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Proven therapeutic utility in blepharitis, conjunctivitis, and other superficial ocular infections

- Profound bactericidal effect against gram-positive pathogens
- Excellent, continued resistance profile—maintains susceptibility, even against methicillin-resistant *Staphylococcus aureus*
- Ointment provides long-lasting ocular surface contact time and greater bioavailability
- Anti-infective efficacy in a lubricating base
- Unsurpassed safety profile—low incidence of adverse events
- Convenient dosing—1 to 3 times daily
- Tier 1 pharmacy benefit status—on most insurance plans

Bacitracin Ophthalmic Ointment is indicated for the treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by Bacitracin susceptible organisms.

Important Safety Information

The low incidence of allergenicity exhibited by Bacitracin means that adverse events are practically non-existent. If such reactions do occur, therapy should be discontinued.

Bacitracin Ophthalmic Ointment should not be used in deep-seated ocular infections or in those that are likely to become systemic.

This product should not be used in patients with a history of hypersensitivity to Bacitracin.

Please see adjacent page for full prescribing information.


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Bacitracin Ophthalmic Ointment USP
STERILE Rx Only

DESCRIPTION: Each gram of ointment contains 500 units of Bacitracin in a low melting special base containing White Petrolatum and Mineral Oil.

CLINICAL PHARMACOLOGY: The antibiotic, Bacitracin, exerts a profound action against many gram-positive pathogens, including the common Streptococci and Staphylococci. It is also destructive for certain gram-negative organisms. It is ineffective against fungi.

INDICATIONS AND USAGE: For the treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by Bacitracin susceptible organisms.

CONTRAINDICATIONS: This product should not be used in patients with a history of hypersensitivity to Bacitracin.

PRECAUTIONS: Bacitracin ophthalmic ointment should not be used in deep-seated ocular infections or in those that are likely to become systemic. The prolonged use of antibiotic containing preparations may result in overgrowth of nonsusceptible organisms particularly fungi. If new infections develop during treatment appropriate antibiotic or chemotherapy should be instituted.

ADVERSE REACTIONS: Bacitracin has such a low incidence of allergenicity that for all practical purposes side reactions are practically non-existent. However, if such reaction should occur, therapy should be discontinued.

To report SUSPECTED ADVERSE REACTIONS, contact Perrigo at 1-866-634-9120 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION: The ointment should be applied directly into the conjunctival sac 1 to 3 times daily. In blepharitis all scales and crusts should be carefully removed and the ointment then spread uniformly over the lid margins. Patients should be instructed to take appropriate measures to avoid gross contamination of the ointment when applying the ointment directly to the infected eye.

HOW SUPPLIED:
NDC 0574-4022-13 3 - 1 g sterile tamper evident tubes with ophthalmic tip.
NDC 0574-4022-35 3.5 g (1/8 oz.) sterile tamper evident tubes with ophthalmic tip.
Store at 20° - 25°C (68° - 77°F)
(see USP Controlled Room Temperature).
Shaky Ground?

By Virginia Pickles, Contributing Editor

If the OIG is asking, you may want to examine your business relationships with anesthesia services providers.
Some of the most important and complex relationships in the ASC arena are those between surgeon-owners and providers of anesthesia services. Not only must the two groups be philosophically aligned when delivering patient care, but they must be in sync with one another’s business operations. As both entities are also striving to maximize profitability, they may employ some creative business strategies that push those boundaries.

Two examples came to light in 2012 when a large anesthesia services provider proposed new business models to better compete in the anesthesia market and sought an advisory opinion from the Office of Inspector General (OIG). Although not declaring either arrangement illegal, the OIG concluded that both would potentially violate the federal anti-kickback statute (AKS) and trigger administrative sanctions and civil monetary penalties. Although the opinion addressed two scenarios specific to one anesthesiology group, the OIG’s detailed discussion of ASC-anesthesia joint ventures prompted others to examine their own financial relationships for compliance risks.

Attorneys Alan E. Reider and Allison Shuren, partners at Arnold & Porter, Washington, DC, specialize in healthcare issues with a focus on compliance and fraud-and-abuse counseling. We asked them to put this advisory opinion in perspective and to discuss the pros and cons of some potential business models involving ASCs and anesthesia services providers. First, we’ll take a quick look at the opinion that prompted some concerns.

