

The Case for Fee-Based Diagnostic Testing

Why such charges make sense in an ophthalmic practice.

BY DANIEL S. DURRIE, MD

As physicians, we routinely send patients to laboratories and diagnostic centers to undergo testing prior to a scheduled surgery or so that we may confirm a diagnosis. When patients have these tests, they pay a fee for the staff's time and the use of the equipment. In contrast, when we perform diagnostic tests in our practices, they are typically part of the examination fee. We should change this practice for a number of reasons.

WHY CHANGE?

Capital Costs

As technological advances have created better, faster, more accurate diagnostic tools, the capital costs have increased. For example, a spectral-domain ocular coherence tomographer (SD-OCT) can easily cost a practice \$60,000.

Point-of-Care Testing

The term *point-of-care testing* refers to tests that patients undergo within the physician's practice. Point-of-care diagnostics enable us to provide better care more rapidly, because we do not need to send the patient to a separate diagnostic facility.

According to a recent article in *Executive Healthcare Management Magazine*,¹ new point-of-care diagnostics permit lab-quality testing anywhere, which makes state-of-the-art technology available even in small, rural practices. For example, the TearLab Osmolarity System (TearLab Corporation, San Diego, CA) recently received 510(k) clearance from the FDA. Although this type of diagnostic test has been used in other areas of medicine for many years, it is new to the field of ophthalmology. The TearLab system's lab-on-a-chip carries out the test and then provides a measurement once the system is docked onto the base.

Connectivity

New high-technology diagnostic devices have information technology systems on board that enable easy, seamless wiring with a practice's electronic medical records system. Such connectivity allows us to show patients the results of

their ocular coherence tomography or other tests on a monitor while they sit in the exam chair. In addition, new data management tools for images such as EyeRoute (Topcon Medical Systems, Inc., Paramus, NJ) enable the pooling and storage of information from various diagnostic devices in an easily accessible database, which can communicate with whatever electronic medical records system our practice has.

CHANGING THE PARADIGM

At Durrie Vision, we have decided to change how we use and charge for diagnostics tests. We now offer patients a high-technology comprehensive examination, which we call *advanced ocular analysis*. This package includes SD-OCT, wavefront aberrometry, slit-lamp photography, fundus photography, and corneal topography. For patient populations that are more prone to dry eye disease, we have introduced what we call *advanced ocular analysis +*, which includes the TearLab Osmolarity Test as well as the Optical Quality Analysis System test (OQAS; Visiometrics, Terrassa, Spain). We describe the advanced ocular analysis as state-of-the-art technology for patients' eye care. Our patients pay a premium for these examination packages, a choice they seem happy to make. They receive a take-home package with the images and printouts as well as an explanation of the results.

In order for the practice to provide this premium service, the staff needed careful training on appropriately screening patients to determine which should be brought in for advanced ocular analysis versus a clinical visit that will be covered by insurance. For example, someone calling about a red, itchy eye can be seen in the clinic without a premium workup and have insurance billed accordingly. If findings during a regular clinical examination would justify imaging (eg, an epiretinal membrane as an indication for optical coherence tomography), we can provide that test as a service that is billable to a third-party payer.

NEW TECHNOLOGY DEMANDS A NEW APPROACH

There is no doubt that current diagnostic technology is sophisticated and will become more so. In recent years,

manufacturers have introduced SD-OCT, the OQAS, the Ocular Response Analyzer (Reichert, Inc., Depew, NY), and the Pascal Dynamic Contour Tonometer (Zeimer Ophthalmic Systems AG, Port, Switzerland). The TearLab System will be widely available in the United States after it receives Clinical Laboratory Improvement Amendments clearance. Plus, the ORange intraoperative wavefront aberrometer (WaveTec Vision, Aliso Viejo, CA) now enables on-the-table, real-time refractive measurements, which should substantially improve the accuracy of limbal relaxing incisions, toric IOL implantation, and IOL power calculations, particularly in eyes with a history of refractive surgery.

It is reasonable to believe that these exciting technologies will become as indispensable as corneal topography and wavefront aberrometry are today. These diagnostic systems cost money. It makes sense for ophthalmologists to charge a fee—as our colleagues in other medical specialties do—to make offering these tests to our patients cost effective. Looking for ways to improve revenue based on diagnostic tests does not make us bad physicians, particularly when Medicare reimbursement levels are facing downward pressure yet again.² ■

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1. Diagnostic Testing. *Executive Healthcare Management Magazine*. November 2009;9. <http://www.executivehcm.com/article/Diagnostic-testing>. Accessed April 22, 2010.
 2. Zhang J. Medicare plans to cut specialists' payments. *The Wall Street Journal*. July 2, 2009. <http://online.wsj.com/article/SB124646885862181139.html?KEYWORDS=Medicare+plans+to+cut+specialists+payments>. Accessed April 9, 2010

Bausch & Lomb
Lotemax[®]
 loteprednol etabonate
 ophthalmic suspension 0.5%

Rx only

Brief Summary

INDICATIONS AND USAGE:

LOTEMAX is indicated for the treatment of steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, selected infective conjunctivitis, when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation.

LOTEMAX is less effective than prednisolone acetate 1% in two 28-day controlled clinical studies in acute anterior uveitis, where 72% of patients treated with LOTEMAX experienced resolution of anterior chamber cells, compared to 87% of patients treated with prednisolone acetate 1%. The incidence of patients with clinically significant increases in IOP (≥ 10 mmHg) was 1% with LOTEMAX and 6% with prednisolone acetate 1%. LOTEMAX should not be used in patients who require a more potent corticosteroid for this indication.

LOTEMAX is also indicated for the treatment of post-operative inflammation following ocular surgery.

