



AMERICAN ACADEMY™
OF OPHTHALMOLOGY

EyeNet®

SUPPLEMENT

Guide for the Young Ophthalmologist

SEPTEMBER 2016



Which Practice Type Is Best for You?

Reimbursement 101: The Basics

Tweet to Jump-Start Your Career

Keys to Patient Satisfaction



JUST

**Xiidra improved patient-reported symptoms of eye dryness
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The safety of lifitegrast was evaluated in 5 clinical studies. 1401 patients received at least one dose of lifitegrast (1287 of which received Xiidra). The most common adverse reactions (5-25%) were instillation site irritation, dysgeusia, and reduced visual acuity.



Xiidra is the only prescription eye drop FDA-approved to treat both the signs and symptoms of Dry Eye Disease

Indication

Xiidra™ (lifitegrast ophthalmic solution) 5% is indicated for the treatment of signs and symptoms of dry eye disease (DED).

Important Safety Information

In clinical trials, the most common adverse reactions reported in 5-25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

To avoid the potential for eye injury or contamination of the solution, patients should not touch the tip of the single-use container to their eye or to any surface.

Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

Safety and efficacy in pediatric patients below the age of 17 years have not been established.

For additional safety information, see accompanying Brief Summary of Safety Information on the following page and Full Prescribing Information on Xiidra-ECP.com.



BRIEF SUMMARY:

Consult the Full Prescribing Information for complete product information.

INDICATIONS AND USAGE

Xiidra™ (lifitegrast ophthalmic solution) 5% is indicated for the treatment of the signs and symptoms of dry eye disease (DED).

DOSAGE AND ADMINISTRATION

Instill one drop of Xiidra twice daily (approximately 12 hours apart) into each eye using a single use container. Discard the single use container immediately after using in each eye. Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in clinical studies of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. In five clinical studies of dry eye disease conducted with lifitegrast ophthalmic solution, 1401 patients received at least 1 dose of lifitegrast (1287 of which received lifitegrast 5%). The majority of patients (84%) had ≤ 3 months of treatment exposure. 170 patients were exposed to lifitegrast for approximately 12 months. The majority of the treated patients were female (77%). The most common adverse reactions reported in 5-25 % of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

USE IN SPECIFIC POPULATIONS

Pregnancy

There are no available data on Xiidra use in pregnant women to inform any drug associated risks. Intravenous (IV) administration of lifitegrast to pregnant rats, from pre-mating through gestation day 17, did not produce teratogenicity at clinically relevant systemic exposures. Intravenous administration of lifitegrast to pregnant rabbits during organogenesis produced an increased incidence of omphalocele at the lowest dose tested, 3 mg/kg/day (400-fold the human plasma exposure at the recommended human ophthalmic dose [RHOD], based on the area under the curve [AUC] level). Since human systemic exposure to lifitegrast following ocular administration of Xiidra at the RHOD is low, the applicability of animal findings to the risk of Xiidra use in humans during pregnancy is unclear.

Animal Data

Lifitegrast administered daily by intravenous (IV) injection to rats, from pre-mating through gestation day 17, caused an increase in mean preimplantation loss and an increased incidence of several minor skeletal anomalies at 30 mg /kg /day, representing 5,400-fold the human plasma exposure at the RHOD of Xiidra, based on AUC. No teratogenicity was observed in the rat at 10 mg /kg /day (460-fold the human plasma exposure at the RHOD, based on AUC). In the rabbit, an increased incidence of omphalocele was observed at the lowest dose tested, 3 mg /kg /day (400-fold the human plasma exposure at the RHOD, based on AUC), when administered by IV injection daily from gestation days 7 through 19. A fetal No Observed Adverse Effect Level (NOAEL) was not identified in the rabbit.

Lactation

There are no data on the presence of lifitegrast in human milk, the effects on the breastfed infant, or the effects on milk production. However, systemic exposure to lifitegrast from ocular administration is low. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for Xiidra and any potential adverse effects on the breastfed child from Xiidra.

Pediatric Use

Safety and efficacy in pediatric patients below the age of 17 years have not been established.

Geriatric Use

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

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis: Animal studies have not been conducted to determine the carcinogenic potential of lifitegrast.

Mutagenesis: Lifitegrast was not mutagenic in the *in vitro* Ames assay. Lifitegrast was not clastogenic in the *in vivo* mouse micronucleus assay. In an *in vitro* chromosomal aberration assay using mammalian cells (Chinese hamster ovary cells), lifitegrast was positive at the highest concentration tested, without metabolic activation.

Impairment of fertility: Lifitegrast administered at intravenous (IV) doses of up to 30 mg/kg/day (5400-fold the human plasma exposure at the recommended human ophthalmic dose (RHOD) of lifitegrast ophthalmic solution, 5%) had no effect on fertility and reproductive performance in male and female treated rats.



Manufactured for: Shire US Inc., 300 Shire Way, Lexington, MA 02421.

For more information, go to www.Xiidra.com or call 1-800-828-2088.

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For definitions of each category, see aao.org/eyenet/disclosures.

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Who are the YOs? The Academy (AAO) and the American Academy of Ophthalmic Executives (AAOE) provide resources and programming for Young Ophthalmologist (YO) members who are at a formative phase of their career—residency, fellowship, and the first 5 years of practice. For information, visit aao.org/yo or email yo@aao.org.

Use your member benefits. For a full list of Academy and AAOE member benefits, go to aao.org/member.

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1st year in practice	\$425/free
2nd year in practice	\$650/\$260
3rd-5th year in practice	\$950/\$260

* Per calendar year.

SOCIAL MEDIA

Twitter as a Tool to Jump-Start Your Career

BY STEVEN M. CHRISTIANSEN, MD (@EYESTEVE).

In medicine, social media is becoming increasingly important as a channel for professional communication. Today's young ophthalmologists (YOs) were in high school and college when the social media revolution began. As a result, we are very familiar with its use as a method of personal communication. However, many of us are less familiar with how to use social media—in particular, Twitter—for professional, career-building purposes.

Why Twitter?

Twitter is the social network of choice for professional medical communications for several reasons:

- **Connect beyond your Facebook friends.** Twitter helps you socially engage with physicians in every specialty and all over the world but allows you to keep your other social networks, like Facebook and Instagram, private and visible to just your family and friends.
- **To the point.** When writing a tweet, you may find that staying under the 140-character limit can be challenging. When reading tweets, you will appreciate that this same character limit yields concise pearls of information.
- **Customized content.** Incoming tweets are based on the Twitter users that you chose to follow.
- **Real-time discussion.** New tweets appear within seconds. This nearly real-time discussion is particularly useful for tweeting at conferences and participating in Twitter chats (see below).
- **YO peers are tweeting.** At AAO 2015, 63% of ophthalmologists tweeting were either trainees or had been in practice for no more than 10 years.¹ Today's YOs will continue to steer the social media conversation for many years to come.

How to Get Started

Set up your account at <https://twitter.com/signup>.

Start before you finish training. Many YOs mistakenly delay establishing a professional online presence (website, social media) until they have completed training and are certain about their practice setting and location. Creating a Twitter account while still in training is an easy, cheap way to jump-start your career—and once you know where you will be practicing, simply update your social media profile with your practice location and details.

