgery. *Clin Ophthalmol*. 2018;12:21-28. **3.** Al-Hashimi S, Donaldson K, Davidson R, et al. Medical and surgical management of the small pupil during cataract surgery. *J Cataract Refract Surg*. 2018;44:1032-1041. **4.** Bucci FA Jr, Michalek B, Fluet AT. Comparison of the frequency of use of a pupil expansion device with and without an intracameral phenylephrine and ketorolac injection 1%/0.3% at the time of routine cataract surgery. *Clin Ophthalmol*. 2017;11:1039-1043. **5.** Roach L, Behndig A, Donnenfeld ED, et al. Strategies for preventing intraoperative miosis. *Eye Net*. 2015;June:29-31. **6.** Walter K, Delwadia N, Coben J. Continuous intracameral phenylephrine–ketorolac irrigation for miosis prevention in femtosecond laser–assisted cataract surgery: reduction in surgical time and iris manipulation. *J Cataract Refract Surg*. 2019;45(4):465-469. **7.** Visco D. Effect of phenylephrine/ketorolac on iris fixation ring use and surgical times in patients at risk of intraoperative miosis. *Clin Ophthalmol*. 2018;12:301-305. **8.** Silverstein SM, Rana VK, Stephens R, et al. Effect of phenylephrine 1.0%–ketorolac 0.3% injection on tamsulosin-associated intraoperative floppy-iris syndrome. *J Cataract Refract Surg*. 2018;44(9):1103-1108. **9.** Visco DM, Bedi R. Effect of intracameral phenylephrine 1.0%–ketorolac 0.3% on postoperative cystoid macular edema, iritis, pain, and photophobia after cataract surgery. *J Cataract Refract Surg*. 2020;46(6):867-872. **10.** Centers for Medicare & Medicaid Services. HCPCS quarterly update. October 2021. Accessed October 8, 2021. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update. **11.** Synovec MS, Jagmin CL, Hochstetler Z, eds, et al. CPT 2022 Professional Edition. American Medical Association. 2021. **12.** Centers for Medicare & Medicaid Services. Billing and coding: use of laterality modifiers. Accessed October 7, 2021. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=56869. **13.** American Medical Association. HCPCS code for global fee urgent care centers S9083. Accessed December 2, 2021. https://www.aapc.com/codes/hcpcs-codes/S9083 **14.** Centers for Medicare & Medicaid Services. CMS-1500 Health Insurance Claim Form. Accessed October 8, 2021. https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf. **15.** Centers for Medicare & Medicaid Services. CMS-1450. Accessed October 8, 2021. https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-1450. Published July 19, 2019. **16.** US Department of Health and Human Services. Centers for Medicare & Medicaid Services. 42 CFR, parts 410, 411, 412, 414, 416, 419, 482, 485, 512 [CMS-1736-FC, 1736-IFC]. *Fed. Register*. 2020;85(249)85866-86305. **17.** US Department of Health and Human Services. Medicare program: hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs; price transparency of hospital standard charges; radiation oncology model; request for information on rural emergency hospitals. *Fed Regist*. 2021;86(147):42018-42360. **18.** Centers for Medicare & Medicaid Services. 2021 ASP Drug Pricing Files. Accessed October 8, 2021. https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2021-asp-drug-pricing-files. Updated June 1, 2021. **19.** Weidner S, Diaz M, Schaedig C, Gordan L. Observations regarding the average sales price reimbursement methodology. *Am J Manag Care*. 2021;27(4):SP156-SP160. **20.** Medicare Payment Advisory Committee. Report to the Congress: *Medicare and the Health Care Delivery System*. Chapter 2. June 2017. Accessed October 11, 2021. http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf?sfvrsn=0. **21.** Koma W, Cubanski J, Neuman T. A snapshot of sources of coverage among Medicare beneficiaries in 2018. Kaiser Family Foundation. Accessed October 11, 2021. https://www.kff.org/medicare/issue-brief/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries-in-2018/. **22.** Beiting J. Weigh costs, benefits when adding surgical technology. *Ophthalmology Times*. Accessed October 11, 2021. https://www.ophthalmologytimes.com/view/weigh-costs-benefits-when-adding-surgical-technology.

Rayner

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

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use OMIDRIA® safely and effectively. See full prescribing information for OMIDRIA.

OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1% / 0.3%, for addition to ocular irrigating solution
Initial U.S. Approval: 2014

INDICATIONS AND USAGE

OMIDRIA is an alpha 1-adrenergic receptor agonist and nonselective cyclooxygenase inhibitor indicated for:

- Maintaining pupil size by preventing intraoperative miosis (1)
- Reducing postoperative pain (1)

OMIDRIA is added to an ocular irrigating solution used during cataract surgery or intraocular lens replacement.

DOSAGE AND ADMINISTRATION

- Each vial of OMIDRIA must be diluted prior to use for administration to a single patient undergoing cataract surgery or intraocular lens replacement.
- Dilute 4 mL of OMIDRIA in 500 mL of ocular irrigating solution. Irrigation solution is to be used as needed for the surgical procedure. (2)

DOSAGE FORMS AND STRENGTHS

Intraocular solution containing phenylephrine 10.16 mg/mL (1%) and ketorolac 2.88 mg/mL (0.3%) for use in a single patient. (3)

CONTRAINDICATIONS

Hypersensitivity to any component of this product (4)

WARNINGS AND PRECAUTIONS

Systemic exposure to phenylephrine may cause elevations in blood pressure. (5.1)

ADVERSE REACTIONS

The most common reported adverse reactions (≥2%) are eye irritation, posterior capsule opacification, increased intraocular pressure, and anterior chamber inflammation. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Omeros Corporation at 1-844-OMEROS1 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

See 17 for PATIENT COUNSELING INFORMATION

Revised: 12/2017

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

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.

2 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. Irrigation solution is to be used as needed for the surgical procedure for a single patient.

The storage period for the diluted product 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.

3 DOSAGE FORMS AND STRENGTHS

Omidria is an intraocular solution containing 10.16 mg/mL (1% w/v) of phenylephrine and 2.88 mg/mL (0.3% w/v) of ketorolac for use in a single patient.

4 CONTRAINDICATIONS

Omidria is contraindicated in patients with a known hypersensitivity to any of its ingredients.

5 WARNINGS AND PRECAUTIONS

5.1 Elevated Blood Pressure

Systemic exposure to phenylephrine can cause elevations in blood pressure.

5.2 Cross-Sensitivity or Hypersensitivity

There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other non-steroidal anti-inflammatory drugs (NSAIDs). There have been reports of bronchospasm or exacerbation of asthma associated with the use of ketorolac in patients who either have a known hypersensitivity to aspirin/NSAIDs or a past medical history of asthma. Therefore, use Omidria with caution in individuals who have previously exhibited sensitivities to these drugs.

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to the rates in the clinical studies of another drug and may not reflect the rates observed in practice.

Table 1 shows frequently reported ocular adverse reactions with an incidence of ≥ 2% of adult patients as seen in the combined clinical trial results from three randomized, placebo-controlled studies *[see Clinical Studies (14)]*.

Table 1: Ocular Adverse Reactions Reported by ≥ 2% of Adult Patients

MedDRA Preferred Term	Placebo (N=462)	Omidria (N=459)
	n (%)	n (%)
Ocular Events		
Anterior Chamber Inflammation	102 (22%)	111 (24%)
Intraocular Pressure Increased	15 (3%)	20 (4%)
Posterior Capsule Opacification	16 (4%)	18 (4%)
Eye Irritation	6 (1%)	9 (2%)
Foreign Body Sensation in Eyes	11 (2%)	8 (2%)

In a safety study that enrolled 72 pediatric patients up to 3 years old, no overall difference in safety was observed between pediatric and adult patients.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on Omidria use in pregnant women or animals to inform any drug-associated risks. Oral administration of ketorolac to rats during late gestation produced dystocia and increased pup mortality at a dose 740-times the plasma exposure at the recommended human ophthalmic dose (RHOD). Since human systemic exposure to Omidria following a lens replacement procedure is low *[see Clinical Pharmacology (12.3)]*, the applicability of animal findings to the risk of Omidria in humans during pregnancy is unclear. Omidria should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

Premature closure of the ductus arteriosus in the fetus has occurred with third trimester use of oral and injectable NSAIDs. Ketorolac plasma concentrations are detectable following ocular Omidria administration *[see Clinical Pharmacology (12.3)]*. The use of Omidria during late pregnancy should be avoided.

Data

Animal Data

No well-controlled animal reproduction studies have been conducted with Omidria or phenylephrine.

