Eye on OMIC

OMIC

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Lipo-Dissolve No Longer Covered

In February 2008, the FDA issued the following (excerpted) statement regarding Lipo-Dissolve:

> "The FDA is aware of the practice of using Lipo-Dissolve. Lipo-Dissolve is not FDA approved for any use… there are no FDA-approved drugs with an indication to dissolve fat. FDA cannot assure the safety and efficacy of these types of drugs. These are unapproved drugs for unapproved uses and FDA cannot guarantee consumers' safety… The use of compounded drugs is not considered "off-label" use… FDA approval of a drug includes approved labeling for use, and means that the FDA has evaluated the safety and efficacy of a drug for a specific use and population. Once approved, a drug may be prescribed by a licensed physician for a use that, based on the physician's professional opinion, is appropriate…but it is expected that the physician is well-informed about the product and that the "off-label" use is based on sound scientific rationale and adequate medical advice…"

Numerous medical associations, including the American Society of Ophthalmic Plastic and Reconstructive Surgery, have issued warnings regarding injection lipolysis and cautioned their membership against performing such treatments. In addition, several states seek to ban or regulate Lipo-Dissolve procedures.

As a result of these developments, the Board of Directors has determined that OMIC will no longer extend coverage for any Lipo-Dissolve, mesotherapy, or similar procedure unless performed as part of an investigational drug trial under an American IRB-approved protocol.

Message from the Chairman

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reported to OMIC. Only about 220, or 5%, have been related to "wrong" events. Since 1997, the percentage of insureds who have reported a wrong site or wrong IOL matter to OMIC has stayed relatively constant at a median annual average of about 0.5%.

However infrequent, these types of errors have drawn the attention of the public and state and federal policymakers, resulting in fines and licensing sanctions against physicians and non-payment of services by Medicare and other payors. The AAO, OMIC, and other ophthalmic societies are taking a two-prong approach to the problem—education and prevention—via the Academy Practice Improvement Task Force and a three-year Academy Campaign to Eliminate Wrong Site/Wrong IOL Surgery.

The first charge of the Practice Improvement Task Force, a group of seven ophthalmologists representing the AAO, ABO, AUPO, and OMIC, is to develop an online CME activity that will allow ophthalmologists to compare their own practice to those that follow evidence-based performance measures and protocols proven to reduce errors. Simple-to-use checklists will help participants adopt the protocols in their own office. Anonymous data collection of pre- and post-education practice activities will enable the task force to evaluate the effectiveness of the practice improvement activity on care outcomes.

The campaign to eradicate "Wrong Site Surgery and Wrong IOL Implantation" in the U.S. within three years is another cooperative group effort of ophthalmologists and is led by Gary S. Schwartz, MD. The group will review suggestions drawn from evidence-based medicine to help surgical teams evaluate and improve their own safety systems to eliminate all sources of wrong site or wrong IOL errors, whether operating in an office, hospital, or ambulatory surgery center.

At the state level, the Florida Society of Ophthalmology is working with OMIC and the Academy to educate FSO members on wrong site/wrong IOL surgery prevention. Florida is "ground zero" when it comes to the regulatory impact of system errors, and ophthalmologists in particular have borne the brunt of fines and licensure sanctions. The reason lies principally with the reporting requirements of ASCs and hospitals to the Florida medical board when a wrong site or wrong IOL error occurs in the operating room. The FSO is partnering with the Florida Board of Medicine to develop a statewide regulatory/disciplinary process to handle and correct the systems that produce such violations.

With the leadership and participation of so many prominent ophthalmic organizations, we hope to make the persistent problem of wrong site/wrong IOL a "never" event.

Joe R. McFarlane Jr., MD, JD
OMIC Chairman of the Board