Facts about OMIDRIA® (phenylephrine and ketorolac injection) 1% / 0.3% and the Pass-Through Regulation

OMIDRIA

After nearly 13 years of research and development, OMIDRIA (phenylephrine and ketorolac injection) 1% / 0.3% received FDA approval in May 2014. Added to ophthalmic irrigation solution used during cataract surgery or intraocular lens replacement, OMIDRIA is the only FDA-approved intraocular product for maintaining pupil size by preventing miosis and for reducing postoperative ocular pain.

In October 2014, the Centers for Medicare and Medicaid Services (CMS) granted pass-through reimbursement status to OMIDRIA, which became effective January 2015. Pass-through status for OMIDRIA will expire on December 31, 2017.

Pass-Through Status[1]

In 2001, Congress established the pass-through regulation as law to promote and foster the use of innovative new drug and device technologies to benefit Medicare patients.

Under the Outpatient Prospective Payment System (OPPS), pass-through products are paid separately (i.e., in addition to the bundled facility fees) by Medicare when the product is used in ambulatory surgery centers (ASCs) or in hospital outpatient departments (HOPDs).

Pass-through status is transitional—if CMS awards a product pass-through status, it lasts for no less than two years and no more than three years.

It allows CMS to track the utilization of the product so that, if it is used during a procedure, CMS can appropriately adjust the associated facility fees when the product's pass-through status expires and the product is ultimately included in the bundled payment.

Reimbursement of the Pass-Through Product OMIDRIA in ASCs and HOPDs

Medicare Part B

The payment rate authorized and listed by CMS for OMIDRIA is the wholesale acquisition cost plus 6 percent (WAC+6%) or $492.90 per vial through September 30, 2015 after which the payment rate will be the average selling price plus 6 percent (ASP+6%).

There is no co-payment for OMIDRIA in the HOPD setting. In the ASC setting, the patient may be subject to a 20% co-payment. Approximately 90% of Medicare Part B patients have some form of supplemental insurance, which covers co-payments.[2] Omeros is working to establish a patient assistance program to provide funding support to those patients who meet certain financial criteria.

Medicare Part C (Medicare Advantage) and Commercial

Medicare Advantage and commercial payers usually follow Medicare Part B.

Before using OMIDRIA in patients with Medicare Advantage or commercial coverage, obtain prior authorization or confer with your payers.

Important Safety Information

Systemic exposure of phenylephrine may cause elevations in blood pressure. The most commonly reported ocular adverse reactions at 2-24% are eye irritation, posterior capsule opacification, increased intraocular pressure, and anterior chamber inflammation. Use of OMIDRIA in children has not been established.

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

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Effects of OMIDRIA® (phenylephrine and ketorolac injection) 1% / 0.3% on Facility Fees, Physician Fees and the Healthcare System

OMIDRIA Will Have a Positive Effect on Facility Fees[1]

Each year, CMS sets aside a pool of funds for all pass-through payments. The estimated utilization of all pass-through products during each year is used to determine the amount to set aside for the following year. As a result, in 2015, OPPS payment rates for all facility services in the HOPDs and ASCs were reduced by a nominal 0.13%. Over the past 10 years, the annual reduction across facility fees has ranged from 0.02%–0.22%.

In 2016 and 2017, OMIDRIA is not expected to have any meaningful effect on facility fees because for each of those years:

- OMIDRIA will be only one of a substantial number of drugs and devices awarded pass-through status.
- The reduction is spread over all services for which Medicare pays in HOPDs and ASCs, not just cataract surgery or even ophthalmology services.

After December 31, 2017, pass-through payments for OMIDRIA terminate and CMS is expected to include OMIDRIA in the bundled facility fee for cataract surgery.

As a result of OMIDRIA being bundled, the facility fees for cataract surgery are expected to increase by an amount that correlates with the magnitude of OMIDRIA utilization during its pass-through status.

OMIDRIA Will Have No Effect on Physician Fees

Payment to the surgeon for cataract surgery under Medicare's Physician Fee Schedule will be unaffected by the use of OMIDRIA or the pass-through payments related to OMIDRIA, now and in the future.

OMIDRIA Will Have No Effect on the Healthcare System

The pass-through regulation is budget-neutral to the healthcare system.

To the extent that ophthalmic surgeons/facilities elect not to access pass-through payments, the funds set aside will be used by other specialties. Any remaining amount will be lost to the system.

Congress and CMS are committed to facilitating access to innovative new technologies through the pass-through regulation for the benefit of Medicare patients. Despite pressures to cut the government budget, Congress has not rolled back the pass-through regulation, again leaving it intact in the most recent major medical bill—repealing the Sustainable Growth Rate (SGR).

Please see the Full Prescribing Information for OMIDRIA or visit
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REFERENCES: 1. Federal Register, April 7, 2000, 65 FR. **2.** Kaiser Family Foundation analysis of the CMS Medicare Current Beneficiary Survey Cost and Use File, 2010.

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