Ketorolac, administered during organogenesis, did not cause embryofetal abnormalities or mortalities in rabbits or rats at oral doses of 3.6 mg/kg/day and 10 mg/kg/day, respectively. These doses produced systemic exposure that is 1150 times and 4960 times the plasma exposure (based on C_{max}) at the RHOD, respectively. When administered to rats during late gestation (after Day 17 of gestation) at oral doses up to 1.5 mg/kg/day (740 times the plasma exposure at the RHOD), ketorolac produced dystocia and increased pup mortality.

8.2 Lactation

Risk Summary

There are no data on the presence of Omidria in human milk, the effects on the breastfed infant, or the effects on milk production. However, systemic exposure to Omidria, following a lens replacement procedure is low *[see Clinical Pharmacology (12.3)]*. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Omidria and any potential adverse effects on the breastfed child from Omidria.

8.4 Pediatric Use

The safety and effectiveness of Omidria have been established in the pediatric population from neonates to adolescents (birth to younger than 17 years). Use of Omidria in this population is supported by evidence from adequate and well-controlled studies of Omidria in adults with additional data from a single active-controlled safety study in pediatric patients up to 3 years old *[see Clinical Studies (14)]*.

No overall differences in safety were observed between pediatric and adult patients.

8.5 Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and adult patients.

10 OVERDOSAGE

Systemic overdosage of phenylephrine may cause a rise in blood pressure. It may also cause headache, anxiety, nausea, vomiting, and ventricular arrhythmias. Supportive care is recommended.

11 DESCRIPTION

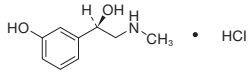
Omidria is a sterile aqueous solution, containing the α1-adrenergic receptor agonist phenylephrine HCl and the nonsteroidal anti-inflammatory ketorolac tromethamine, for addition to ocular irrigating solution.

The descriptions and structural formulae are:

Phenylephrine Hydrochloride Drug Substance:

Common Name: phenylephrine hydrochloride
Chemical Name: (-)-*m*-Hydroxy-α-[(methylamino)methyl]benzyl alcohol hydrochloride
Molecular Formula: $C_9H_{13}NO_2 \cdot HCl$
Molecular Weight: 203.67 g/mole

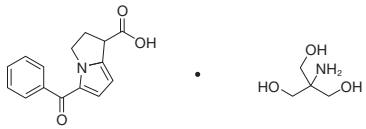
Figure 1: Chemical Structure for Phenylephrine HCl



Ketorolac Tromethamine Drug Substance:

Common Name: ketorolac tromethamine
Chemical Name: (±)-5-Benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxylic acid : 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1)
Molecular Formula: $C_{15}H_{13}NO_3 \cdot C_4H_{11}NO_3$
Molecular Weight: 376.40 g/mole

Figure 2: Chemical Structure for Ketorolac Tromethamine



Omidria is a clear, colorless to slightly yellow, sterile solution concentrate with a pH of approximately 6.3.

Each vial of Omidria contains:

Actives: phenylephrine hydrochloride 12.4 mg/mL equivalent to 10.16 mg/mL of phenylephrine and ketorolac tromethamine 4.24 mg/mL equivalent to 2.88 mg/mL of ketorolac.

Inactives: citric acid monohydrate; sodium citrate dihydrate; water for injection; may include sodium hydroxide and/or hydrochloric acid for pH adjustment.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The two active pharmaceutical ingredients (API) in Omidria, phenylephrine and ketorolac, act to maintain pupil size by preventing intraoperative miosis, and reducing postoperative pain.

Phenylephrine is an α1-adrenergic receptor agonist and, in the eye, acts as a mydriatic agent by contracting the radial muscle of the iris. Ketorolac is a nonsteroidal anti-inflammatory that inhibits both cyclooxygenase enzymes (COX-1 and COX-2), resulting in a decrease in tissue concentrations of prostaglandins to reduce pain due to surgical trauma. Ketorolac, by inhibiting prostaglandin synthesis secondary to ocular surgical insult or direct mechanical stimulation of the iris, also prevents surgically induced miosis.

12.3 Pharmacokinetics

In a pharmacokinetic study evaluating Omidria, systemic exposure to both phenylephrine and ketorolac was low or undetectable.

A single-dose of Omidria as part of the irrigation solution was administered in 14 patients during lens replacement surgery. The volume of irrigation solution used during surgery ranged between 150 mL to 300 mL (median 212.5 mL). Detectable phenylephrine plasma concentrations were observed in one of 14 patients (range 1.2 to 1.4 ng/mL) during the first 2 hours after the initiation of Omidria administration. The observed phenylephrine plasma concentrations could not be distinguished from the preoperative administration of phenylephrine 2.5% ophthalmic solution prior to exposure to Omidria.