**Per-patient Management Fee**

In the first scenario, the anesthesiology group would continue as the ASC’s exclusive provider of services and would pay the ASC a per-patient management fee. The fee, which would be at fair market value and in addition to the facility fee, would cover certain non-physician services, such as nursing assessments, assistance with billing documentation and space for the anesthesiologists, their staff and records. Medicare beneficiaries would be excluded from the management fee calculation.

The OIG noted it has a “long-standing concern about arrangements under which parties ‘carve out’ federal healthcare program beneficiaries or business generated by federal health care programs from otherwise questionable financial arrangements,” suggesting that these arrangements may disguise kickbacks for referrals. The OIG also noted the anesthesiologists would be paying for services already covered by the ASC’s facility fee. Essentially, the ASC would be paid twice for the same services, which could be considered an inducement.

“In this scenario, anesthesiologists would pay the ASC for certain overhead functions related to the surgical cases they would

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“"As long as Medicare continues to pay physicians, there will be issues about improper relationships.”

— Alan E. Reider, Esq., partner at Arnold & Porter, Washington, DC
BEWARE ‘CREATIVE’ EMPLOYMENT ARRANGEMENTS

Employing an anesthesiologist or a CRNA to provide services in your ASC is generally a low-risk arrangement in the realm of the anti-kickback statutes, but even these relationships can raise red flags when creatively manipulated to boost an ASC’s profit.

Mr. Reider relates the following example:

“Many years ago, we learned of an arrangement whereby an ASC employed an anesthesiologist on a part-time basis for certain payers, but for other payers, the anesthesiologist billed independently. They did that because certain payers pay more generously. When the anesthesiologist was acting as an employee, the surgery center or the physician practice would bill for the much more lucrative payment. But for Medicare, which is not as lucrative, or Medicaid, which is even less so, the anesthesiologist was on his own.

“That raised some concerns, because they were essentially cherry-picking,” Mr. Reider says. “I can’t point to a law or regulation that specifically prohibits the practice, but that’s the kind of issue that raises some questions.”

service, essentially, some kind of management fee,” Ms. Shuren says. “They stated they wouldn’t pay that fee on Medicare beneficiaries, because they could see that the government would be very concerned about that. In fact, the government basically stated they were essentially paying for the referrals, which is a kickback.

“The other important take-away is that excluding Medicare beneficiaries from a proposed transaction that might be a problem under the AKS doesn’t take it out of the scope of concern for the Inspector General,” Ms. Shuren says. “Paying kickbacks related to commercial payer patients could, at a minimum, build loyalty or expectations that you will refer Medicare patients, as well.”

Mr. Reider notes, “The Inspector General made a fairly strong statement that this arrangement would not be blessed, and I don’t think anybody would have ever thought it would be blessed. It was a very aggressive and, in my view, improper proposal.”

Sham Companies

In the second scenario, the ASC’s physician-owners would form separate companies to provide anesthesia services. These companies would hire the anesthesiology group as an independent contractor. The subsidiary companies would bill for and furnish all anesthesia services provided at the ASCs, and the anesthesiologists would be paid for services, including recruiting and credentialing, supplies management and overseeing regulatory compliance.

“This would be a joint venture between the anesthesiologists and the surgeons,” Ms. Shuren says. “The surgeons, as owners of the business, would reap dividends on any profits the organization made.”

The OIG determined “more than a minimal risk of fraud and abuse” exists with this arrangement, and it cited longstanding concerns about joint ventures between those in a position to refer business and those furnishing items or services for which Medicare or Medicaid pays. In addition, the ASC’s physician-owners would be expanding into a related area by contracting with the anesthesia provider. This relationship would pose minimal business risk for the ASC owners, and the anesthesia services would depend entirely on referrals from the ASC. The OIG concluded this relationship appeared designed to permit the physician-owners to do indirectly what they cannot do directly (i.e., receive compensation for their referrals to the anesthesiology group).

“This proposal was less aggressive, and the Inspector General’s opinion should not be interpreted too broadly,” Mr. Reider says. “If the facts were changed just a bit, in my view, the relationship could very well have been appropriate.”

Legitimizing Scenario #2

According to Mr. Reider, if physicians establish an independent medical practice to provide anesthesia services, and the practice employs anesthesiologists and certified registered nurse anesthetists (CRNAs) and pays them a fixed fee, thereby maintaining business risk and not merely entering into sham agreements, the relationship shouldn’t trigger AKS liability.