Personal brand vs. practice brand. An official, prac-



tice-based Twitter feed can be a great marketing tool to brand your practice and connect with patients. (Be sure to add a disclaimer that tweets should not be construed as medical advice. Journalists often say retweet ≠ endorsement.) Your personal Twitter feed,

however, will not only synergistically strengthen your practice brand but will give you a public voice to share your unique insights, strengthening your personal brand.

Choose a Twitter username. Keep it simple. If it's still available, use your name followed by MD so others can easily find (and follow!) you.

Which accounts and topics should you follow? Over time, you can create a highly focused news feed that is a close match to your interests. Start by visiting this YO supplement online (aao.org/eyenet) and reading the Web Extra "Developing Your Twitter Account Into an Ophthalmic News Feed," which recommends Twitter accounts and hashtags to follow.

Use Twitter to Share and Connect

Tweet pearls from grand rounds, lectures, or published articles. Twitter can be a good way to take notes and educate others. Tweet clinical pearls, add a relevant link (remember HIPAA!), and credit your sources by using their Twitter handle or ending the tweet with –[Last name] or, if you have space, –Dr. [Last name].

Join a Twitter chat to discuss various health care topics. Engage with other Twitter users in live, regularly scheduled Twitter-based chats. Popular chats for trainees are #meded for medical education (Thursdays at 9:00 p.m., EDT) and #hcsn for social media in health care communications (Sundays at 8:00 p.m., CT). For a list of Twitter chats, go to www.simplur.com/healthcare-hashtags/tweet-chats.

Live-tweet at conferences. Share key points from (and credit!) podium lecturers to enrich the conference experience for those attending the meeting, and help disseminate the meeting highlights to the digital audience worldwide.

1 Christiansen SM et al. *Ophthalmology*. 2016;123(8):1835-1837.



MORE ONLINE. For suggested Twitter accounts and hashtags, find this supplement on the September *EyeNet* home page at aao.org/eyenet.

PROFESSIONAL DEVELOPMENT

Which Type of Practice Works Best for You?

BY WILL PARKE, MD, ROMA PATEL, MD, MBA, AND DIANA R. SHIBA, MD.

Picking a practice type is a career-defining decision. To help you assess your options, *EyeNet* invited 3 ophthalmologists to describe the pros and cons of their practice settings—a private practice, a Kaiser group practice, and an academic-affiliated Veterans Affairs (VA) hospital. (For perspectives on a solo practice, a multisubspecialty practice, and an academic practice, see the 2015 YO supplement at www.nextbook.com/aao/eyenet/yo2015/index.php.)

Life in Private Practice

Will Parke, MD, works at a 12-physician practice. The practice, which is retina only, has been around for almost 30 years, with the founding physicians still very much involved.



DR. PARKE

Years in practice: 3

Subspecialty: Retina

Location: Minneapolis

What I like about working here. Four things attracted me to this practice, and they remain some of the biggest reasons that I love my job.

The first is that I respect the clinical skill, judgment, and innovative acumen of my partners, and I enjoy talking ophthalmology with them. In training, most of us grow accustomed to hanging out with other residents and fellows and comparing notes on a daily basis. I wanted a similar camaraderie in my job.

Second, the physicians in my group have the freedom and ability to grow their careers in whichever way they like. Some have dug into public policy and professional organization leadership, some into research or device development, others into teaching.

Third, the group is very collaborative and inclusive regarding practice management decisions. Right from day 1, I've known that if I bring an idea to a board meeting, it'll receive a serious appraisal.

The last factor is that we treat our responsibility as employers very seriously, and we take great pride in providing rewarding jobs for a large number of people.

None of these characteristics is necessarily specific to this practice setting, but private practice enables us to mold the structure and culture of our organization to reflect our priorities.

Downsides to my practice type. Private practice becomes a daunting place if you don't strike the right balance in your approach to practice management—proactive and deliberate, but not obsessive. If you're not careful, it is easy to get lost in the weeds of business minutiae. On the other hand, details do matter, and topics like billing, employee benefits, office leases, or accounting can evolve as quickly as our clinical practices do. Sticking your head in the sand and eschewing tough business decisions is a recipe for unsustainability.

What surprised me most. Coming out of fellowship in an academic institution, I was stunned at how nimble a private practice can be. Big decisions are appropriately made much more deliberately than small ones, but once they are made, they are enacted very quickly. The bureaucratic hurdles are a fraction of what we're used to in training.

What my day is like. For clinic, I am in a different location each day of the week. I usually have 1.5 to 2 days of surgery per week. I'll start either clinic or surgery at 7:30 a.m. but try to arrive a little early for both in order to take care of emails or paperwork. A lunch break is a memory from medical school that I look back on fondly. Surgery usually finishes in the early afternoon and clinic around 5 p.m., after which I try to spend an hour or so on research before heading home.

In summary. Private practices differ wildly. Rather than decide broadly on private practice versus the alternatives, you should first figure out what you want in your career. Next, check out a few private groups with a culture that will enable you to pursue it.



DR. SHIBA

Years in practice: 7

Subspecialty: Cataract and comprehensive

Location: Los Angeles

Life in a Very Large Group

Diana R. Shiba, MD, joined a medical group that is part of one of the largest integrated care delivery systems in the United States—Kaiser Permanente.

Working for a Permanente medical group has been simply a dream come true. I have incredible work-life balance, great compensation and benefits, and can practice medicine the way I always intended to—without worrying about the business of running a practice. Nationally, there are 18,000 physicians in the various Permanente Medical Groups. In the Southern California Permanente Medical Group (the one I'm part of), we provide care to more than 4.2 million

patients a year. In California alone, there are more than 200 ophthalmologists who are part of the same system.

What I like about my practice. On a personal level, there is a strong emphasis on physician wellness and work-life balance in our practice. For example, I have a flexible schedule that allows me to have a day off during the week to spend with my 3-year-old twins, Zoe and Noah. There is paid educational time, which allows us to teach, conduct research, or attend conferences. Our benefits package has competitive compensation (it's more than the package offered by a well-respected private practice) and includes a pension plan. Professionally, I love being able to go to work, log on to our electronic health record (EHR) system, and just concentrate on my patients. I don't have to focus on coding or running a business, and I have the financial security of knowing that our integrated system is well poised to weather the changes happening in health care. Having access to such a large group of physicians (across all specialties) has also made coordinating care with other specialists easy.

Downsides to my practice type. I do have less autonomy than a physician in solo/private practice—I cannot just reschedule my clinic and go to the golf course on a whim. There are also multiple levels of management, and implementing a large practice change may take more time than if you work in a private setting with, say, 4 other ophthalmologists.

What surprised me most about my practice type. I have found that navigating upper management has not been as difficult as I thought it would be. If anything, management has been supportive of my professional growth. I've also been impressed with the EHR system we use. With 1 click, I can order or review an MRI, email a patient, or contact a colleague at a distant medical center.

What my day is like. I start my clinic at 7:30 a.m., with my last patient at 3:15 p.m. I see approximately 24 patients a day, and have a 1-hour lunch. I have a colleague who starts at 9 a.m., and this flexibility allows her time to drop off her son at day care prior to work. At my center, we all have 4-hour blocks of OR time weekly, as well as built-in educational time, and weekends off. I also have administrative time that I dedicate to advocacy work for the medical group.