CONTRAINDICATIONS:

LOTEMAX, as with other ophthalmic corticosteroids, is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. LOTEMAX is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.

WARNINGS:

Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision, and in posterior subcapsular cataract formation. Steroids should be used with caution in the presence of glaucoma.

Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. In acute purulent conditions of the eye, steroids may mask infection or enhance existing infection.

Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution.

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

PRECAUTIONS:

General: For ophthalmic use only. The initial prescription and renewal of the medication order beyond 14 days should be made by a physician only after examination of the patient with the aid of magnification, such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.

If signs and symptoms fail to improve after two days, the patient should be re-evaluated.

If this product is used for 10 days or longer, intraocular pressure should be monitored even though it may be difficult in children and uncooperative patients (see WARNINGS).

Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal cultures should be taken when appropriate.

Information for Patients: This product is sterile when packaged. Patients should be advised not to allow the dropper tip to touch any surface, as this may contaminate the suspension. If pain develops, redness, itching or inflammation becomes aggravated, the patient should be advised to consult a physician. As with all ophthalmic preparations containing benzalkonium chloride, patients should be advised not to wear soft contact lenses when using LOTEMAX[®].

Carcinogenesis, mutagenesis, impairment of fertility: Long-term animal studies have not been conducted to evaluate the carcinogenic potential of loteprednol etabonate. Loteprednol etabonate was not genotoxic *in vitro* in the Ames test, the mouse lymphoma tk assay, or in a chromosome aberration test in human lymphocytes, or *in vivo* in the single dose mouse micronucleus assay. Treatment of male and female rats with up to 50 mg/kg/day and 25 mg/kg/day of loteprednol etabonate, respectively, (600 and 300 times the maximum clinical dose, respectively) prior to and during mating did not impair fertility in either gender.

Pregnancy: Teratogenic effects: Pregnancy Category C. Loteprednol etabonate has been shown to be embryotoxic (delayed ossification) and teratogenic (increased incidence of meningocele, abnormal left common carotid artery, and limb flexures) when administered orally to rabbits during organogenesis at a dose of 3 mg/kg/day (35 times the maximum daily clinical dose), a dose which caused no maternal toxicity. The no-observed-effect-level (NOEL) for these effects was 0.5 mg/kg/day (6 times the maximum daily clinical dose). Oral treatment of rats during organogenesis resulted in teratogenicity (absent innominate artery at ≥ 5 mg/kg/day doses, and cleft palate and umbilical hernia at ≥ 50 mg/kg/day) and embryotoxicity (increased post-implantation losses at 100 mg/kg/day and decreased fetal body weight and skeletal ossification with ≥ 50 mg/kg/day). Treatment of rats with 0.5 mg/kg/day (6 times the maximum clinical dose) during organogenesis did not result in any reproductive toxicity. Loteprednol etabonate was maternally toxic (significantly reduced body weight gain during treatment) when administered to pregnant rats during organogenesis at doses of ≥ 5 mg/kg/day.

Oral exposure of female rats to 50 mg/kg/day of loteprednol etabonate from the start of the fetal period through the end of lactation, a maternally toxic treatment regimen (significantly decreased body weight gain), gave rise to decreased growth and survival, and retarded development in the offspring during lactation; the NOEL for these effects was 5 mg/kg/day. Loteprednol etabonate had no effect on the duration of gestation or parturition when administered orally to pregnant rats at doses up to 50 mg/kg/day during the fetal period.

Nursing Mothers: It is not known whether topical ophthalmic administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Systemic steroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when LOTEMAX is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS:

Reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera.

Ocular adverse reactions occurring in 5-15% of patients treated with loteprednol etabonate ophthalmic suspension (0.2%-0.5%) in clinical studies included abnormal vision/blurring, burning on instillation, chemosis, discharge, dry eyes, epiphora, foreign body sensation, itching, injection, and photophobia. Other ocular adverse reactions occurring in less than 5% of patients include conjunctivitis, corneal abnormalities, eyelid erythema, keratoconjunctivitis, ocular irritation/pain/discomfort, papillae, and uveitis. Some of these events were similar to the underlying ocular disease being studied.

Non-ocular adverse reactions occurred in less than 15% of patients. These include headache, rhinitis and pharyngitis.

In a summation of controlled, randomized studies of individuals treated for 28 days or longer with loteprednol etabonate, the incidence of significant elevation of intraocular pressure (≥ 10 mmHg) was 2% (15/901) among patients receiving loteprednol etabonate; 7% (11/164) among patients receiving 1% prednisolone acetate and 0.5% (3/583) among patients receiving placebo.

DOSE AND ADMINISTRATION:

SHAKE VIGOROUSLY BEFORE USING.

Steroid Responsive Disease Treatment: Apply one to two drops of LOTEMAX into the conjunctival sac of the affected eye(s) four times daily. During the initial treatment within the first week, the dosing may be increased, up to 1 drop every hour, if necessary. Care should be taken not to discontinue therapy prematurely. If signs and symptoms fail to improve after two days, the patient should be re-evaluated (See PRECAUTIONS).

Post-Operative Inflammation: Apply one to two drops of LOTEMAX into the conjunctival sac of the operated eye(s) four times daily beginning 24 hours after surgery and continuing throughout the first 2 weeks of the post-operative period.

Storage: Store upright between 15°-25°C (59°-77°F). DO NOT FREEZE.

KEEP OUT OF REACH OF CHILDREN.

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Bausch & Lomb Incorporated, Tampa, Florida 33637

U.S. Patent No. 4,996,335

U.S. Patent No. 5,540,930

U.S. Patent No. 5,747,061

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STERILE OPHTHALMIC SUSPENSION