“In fact, such an arrangement may be required by limitations in state law,” he says. “For example, state law may prohibit an ASC from employing physicians, and this would be a reason to establish a separate practice to employ or contract with an anesthesiologist to provide services at an ASC.”

Similarly, insurance considerations may also serve as the basis for establishing a separate medical practice, rather than employing the anesthesiologist in the surgeons’ practice. “As long as the arrangement is structured so that the anesthesiologists are compensated by
the practice in a manner that reflects fair market value, particularly at a fixed salary so that the practice assumes risk, the risk of triggering the AKS should be minimized,” Mr. Reider says.

**Other Appropriate Business Models**

Although the scenarios described in OIG Advisory Opinion 12-06 were proposed by a specific anesthesiology group — the “requestor,” in OIG terms, isn’t identified when the opinion is made public — the opinion sent a ripple through the ASC community, as physician-owners and administrators examined their own contracts with anesthesiologists.

“Several clients asked for our help to make sure they were in compliance,” Mr. Reider says. “One in particular employed an anesthesiologist and a nurse anesthetist and wanted us to review their employment contracts. This is not the relationship that was presented in the advisory opinion, but the ASC administrator realized there could be potential issues and wanted to make sure they were doing things the right way. Obviously, in our view, that’s a good thing.”

In fact, Mr. Reider notes, the employment model, whereby an ASC or an ASC subsidiary or a physician’s group employs an anesthesiologist or CRNA, is generally one of the “safest” types of relationships. (For an exception, see “Beware ‘Creative’ Employment Arrangements.”)

“In the employment model, anesthesia services are billed by the surgery center or the physician practice, whichever the employer is, and the anesthesiologists are paid a flat fee or on a per-procedure or per-diem basis,” he explains. “The only general issue that we focus on is making sure it’s a bona fide employment agreement and that the compensation is a fair reflection of the work performed.”

The staff-privilege model is also a fairly straightforward business relationship. “Similar to a physician who has staff privileges at an institution, the anesthesiologists or CRNAs have privileges at the ASC but otherwise maintain a completely independent relationship, billing patients directly for their respective services,” Mr. Reider says.

In the contract model, an independent anesthesiologist provides all anesthesia services in an ASC on a contractual basis, being paid a flat amount or per diem. “Essentially, the anesthesiologist is assigning the right to bill and collect payments for the individual services to the ASC, and the ASC assumes the risk if volume is down,” Mr. Reider says.

**An Intelligent Approach**

According to Mr. Reider, some news reports and editorials published immediately after the release of OIG Advisory Opinion 12-06 suggested that all relationships between ASCs and anesthesiologists were illegal, which is simply not true.

“It’s important to keep in mind that advisory opinions are not statements by the government that something is illegal,” Mr. Reider says. “The government is simply stating it’s not going to bless these arrangements. Obviously, there are opportunities for surgeons to have improper relationships, which do create some serious compliance risks, but if relationships are structured correctly, that should not happen.

“As long as Medicare continues to pay physicians, there will be issues about improper relationships,” Mr. Reider adds. “I think this advisory opinion did a service, because it sensitized the industry to potential compliance risks associated with anesthesiology contracts. It’s just another reminder that physicians have to be intelligent about how they go about their financial relationships with referral sources.”
All This and Much, Much More

OOSS boasts an ever-expanding menu of benefits that are focused on your unique interests.

Advocacy, benchmarking, education, expert advice and insights on hot topics … the list goes on. And, in 2014, that list expands to include even more offerings from the Outpatient Ophthalmic Surgery Society (OOSS).

“This is an exciting time at OOSS,” says President Y. Ralph Chu, MD. “With the current regulatory, economic and legislative landscape, understanding the ASC industry is more critical than ever for practicing ophthalmologists who own or work within an ASC.