In summary. I believe working for a very large medical group has many more pros than cons, and it has enabled me to find happiness on both a personal and professional level.

Life at an Academic VA

Roma Patel, MD, MBA, combines resident teaching with independent practice. After completing residency at the University of California, Davis, and a glaucoma fellowship at Duke, I returned to the Sacramento VA where I had worked as a resident. I am currently the chief of ophthalmology for the Sacramento Mather VA and an assistant clinical professor at the UC Davis Eye Center. Our VA serves as the subspecialty referral center (glaucoma, retina, and cornea) for most of the Northern California region. My clinics are focused on secondary- and tertiary-level glaucoma care, I operate independently on my glaucoma patients, and I teach residents cataract surgery and clinical skills.



DR. PATEL

Years in practice: 1

Subspecialty:
Glaucoma

Location:
Sacramento, CA

What I like about my practice. I love that I work with close friends and great colleagues, I enjoy teaching residents, and the veterans are wonderful to work with as patients—they are extremely grateful, recognize our team's ability to provide great care, and have a great viewpoint on life and on what is important.

In our closed system, patient-related finances are the least of my worries. I can choose the appropriate care for my patient without concern for insurance approval or the ability of my patient to pay for medications or surgical procedures. The level of glaucoma pathology

is high at the VA, and I feel fulfilled and challenged by utilizing the full capacity of my training and skills. As a young mother, I appreciate the perks of not taking primary call and having a stable income with ample guilt-free paid vacation time. Depending on your VA, you can have supported time and funds for research, attending conferences, and attending leadership courses.

Downsides to my practice type. Working in a VA can be challenging. You sometimes have fewer resources than your colleagues in private or academic practice—less technical and ancillary support, for example. Furthermore, due to employee protections, it is hard to find accountable non-physicians, but I have begun to build my network. As chief, I have many responsibilities in addition to my patients—I am trying to improve and grow our staff, increase our efficiency and access, and I am working on plans for our new eye clinic. As a part-time professor, I am exploring possible minor research projects, and teaching often takes longer than just doing it yourself. It can be hard to balance all of this.

What surprised me most about my practice type. I have learned that each VA is very different. Much depends on leadership and the structure of physician teams. Those that are closely academically affiliated are often filled with excellent physicians and have a higher level of care. Some VAs are structured such that only residents operate—this might not be the best choice for a young ophthalmologist, as you need to nurture your own skills early on in your career. The VA funding is also interesting in that it is easier to get equipment funded than personnel.

What my day is like. In a typical week, I am in my glaucoma clinic 2 days, in the OR 1 day, have administrative/academic time for 1.5 days, and supervise consult residents at UC Davis for half a day. I start work usually around 8 a.m. Clinical work is finished by 4:30 p.m., but I tend to stay until 6 p.m. for my administrative work. Once I am home, I try to focus on family and home life.

In summary. VAs across the country are looking for potential young leaders. If you are keen to teach residents but not so excited about doing research, it could be the perfect fit. And you would be hard pressed to find a more grateful patient population!

PROFESSIONAL DEVELOPMENT

Get Involved in Mission Work: Here Are Your Options and What to Expect

BY LESLIE BURLING-PHILLIPS, CONTRIBUTING WRITER, INTERVIEWING MICHAEL FEILMEIER, MD, ANDREAS LAUER, MD, AND GRACE SUN, MD.

Young physicians are increasingly interested in volunteering overseas, but they are unsure about how to get involved or what they need to know before they go. This article describes the main options, explains how to get started, and discusses what to expect from this type of service.

What Are Your Options?

Fellowships, residency programs, and other opportunities of various lengths and capacities are available.

Residency programs. Not so long ago, U.S. residency programs typically didn't integrate overseas experiences into their educational program, with one rare exception being the well-established relationship between Aravind Eye Hospital and Wilmer Eye Institute. However, global ophthalmology rotations are becoming more common now that the Accreditation Council for Graduate Medical Education (ACGME) has made overseas education permissible within ophthalmology program requirements. "Because residents are not yet competent or qualified to practice independently, the home institution must engage in a program letter of agreement [PLA] with the hosting site in order for the extramural

experience to be considered part of the educational curriculum," said Andreas Lauer, MD, vice-chair for education and professor of ophthalmology at the Oregon Health & Science University's (OHSU) Casey Eye Institute in Portland. "The PLA clearly outlines the duration of time that the resident will spend at the location, define the expected learning experience and who will supervise and evaluate the resident, detail the scope of patient care involved, and describe the institutional protections the resident will receive."

Fellowships. Currently, there are 5 formal global eye care fellowships offered through academic institutions:

- Truhlsen Eye Institute's Prevention of Global Blindness Fellowship (University of Nebraska; www.unmc.edu/eye/residencies-fellowships/fellowship/index.html)
- Moran Eye Center's Moran International Fellowship (University of Utah; medicine.utah.edu/ophthalmology/education/fellowship/international.php)
- Dean McGee Eye Institute's Global Eye Care Fellowship (University of Oklahoma; dmei.org/fellowship-programs)
- Emory Eye Center's Global Ophthalmology Fellowship (Emory University; www.eyecenter.emory.edu/education/)

Helping an Isolated Population

Spanning 5 islands and 2 coral atolls, and serving as home to approximately 55,000 people, American Samoa had only 1 ophthalmologist—and he was slated to retire. Without assistance, the population in this U.S. territory in the middle of the South Pacific would potentially be left without eye care. "David J. Wilson, our chairman [at OHSU], thought that training someone to serve that community would be an important contribution to global health," said Dr. Lauer. In cooperation with ophthalmology faculty members, university support, and philanthropic backing, Dr. Lauer described a departmental initiative

to establish a reciprocal arrangement between OHSU and the Lyndon B. Johnson Tropical Medical Center at Pago Pago, the capital of American Samoa. "The premise behind the initiative was to enable individuals to visit our program and learn from our team, and for our team to learn from other medical communities," he said. As part of this program, Benjamin Siatu'u, MD, went to Oregon for intensive training in ophthalmology. Now back in Samoa, he is working with Casey Eye Institute



AMERICAN SAMOA'S NEW OPHTHALMOLOGIST.
Dr. Siatu'u (left) with OHSU's Dr. Lauer (right).

to finish building up the other critical elements of a regional eye care program. (For more information, go to www.ohsu.edu and search for "Vision in American Samoa.")

[global_ophthalmology_fellowship.htm](#))

- Wills Eye Center for Academic Global Ophthalmology Fellowship (Wills Eye Hospital; www.willseye.org/academic-global-ophthalmology-fellowship)

“These are the best avenues for people who want to pursue global eye care; however, there are also less formal programs available,” said Michael Feilmeier, MD, who completed the first fellowship offered by Moran Eye Center in 2009 and went on to create a 1-year fellowship program at Truhlsen Eye Institute, where he is now the medical director of the international division of ophthalmology.

