Ambulatory Surgical Center (ASC) Billing Mitosol® J7315
Provided by Institute for Quality Resource Management

Subject: Reimbursement information to support billing for Mitosol® (mitomycin for solution), 0.2mg/vial Kit for Ophthalmic Use

1. **Mitosol®, coded with J7315, is the only FDA approved, cGMP manufactured topical and ophthalmic mitomycin granted Orphan Drug status.** Mitosol® is not generic mitomycin. Mitosol is an FDA approved, Orphan Drug designated, cGMP manufactured ophthalmic topical antifibrotic available as a closed, sterile kit to reduce scarring in glaucoma surgery.¹

2. **The Department of Health and Human Services (HHS) requires the use of an FDA approved drug in place of a pharmacy compounded drug.**

3. **Mitosol® has been priced as a separately payable drug** by the Centers for Medicare and Medicaid (CMS) by granting pass-through status for a drug. *(Table 1).*

4. **CMS allows separate payment for Mitosol®, billed with HCPCS code J7315.** In 2013 CMS established pass-through status for Mitosol® and created the new HCPCS code J7315 with instructions for to receive separate payment. CMS provided instructions for the outpatient code editor to separately reimburse HCPCS code J7315.²

A. **The HHS and the FDA reject the use of pharmacy compounded drugs when an FDA approved product is available.**³ The use of Mitosol® meets the recommendations by the HHS and the FDA as it is specifically indicated as an anti-fibrotic drug to aid healing of the eye subsequent to glaucoma surgery. HHS and the FDA recognize the significant risk to the patient and lack of quality control of pharmacy compounded drugs.

B. **In 2010 Medicare intended to have more similar coverage for procedures billed from an ASC and a Hospital Outpatient place of service.**⁴⁵ In this context, as stated by CMS, J7315 is an active code with reimbursement when used in an ASC. Therefore the section h. in Transmittal 2903 allows for payment of J7315 when supplied during a procedure performed in an ASC.⁶

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¹ Mitosol package insert
² CMS Manual System Department of Health & Human Services (DHHS) Pub 100-04 Medicare Claims Processing Centers for Medicare & Medicaid Services (CMS) Transmittal 2664 Date: March 1, 2013 Change Request 8228
³ U.S. Food and Drug Administration, The Special Risks of Pharmacy Compounding, Available at http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107836.htm (Accessed June 21, 2013)
⁴ Medicare Claims Processing Manual Chapter 14-Ambulatory Surgical Centers Table of Contents (Rev.2020,08-06-10).
⁵ CMS Transmittal 2378 Change Request 7682 December 29, 2011.
⁶ CMS Manual System Department of Health & Human Services (DHHS) Pub 100-04 Medicare Claims Processing Centers for Medicare & Medicaid Services (CMS) Transmittal 2903 Date: March 11, 2014 Change Request 8653
ASC CMS Fee Schedule for J7315 Mitosol®

Table 1 Medicare Fee Schedule Information Ambulatory Surgical Center (ASC) Payment Rate

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
<th>K2 Indicator</th>
<th>Final CY 2014 Payment Weight</th>
<th>Final CY 2014 Payment Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>J7315</td>
<td>Ophthalmic mitomycin</td>
<td></td>
<td></td>
<td>$379.48</td>
</tr>
</tbody>
</table>

When completing an insurance claim form for payment from Medicare or other Insurers, the following facility codes are provided to assist with correct claim submission.

1. Insurance Claim Form CMS 1500 use Place of Service Code 24,
2. Insurance Claim Form UB-04 use Bill Type 083X
3. CMS ASC Payment Comment Indicator K2 indicates specific payment for drugs to be paid separately when provided integral to a surgical procedure on the ASC list; payment based on OPPS rate.

Source: July 2014 Update of the Medicare ASC Fee Schedule Addendum BB -- Final ASC Covered Ancillary Services Integral to Covered Surgical Procedures for CY 2014

Please feel free to call Leah Amir Executive Director of the Institute for Quality Resource Management at 314-458-7552 or leahamir@vantageview.com if you have further questions.