“OOSS is the only organization that’s focused on protecting the surgery center for ophthalmology,” he continues. “I think that’s why we’re seeing a great deal of positive momentum, particularly as we partner with large ophthalmology and ASC organizations, such as the Ambulatory Surgery Center Association (ASCA), the American Academy of Ophthalmology (AAO), the American Society of Cataract and Refractive Surgery (ASCRS), the Society for Excellence in Eyecare (SEE), the American College of Eye Surgeons (ACES) and the American-European Congress of Ophthalmic Surgery (ACOS).
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“These are progressive-minded societies of practicing ophthalmologists, many of whom are already involved in surgery centers,” Dr. Chu says. “They see OOSS as an important resource for government advocacy and lobbying efforts to protect the surgery enters.”

In fact, it was OOSS’s commitment to advocacy that prompted Dr. Chu to join the organization. “I built my ASC 5 years ago during a time of increased regulatory scrutiny, rules changes and a flurry of audits,” he says. “It wasn’t business as usual any more, and I had to seek outside help to navigate those waters. I immediately saw the value of OOSS’s advocacy voice and the resources available to me as part of an organization focused solely on ophthalmic ASCs.”

**Full-time Focused Advocacy**

As OOSS’s representative in Washington, attorney Michael A. Romansky has a unique perspective on the challenges facing ophthalmic ASCs. Although his responsibilities are grouped under a “lobbying” umbrella, Mr. Romansky’s role far surpasses the traditional concept of a lobbyist buttonholing legislators in the halls of Congress.

“The regulatory environment is a constant full-court press for us now,” says OOSS Executive Director Kent Jackson. “The good news is that Mike, in collaboration with the AAO, the ASCRS, the ASCA and various subspecialty groups, is doing an incredible job of informing and working with regulators. When the time is right, he knows who to pull into the room, who to engage in the conversation, how to time these encounters and when to reach out to our members for expert input.”

Ensuring adequate payment and expanding the array of ophthalmic services permitted in an ASC are ongoing concerns, according to Mr. Romansky. “Today, essentially every ophthalmic procedure is reimbursed in an ASC — not always at a fee that’s as high as we would like, but it’s all there,” he says. Other issues that are always on the table are the movement toward leveling the playing field between what hospitals and ASCs are paid for services, and any legislation or regulation that would limit a physician’s ability to invest in an ASC and treat his own patients there. “So far, we’ve been able to prevent these types of limitations from applying to ASCs, but that’s certainly
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The VERION™ Digital Marker links to compatible surgical microscopes to display concurrently the reference and microscope images, allowing the surgeon to account for lateral and rotational eye movements. In addition, the planned capsulorhexis position and radius, IOL positioning, and implantation axis from the VERION™ Reference Unit surgical plan can be overlaid on a computer screen or the physician’s microscope view.

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Only trained personnel familiar with the process of IOL power calculation and astigmatism correction planning should use the VERION™ Reference Unit. Poor quality or inadequate biometer measurements will affect the accuracy of surgical plans prepared with the VERION™ Reference Unit.

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WARNINGS: Only properly trained personnel should operate the VERION™ Reference Unit and VERION™ Digital Marker.

Only use the provided medical power supplies and data communication cable. The power supplies for the VERION™ Reference Unit and the VERION™ Digital Marker must be uninterruptible. Do not use these devices in combination with an extension cord. Do not cover any of the component devices while turned on.

Only use a VERION™ USB stick to transfer data. The VERION™ USB stick should only be connected to the VERION™ Reference Unit, the VERION™ Digital Marker, and other compatible devices. Do not disconnect the VERION™ USB stick from the VERION™ Reference Unit during shutdown of the system.

The VERION™ Reference Unit uses infrared light. Unless necessary, medical personnel and patients should avoid direct eye exposure to the emitted or reflected beam.

PRECAUTIONS: To ensure the accuracy of VERION™ Reference Unit measurements, device calibration and the reference measurement should be conducted in dimmed ambient light conditions. Only use the VERION™ Digital Marker in conjunction with compatible surgical microscopes.

ATTENTION: Refer to the user manuals for the VERION™ Reference Unit and the VERION™ Digital Marker for a complete description of proper use and maintenance of these devices, as well as a complete list of contraindications, warnings and precautions.

the VERION™ Reference Unit is a preoperative measurement device

The VERION™ Digital Marker links to compatible surgical microscopes to display concurrently the reference and microscope images, allowing the surgeon to account for lateral and rotational eye movements. In addition, the planned capsulorhexis position and radius, IOL positioning, and implantation axis from the VERION™ Reference Unit surgical plan can be overlaid on a computer screen or the physician’s microscope view.