Volunteer through a charitable organization. There are many organizations that seek to serve the visually impaired, both overseas and in the United States. These include:

- **Orbis International.** The “flying eye hospital” is one of the oldest models for bringing surgical knowledge and skills to doctors in developing countries. “Although ineligible to perform surgery, residents can volunteer as an associate ophthalmologist for a week or two and provide ophthalmic education or care to patients,” said Dr. Lauer. It serves more than 90 countries and trains thousands of medical professionals each year (www.orbis.org).

- **Seva Foundation.** Working with local partners in 20 different countries, Seva strives to create self-sustaining programs to preserve and restore vision (www.seva.org).

- **Himalayan Cataract Project (HCP).** Initially founded to establish a sustainable infrastructure for eye care in the Himalaya, HCP now has programs in 7 countries—Bhutan, Ethiopia, Ghana, India, Myanmar, Nepal, and Rwanda (www.cureblindness.org).

- **EyeCare America (ECA).** ECA provides an opportunity to volunteer in the United States. “When we think of global health, it is not solely international health—it centers on the idea of basic eye care for all, which includes those who are underserved in the United States,” said Grace Sun, MD, assistant professor of ophthalmology and head of the residency program at Weill Cornell Medical College in New York. “Sign up with the Academy’s EyeCare America program to treat uninsured and underinsured patients without charge.” (aao.org/eyecare-america.)

Prepare for AAO 2016 by using the Mobile Meeting Guide, which launches on Sept. 7, to see which organizations will have an informational poster on display. The Academy is also redesigning its EyeCare Volunteer Registry. To volunteer—or if you work with an organization that offers volunteer opportunities—email intoutreach@aao.org.

Know Before You Go

Expect the unexpected. Not everyone has the moxie to work in locations where things can be unpredictable. Challenges are common when providing care abroad—from encountering a lack of supplies to operating with outdated equipment. “If you have international travel experience, you probably understand that the unexpected is almost always to be expected, which requires patience and flexibility. And, although you are there to share your expertise, you are also a guest and must be respectful even if procedures are different from what you

might be accustomed to,” Dr. Sun cautioned. When selecting a fellow for a mission, Dr. Feilmeier evaluates both qualifications and personality. “The most important aspects aside from these items are the resident’s motivation, career aspirations, and anticipated end result,” he said.

Seek long-term, sustainable improvements. “The best kind of mission work involves creating connections that build with each visit. The goal is to develop long-term and mutually beneficial relationships that improve the existing situation in an underserved location and to facilitate these changes in a sustainable way,” said Dr. Feilmeier.

Ten important considerations. According to Drs. Feilmeier, Lauer, and Sun, these are the top 10 things that every resident should know or do before engaging in a mission:

1. Think about not only where you want to go and your goals but also where you will have the greatest impact.
2. Go to a country that welcomes you—not just somewhere you want to visit.
3. During your first few trips, choose a mentor and go with someone who is experienced with the site you’re visiting.
4. Study and respect local customs.
5. Focus on the sustainability of your service and work toward the long-term improvement of eye care delivery.
6. Make sure that all of your credentialing is up to date.
7. Make sure that your malpractice insurance is up to date and will cover you while serving abroad.
8. Interpreters are provided in most locations, but it is helpful to learn the words used during a basic eye exam.
9. Get the appropriate immunization(s).
10. Take advantage of Academy resources:

- Go to the Global Ophthalmology (GO) Guide at aao.org/goguide and scroll down to “Education” for 3 online CME courses from the Johns Hopkins Bloomberg School of Public Health: So You Want to Work Overseas?; The Major Causes of Blindness; and Assessing Outcomes in Global Health Programs.

- At AAO 2016, attend 2 free events—Meet With an International Expert (Saturday, Oct. 15, 11:30 a.m.-1:30 p.m. in the YO Lounge, Grand Concourse) and the Global Forum and Volunteer Fair (Sym27, Monday, Oct. 17, 8:30-11:00 a.m. Room S101ab). For more information, go to aao.org/programsearch and search by special interest “Global Ophthalmology.”

Reap the rewards. People who engage in mission work “experience a sense of satisfaction because they are able to donate their skill set and abilities to others who would not otherwise have access to that type of care. This just feels good, and it is the right thing to do,” said Dr. Lauer.

Mission work may change the way you practice medicine and look at how health care is delivered. “My mission work experiences have led me to become significantly more resourceful, flexible, and comfortable—both in the clinic and in the operating room,” said Dr. Feilmeier. Dr. Sun agreed, adding, “You develop an understanding with these experiences that things can be done well elsewhere, even when done differently than how we were taught during medical school.”

CODING & REIMBURSEMENT

Reimbursement 101: A Quick Guide to Getting Paid

BY SUE VICCHRILLI, COT, OCS, AND JENNY EDGAR, CPC, CPCO, OCS.

The reimbursement processes of federal and commercial payers have many moving parts, some of which move in mysterious ways. Fortunately, there are plenty of resources to help you learn both the standard coding rules and the idiosyncrasies of your payers' policies (see "Further Reading" and "Know your local rules," page 14). And you'll find those detailed rules much easier to absorb after reading this quick overview of 1) the billing process (including use of CPT codes, ICD-10 codes, and modifiers; coding for the office visit; and the pitfalls of global periods and bundled codes), 2) the payment process (fee schedules, allowables, patient payments, and audits), and 3) the different types of payer.

Use CPT Codes to Report What You Did

To get reimbursed for patient care by third-party payers, you must submit Current Procedural Terminology (CPT) codes along with International Classification of Disease (ICD-10) codes. The CPT codes represent what you have done (e.g., a

surgical procedure) and the ICD-10 codes represent why you did it (e.g., the diagnosis that justifies that surgery). Most of the time you'll use Category I, Level I CPT codes, but there also are 3 other types of CPT codes that you might use.

Category I, Level I codes represent exams, testing services, and surgical procedures using a 5-character numeric code—e.g., 66984 *Extracapsular cataract removal with insertion of an IOL*.

Category I, Level II codes (also known as HCPCS codes) document supplies, injectable solutions, glasses, contact lenses, and screening using a 5-character alphanumeric code—e.g., J9190 for injecting 5-fluorouracil.

Category II codes report quality measures for the Physician Quality Reporting System (PQRS), which will be absorbed into the Merit-Based Incentive Payment System (MIPS), as of Jan. 1, 2017. They use a 5-character alphanumeric code—e.g., 2027F *Optic nerve head evaluation performed*.

Category III codes help the CPT Editorial Panel collect data on emerging technologies, services, and procedures.

The Billing Process

Step 1: Documentation.

Create a chart for a new patient or update the existing chart for an established patient. (An *established patient* is defined as one who has received professional services within the past 3 years from the physician or another physician within the same group practice and of the exact same specialty and subspecialty.)

The CPT and ICD-10 codes you submit to the payer must be supported by the day's chart documentation.

Step 2: Code selection.

Select a CPT code (or codes) and a corresponding ICD-10 code (or codes).

Append appropriate modifiers to CPT codes when needed.

If you performed multiple tests or surgical procedures, watch out for bundling (CCI) edits and check whether the Multiple Procedure Payment Reduction applies.

Step 3: Claim submission.

Submit the claim to the payer using the CMS-1500 form.

If you submit it electronically, a clean claim will be processed within 14 days; if on paper, within 21 days.