Sincerely,

Leah Amir
Leah Amir, MS, MHA
Executive Director
Reference Information To Aid Payers CMS Guidance for Correct Coding and Payment for J7315

Please note Transmittal 2903 h. Billing Guidance for the Topical Application of Mitomycin During or Following Ophthalmic Surgery: “Hospital outpatient departments should only bill HCPCS code J7315 (Mitomycin, ophthalmic, 0.2 mg) or HCPCS code J3490 (unclassified drugs) for the topical application of mitomycin during or following ophthalmic surgery. J7315 may be reported only if the hospital uses mitomycin with the trade name Mitosol®. Any other topical mitomycin should be reported with J3490. Hospital outpatient departments are not permitted to bill HCPCS code J9280 (Injection, mitomycin, 5 mg) for the topical application of mitomycin. The CMS HCPCS coding file identifies J7315 to be paid as a drug.

CMS clearly CMS intends for Mitosol® assigned to HCPCS code J7315 to be a separately payable drug

The HCPCS 2014_ANWEB file defines J7315 as Mitomycin, ophthalmic, 0.2 mg as an active code to be paid as a drug to pay ASP plus 6%.

7 CMS Manual System Department of Health & Human Services (DHHS) Pub 100-04 Medicare Claims Processing Centers for Medicare & Medicaid Services (CMS) Transmittal 2903 Date: March 11, 2014 Change Request 8653
INDICATIONS AND USAGE: Mitosol® is an antimitabolite indicated for use as an adjunct to ab externo glaucoma surgery.

CONTRAINDICATIONS: Hypersensitivity: Mitosol® is contraindicated in patients that have demonstrated a hypersensitivity to mitomycin in the past. Pregnant women: Mitosol® may cause fetal harm when administered to a pregnant woman. Mitomycin administered parenterally has been shown to be teratogenic in mice and rats when given at doses equivalent to the usual human intravenous dose. Mitosol® is contraindicated in women who are or may become pregnant during therapy. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.

WARNINGS AND PRECAUTIONS: Cell Death: Mitomycin is cytotoxic. Use of mitomycin in concentrations higher than 0.2 mg/mL or use for longer than 2 minutes may lead to unintended corneal and/or scleral damage including thinning or perforation. Direct contact with the corneal endothelium will result in cell death. Hypotony: The use of mitomycin has been associated with an increased instance of post-operative hypotony. Cataract Formation: Use in phakic patients has been correlated to a higher instance of lenticular change and cataract formation.

ADVERSE REACTIONS: Ophthalmic Adverse Reactions: The most frequent adverse reactions to Mitosol® occur locally, as an extension of the pharmacological activity of the drug. These reactions include: Blebitis: bleb ulceration, chronic bleb leak, encapsulated/cystic bleb, bleb-related infection, wound dehiscence, conjunctival necrosis, thin-walled bleb; Cornea: corneal endothelial damage, epithelial defect, anterior synechiae, superficial punctate keratitis, Descemet’s detachment, induced astigmatism; Endophthalmitis; Hypotony: choroidal reactions (choroidal detachment, choroidal effusion, serous choroidal detachment, suprachoroidal hemorrhage, hypotony maculopathy, presence of supraciliochoroidal fluid, hypoechogenic suprachoroidal effusion); Inflammation: iritis, fibrin reaction; Lens: cataract development, cataract progression, capsule opacification, capsular constriction and/or capsulotomy rupture, posterior synechiae; Retina: retinal pigment epithelial tear, retinal detachment (serous and rhegatogenous); Scleritis: wound dehiscence; Vascular: hyphema, central retinal vein occlusion, hemiretinal vein occlusion, retinal hemorrhage, vitreal hemorrhage and blood clot, subconjunctival hemorrhage, disk hemorrhage; Additional Reactions: macular edema, sclera thinning or ulceration, intraocular lens capture, disk swelling, malignant glaucoma, lacrimal drainage system obstruction, ciliary block, corneal vascularization, visual acuity decrease, cystic conjunctival degeneration, upper eyelid retraction, dislocated implants, severe loss of vision.

USE IN SPECIFIC POPULATIONS: Pregnancy: Teratogenic Effects: Pregnancy Category X (see Contraindications). Nursing Mother: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from Mitosol®, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. It is recommended that women receiving Mitosol® not breast feed because of the potential for serious adverse reactions in nursing infants. Pediatric Use: Safety and effectiveness in pediatric patients have not been established. Geriatric Use: No overall differences in safety and effectiveness have been observed between elderly and younger patients.

More detailed information is available upon request.
For information about Mitosol® contact: 1-877-EYE-MITO (1-877-393-6486)
Please also see full Prescribing Information at MobiusTherapeutics.com