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Signature Benchmarking Survey

OSS is also well known in the industry as the organization that conducts an annual survey for clinical and business benchmarking, the only survey of its kind designed specifically for ophthalmic ASCs. The OOSSMARK ASC Performance Metrics survey enables participating facilities to evaluate year-over-year performance, as well as compare their performance with that of other ophthalmic-driven ASCs across the country. Not content to rest on its laurels, OSS recently launched an elegant new cloud-based platform that features a secure and confidential data collection tool with expanded utility.

“In the past, we were limited in what we could do, because another major area we're always monitoring very carefully," Mr. Romansky says.

The most recent hot topic to emerge is the move by the Centers for Medicare & Medicaid Services (CMS) to impose certain quality reporting requirements on ophthalmic ASCs. “ASC-11 is an ophthalmic-specific quality measure requiring ASCs to report improvements in visual function within 90 days following cataract surgery,” Mr. Romansky explains. “Our position is this, if that type of data must be collected, it should be collected by the surgeon under the Physician Quality Reporting System not the ASC. OSS, along with the other ophthalmology and ASC organizations, has been fighting this measure. And on April 2, CMS suspended the measure, promising to address challenging operational difficulties and implement it on Jan. 1, 2015.”

Dr. Chu notes, “Advocacy is a constant presence in an organization like this. Some of our initiatives are reaching deeper into the surgery centers, to involve not just the owners but also the people who perform the day-to-day work, such as the clinical directors, the nurses and the technicians. That team makes our ASCs work, and they're most affected by many of the changes in the rules.”

Mr. Romansky maintains a high profile and accessibility to OSS members who have questions on quality reporting or any issue. “I communicate regularly with our members, keeping them abreast of what's happening through our legislative alerts and other articles,” he says. “I speak on these topics all over the country. It's important that the nation's thousand or so ophthalmic ASCs be updated. I also help OSS develop materials and programs, not just to inform our members, but also to enable them to respond and make the changes necessary to comply with this ever-enlarging array of regulatory, legislative and reimbursement challenges.”
the survey required manual calculations and tallying,” says Member Services Consultant Albert Castillo. “With this new platform, all data are collected electronically and graphs and charts can be generated for reporting to ASC owners.”

Mr. Jackson notes, “The benchmarking survey remains open to all interested ophthalmic-driven ASCs. OOSS has always had a philosophy that we are about providing industry leadership, and our members are sustaining investors in that leadership position.”

The new benchmarking platform went live in November 2013, and 2012 reports were available in March. Data collection for 2013 began on March 1, and reports will be available as early as June 2014.

**Education at OOSSUniversity**

OOSS is also at the forefront of identifying and developing educational programs designed for the ophthalmic ASC. Through enhanced partnerships with other organizations, offerings that carry the mark of OOSSUniversity are designed to address subjects of importance to the entire ASC team.

“Today, we work closely with the American Academy of Ophthalmic Executives and the American Society of Ophthalmic Administrators to identify courses that fit their meeting settings and complement our annual OOSS events, the OOSS Symposium at the AAO meeting in the fall and the OOSS Perspective at the ASCRS meeting in the spring,” Mr. Jackson says. “The good news for our members is that OR nurses, administrators and other staff members who are members of these organizations can take advantage of this education without incurring additional costs for travel or time away from the office.”

OOSS is also forging working relationships with other organizations, such as ASCA, SEE, ACES, ACOS and ophthalmic specialty groups to enhance educational reach and collaboration on legislative and regulatory issues. “We have common leadership in these groups,” Mr. Jackson says, “and they’re interested in having an ASC focus at their meetings driven or supported by OOSS.”

“Every 3 years, OOSS board members meet to discuss our mission and goals and how we can keep them relevant to the times ahead,” notes Dr. Chu. “OOSSUniversity is a direct result of these discussions, enabling us to reach out not only to surgery center owners, but also to nurses and clinical directors to help them stay current with changes in the industry.”

Additional educational opportunities are available through OOSS partners, such as BSM Consulting and Progressive Surgical Solutions, both of whom offer pricing advantages for OOSS members.