Step 4: Payment (or rejection).

You will be sent Remittance Advice (RA; formally known as the Explanation of Benefits [EOB]) and, if all went well, payment.

If your claim was rejected, review the RA; rethink your choice of codes, modifiers, and/or linked diagnosis; and resubmit a corrected claim.

These data are then used to determine whether new Category I codes are needed. They use a 5-character alphanumeric code ending with T—e.g., 0198T *Measurement of ocular blood flow by repetitive IOP sampling, with interpretation and report*. Insurers can choose whether or not to reimburse Category III codes; if they don't, the patient is typically responsible for payment (see “Give patients advance notice of uncovered services,” page 14).

Category I and II codes are updated annually by the AMA's CPT Editorial Panel, with changes coming into effect on Jan. 1. Category III codes are updated twice a year, in January and July.

Use ICD-10 Codes to Justify What You Did

ICD-10 codes are alphanumeric codes that you use to show your payer why a particular service (i.e., the CPT code that you submitted) was medically necessary. They can be up to 7 characters long.

Example. H40.2232 represents bilateral chronic angle-closure glaucoma, moderate stage. Breaking that down, the first 5 characters (H40.22) represent the condition (chronic

angle-closure glaucoma), the 6th position represents laterality (1, right; 2, left; and 3, bilateral) and the 7th character represents the stage of glaucoma (0, unspecified; 1, mild; 2, moderate; 3, severe; and 4, indeterminate).

Must select the most complete code. If there is a 4th, 5th, 6th, or 7th code available, you must use it.

Must select the most accurate code. The best code is the actual diagnosis, the next best is a sign or symptom, and the last resort is a circumstance (Z code). Be sure that you only code established conditions (not probable, suspected, possible, or rule-out conditions).

Be Careful When Coding the Exam

When a patient visits your office for an exam, you can choose from 2 types of CPT Category I code—Evaluation and Management (E&M) codes or Eye visit codes (previously known as Eye codes).

E&M codes are 5 digits long and always start with 99—e.g., 99203 *New patient, level 3*. Documentation

Documentation of exams is the number one issue in audits.

rules are standardized for all payers nationwide, there are no frequency edits (the number of times a provider can bill a CPT code each year), and they can be linked to almost any diagnosis code.

Eye visit codes are 5 digits long and always start with 92—e.g., 92002 *Intermediate new patient exam*. These may also be used for vision exams, though payers' rules vary. Non-Medicare payers impose frequency edits (the number of times a provider can bill a CPT code each year), but Medicare Part B does not. Diagnosis coverage is limited by commercial payers, but not by Medicare Part B.

Levels of service. It takes more work to examine some patients than others, which is why E&M codes and Eye visit codes provide a range of options that represent different levels of service and are reimbursed accordingly.

10 E&M codes. There are 5 for an office visit from a new patient (99201-99205) and another 5 for the established patient (99211-99215).

4 Eye visit codes. There are 2 for the new patient (92002 and 92004) and 2 for the established patient (92012 and 92014).

Documentation is critical. Your chart documentation must support the level of service that you bill for, and that is where practices run into trouble—documentation of exams is the number one issue in audits. For instance, if you examine a new patient and submit CPT code 99205, which is the most remunerative E&M code, the patient chart must document that the patient history and exam were both “comprehensive” and that decision making of “high complexity” was involved. There is a step-by-step process for determining whether the documentation reaches those thresholds.

E&M code or Eye visit code? Some commercial payers require use of Eye visit codes for refractive or routine vision exams and E&M codes for medical exams, in which case you should consider why the patient came to see you, as deter-

MODIFIERS: When to Use Them

The CPT codes that you submit to your payer don't always tell the whole story. Suppose, for instance, you submit 2 CPT codes for the same patient—the first for surgery and the second for an eye exam that took place during the surgery's global period. Payers wouldn't reimburse you for that second CPT code because they would assume that the service was related to the initial surgery, in which case it would already be covered by their payment to you for the global surgery package (see “Be Mindful of Surgery's Global Period,” page 13). To be paid, you must notify the payer that the exam had nothing to do with the surgery, which you do by appending modifier -24 to the exam's CPT code. Commonly used modifiers include the following.

For exams:

- 24 *Unrelated E&M [or Eye visit code] service during postoperative period*
- 25 *Significant, separate E&M [or Eye visit code] service on the same day as a minor procedure*
- 57 *Decision to perform major surgery*

For surgery:

- 50 *Bilateral procedure*
- 54 *Surgical care only*
- 55 *Postoperative care only*
- 58 *Staged/related procedure during surgery*
- 78 *Unplanned return to operating room (OR)/procedure room for related procedures by the same physician during postop period*
- 79 *Unrelated procedure or service by the same physician during postop period*

mined by the chief complaint.

Pick the more remunerative option. If you have the option of selecting either an E&M code or an Eye visit code, it is permissible to select the code that has the highest reimbursement: Check the documentation in the chart and determine what level of E&M code it supports and what level of Eye visit code it supports; next, see what the payer will pay (the “allowable”) for each of those codes. (Many non-Medicare payers have higher allowables for E&M codes; most Medicare Part B payers have higher allowables for Eye visit codes.)

Tip—create a cheat sheet. To help you pick the more remunerative option, you should create a quick reference that lists what your main payers will pay for each E&M code and Eye visit code.

Be Mindful of Surgery’s Global Period

For surgery, the payer’s coverage is known as the global surgical package. This covers the surgery plus certain related services and postop visits that take place during a set number of days, known as the global period.

How long does the global period last? It depends on the CPT code and the payer. Payers classify surgical CPT codes as either minor or major.

For Medicare Part B:

- Minor procedures have either 0 or 10 days of postop care.
- Major procedures have 90 days.

For non-Medicare payers:

- Minor procedures have 0 or 10 days of postop care.
- Major procedures have 45, 60, or 90 days.

Payers’ fee schedules indicate the global period of each surgical CPT code.

Why the global period matters. If a patient encounter takes place during the global period, the payer is likely to assume that it was covered by the global surgical package. Suppose, however, that the encounter was unrelated to the earlier surgery. You should flag that fact by appending a modifier (e.g., -24) to the CPT code. If you don’t, you won’t get paid.

Don’t Bungle When You Unbundle

Bundled codes (aka CCI edits). Bundled codes are pairs of codes representing services that can’t both be billed when performed by the same physician on the same eye on the same day. These pairs are also often referred to as CCI edits or, sometimes, NCCI edits, which is a reference to the National Correct Coding Initiative that publishes lists of those pairs. These lists are updated quarterly.

Unbundling CCI edits. Some CCI edits (pairs of bundled codes) can be billed separately, but only under certain circumstances. You indicate to your payer that those circumstances apply by appending an appropriate modifier to the CPT code, a process known as unbundling.

Mutually exclusive CCI edits. Some CCI edits can never be unbundled. These are known as mutually exclusive edits and have an indicator of 0 in the NCCI listings.

How do you know which CCI edits can be unbundled? In NCCI’s lists of CCI edits, pairs of codes that can be unbun-

dled (with the help of a modifier) have an indicator of 1. Pairs that can’t have an indicator of 0. You’ll also find this in *2016 Coding Coach* (see “Further Reading,” page 14).