Ketorolac plasma concentrations were detected in 10 of 14 patients (range 1.0 to 4.2 ng/mL) during the first 8 hours after the initiation of Omidria administration. The maximum ketorolac concentration was 15 ng/mL at 24 hours after the initiation of Omidria administration, which may have been due to application of postoperative ketorolac ophthalmic solution.

14 CLINICAL STUDIES

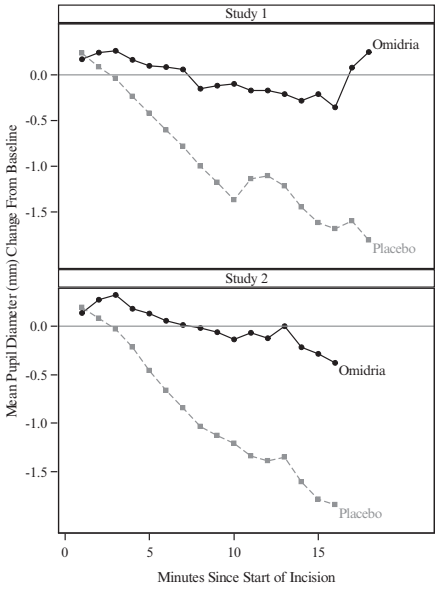
Studies in Adults

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.

Patients were randomized to either Omidria or placebo. Patients were treated with preoperative topical mydriatic and anesthetic agents. Pupil diameter was measured throughout the surgical procedure. Postoperative pain was evaluated by self-administered 0-100 mm visual analog scales (VAS).

Mydriasis was maintained in the Omidria-treated groups while the placebo-treated groups experienced progressive constriction.

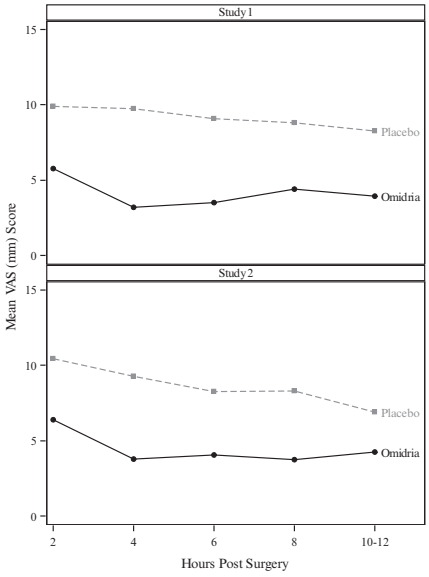
Figure 3: Intraoperative Pupil Diameter (mm) Change-from-Baseline



At the end of cortical clean-up, 23% of placebo-treated patients and 4% of Omidria-treated patients had a pupil diameter less than 6 mm ($p < 0.01$).

Pain during the initial 10-12 hours postoperatively was statistically significantly less in the Omidria-treated groups than in the placebo-treated groups.

Figure 4: Postoperative Mean Visual Analog Scale (VAS) Scores for Pain



During the 10-12 hours postoperatively, 26% of Omidria-treated patients reported no pain (VAS = 0 at all timepoints) while 17% of placebo-treated patients reported no pain ($p < 0.01$).

Study in Pediatric Patients

The safety of Omidria was evaluated in a single, randomized, multicenter, double-masked, active-controlled clinical study in 72 pediatric patients up to 3 years old undergoing cataract surgery with or without intraocular lens replacement.

Patients were randomized to either Omidria or phenylephrine. Patients were treated with preoperative topical mydriatic and anesthetic agents. As in the adult studies, mydriasis was maintained in the Omidria-treated group. No overall differences in safety were observed between pediatric and adult patients.

16 HOW SUPPLIED/STORAGE AND HANDLING

Omidria (phenylephrine and ketorolac intraocular solution) 1% / 0.3% is supplied in a clear, 5-mL glass, single-patient-use vial containing 4 mL of sterile solution, for addition to ocular irrigating solution.

Omidria is supplied in a multi-pack containing:
4 vials: NDC 62225-600-04 or
10 vials: NDC 62225-600-10

Storage: Store at 20° to 25°C (68° to 77°F). Protect from light.

17 PATIENT COUNSELING INFORMATION

Inform patients that they may experience sensitivity to light.

Omeros Corporation
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