Why bundled codes matter. When 2 CPT codes can’t be unbundled, it is best to submit only the more remunerative one. If you don’t, you’re likely to be paid for the less remunerative one.

Understand the Payment Process

Practices and payers each have their own fee schedule. For practices, the fee schedule shows what they will bill for each CPT code; for payers, it shows what they will pay. When you contract to participate in an insurance plan, you agree to the plan’s fee schedule.

Billing for physician services is based on the practice’s fee schedule. When practices bill a third-party payer for a service, they typically charge the amount that their own fee schedule lists for that service (e.g., \$100), even if the third-party payer’s fee schedule lists a smaller amount (e.g., \$70).

Payments are based on the payer’s fee schedule. The practice will get paid only the amount that is on the payer’s fee schedule. This amount is known as the allowable. Suppose, for example, a service is listed as \$100 on your schedule and \$70 on the payer’s schedule. Although you charge \$100,

AUDITS: Not If, But When

Audits by third-party payers are becoming increasingly common. When they request records—whether for a postpayment audit or a prepayment review—they may put you on a tight deadline, so it is important to be prepared: Make sure your practice knows its payers’ policies, maintains a response protocol, trains its staff, and conducts a self-audit.¹

Denied payment for cataract surgery. Palmetto, one of Medicare Part B’s MACs, performed a prepayment review on 137 claims for CPT code 66984, Extracapsular cataract removal with insertion of an IOL.²

Palmetto partially or completely denied payment for 21 claims (15.3%) after identifying 30 documentation problems:

- No evidence of patient’s Snellen BCVA in record—14 occurrences
- No evidence of patient-reported impairment of visual function resulting in restriction of activities of daily living—12
- No evidence/documentation that comprehensive eye exam and a single diagnostic A-scan was done—2
- A signed operative note/report not present—2

1 aao.org/young-ophthalmologists/yo-info/article/how-to-prepare-medical-record-review. Accessed July 20, 2016.

2 <http://palmettogba.com/palmetto/providers.nsf/DocsCat/Providers-JM%20Part%20A-Medical%20Review-Results-9Y-GLDR3375?open>. Accessed June 8, 2015.

you will only get paid \$70, and the patient may pay some or all of that (see “Patient payments,” immediately below).

You can’t bill the patient for the balance. Your contract with the payer includes a “contractual adjustment” term, which obliges you to write off (or “adjust off”) the negative balance (\$30, in the example above).

Patients payments can involve copays, coinsurance, and deductibles. In recent years, patients have been picking up more of the tab because of 2 trends among insurance plans: 1) the move from copays to coinsurance and 2) the boom in

Your best source of information about commercial insurers is the payer’s website or a payer’s representative

high-deductible health plans.

The copay is when the patient pays a fixed amount for a service. This amount

may vary depending on the type of service (e.g., more for a visit to the emergency room than for an office visit), and the insurance company is responsible for the balance.

Coinsurance is when the patient has to pay a percentage of the fee. Typically, the patient has a deductible—which is a dollar amount (e.g., \$1,000)—and the patient pays 100% of the fees until the cumulative payments total the amount of the deductible.

Further Reading

Coding advice for YOs:

Go to aao.org/young-ophthalmologists and click “Learn to Code.”

Practice management coding resources:

Go to aao.org/practice-management and select “Coding.”

AAOE reference materials:

2016 Coding Coach: Complete Ophthalmic Coding Reference, a detailed 671-page guide (also available online) tells you everything you need to know about every CPT code that you’re likely to use, including relevant ICD-10 codes, relevant modifiers, global surgical periods, CCI edits, and more.

2016 ICD-10-CM for Ophthalmology: The Complete Reference (available as a book or online)

2016 Retina Coding: Complete Reference Guide

2016 CPT: The Complete Pocket Ophthalmic Reference

AAOE Primers:

The *Learn to Code* series includes *Learn to Code the Essentials* and 6 subspecialty modules (cataract and anterior segment, cornea, glaucoma, oculofacial, optical shop, pediatrics and strabismus).

For more information and to purchase products, visit aao.org/store.

In both cases, the fee would be based on the insurer’s fee schedule, and the practice is responsible for collecting payment from the patient.

Give patients advance notice of uncovered services. If you anticipate that Medicare will deny payment for a service, you should ask the Part B patient to sign an Advance Beneficiary Notice (ABN) of Noncoverage ahead of time. By signing the ABN, the patient accepts responsibility for making payment if Medicare denies reimbursement; without an ABN, you can’t bill the patient. Note: The ABN is for Medicare Part B patients only; commercial payers may have their own form or may require prior authorization to determine coverage.

Know Your Key Payers

Most of the claims that your practice initially sends out don’t go to your patients; they go to third-party payers, such as Medicare Part B, Medicare Advantage plans, and commercial insurers. Each has a detailed set of rules for reimbursement.

Medicare Part B. Medicare mainly covers people who are age 65 years or older and who have paid (or whose spouses have paid) taxes for at least 10 years. Part B of the Medicare program covers payments to physicians. Thus, unless you work in a pediatric practice, Medicare Part B is likely to be your biggest source of revenue.

Medicare Advantage (MA) plans. MA plans replace a patient’s traditional Part B Medicare, and they typically do not follow traditional Medicare rules. Although they have to cover services that are covered by Medicare Part B, each MA plan can offer extra services and charge different out-of-pocket costs, and they have different rules about access. They tend to follow the rules of the commercial payer administering the plan.

Commercial insurance. From Aetna to United HealthCare, commercial insurance companies have their own rules, regulations, bundling edits, fee schedules, and global periods for surgical procedures. Your best source of information is the payer’s website or a payer’s representative.

Medicaid. Medicaid is insurance coverage for low-income patients. Insurance should be verified prior to each scheduled visit. Preauthorization is required in all cases.

Know your local rules. Under Medicare Part B, CMS delegates the reimbursement process to Medicare Administrative Contractors (MACs) who can develop their own coverage policies for tests and surgical procedures. They publish these policies—known as local coverage determinations (LCDs)—on their websites. LCDs can be specific to a state or to a region and are sometimes accompanied by an article that offers additional information. There is much variation among the LCDs of different contractors, so it is important to read the policies that are applicable in your locality.

For more on LCDs, go to aao.org/eyenet and read “What’s in a Name? Defining and Understanding LCDs” (Savvy Coder, July 2013). To find your MAC’s LCDs, go to aao.org/practice-management/coding/updates-resources, where you’ll find a link to Medicare’s coverage database.

PATIENT SATISFACTION

You, Your Staff, and the Satisfied Patient

BY NANCY BAKER AND SUE VICCHRILLI, COT, OCS.

Perceptions can make or break a practice. If patients feel they've been treated competently and considerately, they're likely to recommend you to their family and friends. But few patients are able to make an objective judgment about a physician's clinical acumen, so they frequently make inferences based on other factors—and this is where staff interactions with patients can make a difference.

Leadership from the top is necessary. When the physician prioritizes patient satisfaction, staff members will follow that lead—particularly if the physician takes a clear interest in whether staff behavior is supporting that goal.

Watch for red flags. Are patients in their lane within 15 minutes of their appointment time? Are your Accounts Receivable (AR) numbers within or above benchmarks? Excessive wait times and confusion about payments are big drivers of patient dissatisfaction, and these problems suggest that the practice isn't running smoothly. Other problems to look for include:

- **Data entry problems.** Typos can lead to more than misspelled names or addresses—they can cause claim denials. This hits your bottom line and can prompt patients to question your practice's competence.
- **Patient complaints.** Is somebody tracking patient complaints? Do you notice a common theme? If there is an uptick in complaints, can it be correlated with any changes in the practice?
- **Fees aren't being collected when due.** If patients are delinquent with copayments, deductibles, and payments for noncovered services, you need to identify the reason(s). For example, staff at the front desk may need to do a better job of explaining payments. Suppose the checkout clerk says, "Mrs. Smith, you owe \$40 today"—the patient might assume that she is responsible only for that \$40. The clerk should have said, "Your total charges today are \$200,

of which we'll collect an initial \$40. After your insurance has processed the claim, you'll receive a statement for any remaining balance that you might owe."

Nurture patient satisfaction. Staff members should speak to the patient the same way they would speak to a family friend. This instantly creates respect and warmth, and it makes a patient feel appreciated and valued.

Turn satisfied patients into referrers. Each patient should leave with something that includes the practice's contact information. You also should display a sign that states, "We appreciate the confidence you place in our practice by referring friends and family." When patients do refer somebody to your practice, send them a thank you card or, at the very least, make a note in their charts so that the physician can personally thank them at their next visit.

Staff Roles

The front office. A large practice can have several people in the front office, including a receptionist, a checkout clerk, and an Accounts Receivable (AR) representative. They should have excellent communication skills—not just with the patients but with all levels of the practice team. Although dealing with confused and irate patients can be stressful, staff must maintain their poise and not take any complaints personally. It is not enough for a receptionist to be "nice"—he or she needs to take a global view of what is going on in order to anticipate and deal with problems before they derail the day.

Allied health staff. Some practices have ophthalmic assistants or technicians who are responsible for taking the history and performing tests before the doctor sees the patient. While gathering this information from the patient, they need to tread a fine line between staying on schedule and making sure that patients feel like their concerns are being heard. Staff must also be alert for any unexpected developments—for instance, the patient may make it clear that she doesn't want to pay for a refraction. If appropriate, the staff member should notify the doctor.

For a more detailed summary of the staff roles, along with tips for boosting performance, see the 2015 YO supplement at www.nxtbook.com/aao/eyenet/yo2015/index.php.





EyeNet Corporate Lunches

EyeNet® Magazine helps you make the most of your learning time at AAO 2016 by bringing you free corporate educational program lunches* onsite at McCormick Place.

These conveniently located industry-developed lunches ensure that you maximize your education in Chicago during the break between sessions.

Room E353b, Lakeside

McCormick Place

Check-in and Lunch Pickup

12:15-12:30 p.m. Lunches are provided on a first-come basis.

Program

12:30-1:30 p.m.

Programs

Saturday, Oct. 15 Diabetic Eye Disease: Clinical Challenges and Practical Tips for Multidisciplinary Disease Management

Speakers: Mandeep Brar, MD (endocrinologist), W. Lloyd Clark, MD, John W. Kitchens, MD

Supported by Regeneron Pharmaceuticals

Sunday, Oct. 16 A Novel Therapy for DME Patients Requiring Persistent Treatment

Speakers: Christopher D. Riemann, MD, Nathan M. Radcliffe, MD

Supported by Alimera Sciences

Monday, Oct. 17 Cataract Surgery: Life Is Beautiful When the Pupil Behaves

Speakers: Johnny L. Gayton, MD, Richard L. Lindstrom, MD, Robert H. Osher, MD, Keith A. Walter, MD, Robert J. Weinstock, MD, Elizabeth Yeu, MD

Supported by Omeros Corporation

Check aao.org/eyenet/corporate-lunches for updated program information.

* These programs are non-CME and are developed independently by industry. They are not affiliated with the official program of AAO 2016 or Subspecialty Day. By attending a lunch, you may be subject to reporting under the Physician Payment Sunshine Act.

PATIENT SATISFACTION

9 Tips for Delivering Bad News

BY DENNY SMITH, CONTRIBUTING WRITER, INTERVIEWING ROSA BRAGA-MELE, MD, MED, SUSAN H. DAY, MD, AND IVAN R. SCHWAB, MD.

Delivering bad news to patients is a highly sensitive challenge that, sooner or later, all physicians must face. Unfortunately, patients aren't always happy with how that news is broken. "Communication problems on the part of physicians have been cited as the most frequent complaint by patients, while inadequate communication, rather than medical negligence, is the most common cause of health care litigation,"¹ said Rosa Braga-Mele, MD, MEd, professor of ophthalmology at the University of Toronto.

How to Deliver Bad News

What steps can you take to communicate better with a patient when you need to deliver unwelcome news? Here are 9 practical techniques that you can use.

Build a relationship. Early on, solidify your relationship with the patient, said Susan H. Day, MD, a pediatric ophthalmologist. By building a rapport based on warmth and trust, you establish a good foundation for any difficult conversations that may be needed later on, said Dr. Day, a former chair of ophthalmology at California Pacific Medical Center in San Francisco, who is now vice president of medical affairs at ACGME International.

Demonstrate empathy. When delivering bad news, Dr. Braga-Mele puts a premium on the value of empathy—which is derived from the Greek word *empathia*, for passion or suffering. "Your most important tools are your own feelings," said Ivan R. Schwab, MD, professor of ophthalmology and director of the cornea and external disease service at the University of California, Davis. "Bad news comes to us all at

some point, and if you deliver news to a patient using your own feelings, you will be a powerful support. Realize that you can never feel the way the recipient feels or truly understand their emotions, but you can comfort and support them as if you were at the threshold of understanding. To start, we should put ourselves in the patient's position even if we have never received such news. For example—how would we feel if told we would be blind forever?"

Understand the patient's perspective. "We must constantly be aware of the patient's, rather than the physician's, grasp of a specific situation," said Dr. Day. "As a patient asks basic questions—such as 'Will things get worse?'—we need to be clear about what we mean by 'worse,' rather than assume that the patient's concept of 'worse' is the same as ours."

Speak in plain language. Use vernacular, conversational language, advised Dr. Day; most patients will not be fluent in the vocabulary of peer-reviewed medical literature. "My sense is that we too often talk in medical terms, rather than in terms that our patients understand," said Dr. Day.

Schedule enough time for your news and their questions. Dr. Braga-Mele pointed out that even the most attentive physicians don't always allow sufficient time in their discussions with patients to methodically lay out all aspects of unwelcome developments. Dr. Day added that patients must be given a clear opportunity to ask questions, even if they aren't the questions that the physician is concerned with. "Physicians may present the information accurately and yet completely miss what might be worrying the patient. One common example occurs when we tell patients their visual acuity will not be great. Their next assumption is often 'Well, surely you can give me glasses to correct it.'"

Remain available for more interaction. After bad news is delivered, the patient's ability to absorb subsequent information during that same visit is often lost. As the news sinks in and realities surface, the patient often benefits from further discussions, said Dr. Day.

Optimize the next visit. You can, for example, ask patients if they would like to bring a friend or relative on a follow-up visit, when matters will be addressed in more depth. Beyond

"Your most important tools are your own feelings"—*Dr. Schwab*

Don't Shield Patients From the Facts

The most serious mistakes in delivering bad news may be simply avoiding it altogether or not fully relaying the severity of the situation, said Dr. Braga-Mele. "We naturally feel sorry for the patient in this moment and want to give them hope. Hope is good, of course—but only in the context of remaining truthful and realistic so that, moving forward, the correct care and support systems can be set up."

helping your patient remember what was said during the visit, this additional person could potentially act as your advocate, helping you get your message across. (But make sure this third party doesn't hijack the consent process.)

Encourage second opinions. When appropriate, another physician's assessment is reasonable and could be reassuring.

Allow for hope. Even a glimmer of hope is better than none at all, said Dr. Day.

Being There for the Patient

"Reassure the patient that you will do all you can to help, including helping them plug into community resources," said Dr. Schwab. "Keep the patient from feeling alone, and assure him or her by discussing any potential rehabilitation that might help. But, above all, patients must know that their physician will accompany them throughout the difficulties.

In medicine, our greatest strength is the ability to accompany another person through life's difficulties. You may not always be able to help, but you can always comfort."

Know your patient. In the end, "Bad news is still bad news," said Dr. Day, and it is best handled as a dialogue between the physician and patient. "Such a dialogue requires that the physician know with whom he or she is talking." This means taking into account such factors as the individual's capacity to comprehend a big change and any coping mechanisms that the individual is known to have (as evidenced by past events in his or her life). It also entails being sensitive to the patient's cultural propensities—there may, for instance, be cultural beliefs, fears, or myths that cause a patient to refuse a particular treatment.

1 Simpson M et al. *Br Med J*. 1991;303(6814):1385-1387.

MEET THE EXPERTS

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For full disclosures, see this supplement online: Go to aao.org/eyenet and visit the September 2016 issue of *EyeNet*.



BRIEF SUMMARY:

Consult the Full Prescribing Information for complete product information.

INDICATIONS AND USAGE

Xiidra™ (lifitegrast ophthalmic solution) 5% is indicated for the treatment of the signs and symptoms of dry eye disease (DED).

DOSAGE AND ADMINISTRATION

Instill one drop of Xiidra twice daily (approximately 12 hours apart) into each eye using a single use container. Discard the single use container immediately after using in each eye. Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in clinical studies of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. In five clinical studies of dry eye disease conducted with lifitegrast ophthalmic solution, 1401 patients received at least 1 dose of lifitegrast (1287 of which received lifitegrast 5%). The majority of patients (84%) had ≤ 3 months of treatment exposure. 170 patients were exposed to lifitegrast for approximately 12 months. The majority of the treated patients were female (77%). The most common adverse reactions reported in 5-25 % of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

USE IN SPECIFIC POPULATIONS

Pregnancy

There are no available data on Xiidra use in pregnant women to inform any drug associated risks. Intravenous (IV) administration of lifitegrast to pregnant rats, from pre-mating through gestation day 17, did not produce teratogenicity at clinically relevant systemic exposures. Intravenous administration of lifitegrast to pregnant rabbits during organogenesis produced an increased incidence of omphalocele at the lowest dose tested, 3 mg/kg/day (400-fold the human plasma exposure at the recommended human ophthalmic dose [RHOD], based on the area under the curve [AUC] level). Since human systemic exposure to lifitegrast following ocular administration of Xiidra at the RHOD is low, the applicability of animal findings to the risk of Xiidra use in humans during pregnancy is unclear.

Animal Data

Lifitegrast administered daily by intravenous (IV) injection to rats, from pre-mating through gestation day 17, caused an increase in mean preimplantation loss and an increased incidence of several minor skeletal anomalies at 30 mg /kg /day, representing 5,400-fold the human plasma exposure at the RHOD of Xiidra, based on AUC. No teratogenicity was observed in the rat at 10 mg /kg /day (460-fold the human plasma exposure at the RHOD, based on AUC). In the rabbit, an increased incidence of omphalocele was observed at the lowest dose tested, 3 mg /kg /day (400-fold the human plasma exposure at the RHOD, based on AUC), when administered by IV injection daily from gestation days 7 through 19. A fetal No Observed Adverse Effect Level (NOAEL) was not identified in the rabbit.

Lactation

There are no data on the presence of lifitegrast in human milk, the effects on the breastfed infant, or the effects on milk production. However, systemic exposure to lifitegrast from ocular administration is low. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for Xiidra and any potential adverse effects on the breastfed child from Xiidra.

Pediatric Use

Safety and efficacy in pediatric patients below the age of 17 years have not been established.

Geriatric Use

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

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis: Animal studies have not been conducted to determine the carcinogenic potential of lifitegrast.

Mutagenesis: Lifitegrast was not mutagenic in the *in vitro* Ames assay. Lifitegrast was not clastogenic in the *in vivo* mouse micronucleus assay. In an *in vitro* chromosomal aberration assay using mammalian cells (Chinese hamster ovary cells), lifitegrast was positive at the highest concentration tested, without metabolic activation.

Impairment of fertility: Lifitegrast administered at intravenous (IV) doses of up to 30 mg/kg/day (5400-fold the human plasma exposure at the recommended human ophthalmic dose (RHOD) of lifitegrast ophthalmic solution, 5%) had no effect on fertility and reproductive performance in male and female treated rats.



Manufactured for: Shire US Inc., 300 Shire Way, Lexington, MA 02421.

For more information, go to www.Xiidra.com or call 1-800-828-2088.

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US Patents: 8367701; 9353088; 7314938; 7745460; 7790743; 7928122; 9216174; 8168655; 8084047; 8592450; 9085553 and pending patent applications.

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JUST iIN

Xiidra is the only prescription eye drop FDA-approved to treat both the signs and symptoms of Dry Eye Disease

Xiidra improved patient-reported symptoms of eye dryness and improved signs of inferior corneal staining.

Check it out at Xiidra-ECP.com

Four randomized, double-masked, 12-week trials evaluated the efficacy and safety of Xiidra versus vehicle as assessed by improvement in the signs (measured by Inferior Corneal Staining Score) and/or symptoms (measured by Eye Dryness Score) of Dry Eye Disease (N=2133).

The safety of lifitegrast was evaluated in 5 clinical studies. 1401 patients received at least one dose of lifitegrast (1287 of which received Xiidra). The most common adverse reactions (5-25%) were instillation site irritation, dysgeusia, and reduced visual acuity.

Indication

Xiidra™ (lifitegrast ophthalmic solution) 5% is indicated for the treatment of signs and symptoms of dry eye disease (DED).

Important Safety Information

In clinical trials, the most common adverse reactions reported in 5-25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

To avoid the potential for eye injury or contamination of the solution, patients should not touch the tip of the single-use container to their eye or to any surface.

Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

Safety and efficacy in pediatric patients below the age of 17 years have not been established.

For additional safety information, see accompanying Brief Summary of Safety Information on the following page and Full Prescribing Information on Xiidra-ECP.com.