**Expert Advice On- and Offline**

OOSS members have long been able to “ask the experts” their business and clinical questions informally via e-mail and receive timely, personalized responses. “Members have full access to me, Mike Romansky and Kent Jackson via e-mail and cell phone,” says Mr. Castillo. “They contact us with a problem or question, and we either answer the question ourselves or obtain the answer from one of our affiliates, usually within 24 hours.”

Mr. Jackson notes, “With the launch of our new website, we’re taking that resource a step further. Members will be able to ask their questions online any time, day or night, and we’ll post the questions and the experts’ responses (with the questioner’s permission) online, making them available to the rest of the membership, essentially systematizing the notion of frequently asked questions. Born of our strategic planning process, this program will be accessible under the banner of OOSSAnswers.”

According to Dr. Chu, this immediate access to expert advice is one of the reasons he joined OOSS. “If you have an issue, you can contact OOSS and receive an answer to your questions in a timely manner,” he says.

“The benchmarking survey remains open to all interested ophthalmic-driven ASCs. OOSS has always had a philosophy that we are about providing industry leadership, and our members are sustaining investors in that leadership position.”

— Kent Jackson, OOSS Executive Director
“That’s an invaluable tool that’s available to surgery center directors, as well as owners.”

The improved website will be more comprehensive and the interactions more collaborative, according to Mr. Jackson, because it will facilitate staff-to-staff networking in a social media format. “A real challenge for most ASCs is that they operate like islands,” he says. “Often, they’re the only ASC in town and there’s a certain degree of isolation in the way they operate. The new site will provide networking opportunities for people to connect and will provide forums for the discussion of business and clinical issues our members face every day.”

**Insights on Hot Topics**

OSSAnswers provides personalized responses to individual members’ questions, and OOSS disseminates news in its regular publications, such as “Washington Update,” “Eye on OOSS,” and Outlook magazine. But what about breaking news that requires in-depth coverage? Or advice on how to address the impact of changes? OOSS members need look no further than the organization’s hot-topic webinars.

“When the ASC-11 quality reporting mandate was issued along with a fixed deadline, our members needed guidance,” Mr. Jackson says. “We developed a webinar that attracted more than 400 people — including administrators and directors of nursing — and taught them how to prepare for this new reporting cycle. We’ve also developed webinars on other issues, such as introducing retina surgery into the OR and introducing EHR into the ASC. Combined with survey and polling methods, we can quickly assess where our members are with respect to a hot topic and, with their help, determine exactly the kind of programming we need.”

**Focused on Your Needs**

Why join OOSS? “The benefit of OOSS membership is, first and foremost, being able to associate with the best in the ophthalmic ASC industry,” Mr. Jackson says. “Our members do an incredible job financially and clinically in terms of delivering excellent outcomes and sustaining profitable enterprises at the same time. Nowhere else will you have the networking opportunities that you will have with OOSS. If your objective is to be the best, then you’ll want to associate with the best.”

Mr. Jackson notes that OOSS members are industry leaders who can be instrumental in shaping regulatory and legislative decisions that will ensure the future of the ophthalmic ASC.

This quickly became evident to Dr. Chu. “Even during my short tenure as a surgery center owner, OOSS has been involved in some significant gains for surgery center owners,” he says. “For example, we weren’t permitted to perform same-day YAG capsulotomies in an ASC; however, OOSS worked closely with the AAO and the ASCRS to have that ruling reversed. I think we’ll see many changes associated with the Affordable Care Act, and OOSS’s legislative efforts will be front and center.”

Romansky notes, “The bottom line is that for most practices that have ASCs, the facility is the most profitable part of the practice, and that’s an asset worth preserving and growing. That’s where OOSS plays a vital role.”

“The unique aspect of OOSS is that it’s completely focused on the well-being of the surgery center,” Dr. Chu says. “It is the voice for all ophthalmic surgery centers — the facility, the owners and the people who work within them — and its role is complementary to the ophthalmology- and ASC-focused organizations. These are synergistic relationships and membership in OOSS is a nice value add for clinicians who are part of those organizations.”

“The leadership of OOSS,” concludes Mr. Jackson, “has made a decisive commitment to continue to serve the exclusive and unique interests of the ophthalmic ASC.”

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**Coming Soon: OASC Salary Survey**

In partnership with the American Academy of Ophthalmic Executives (AAOE) and with technical support from BSM Consulting, OOSS launched the first ophthalmic-specific ASC salary survey in April. “Although some other organizations conduct salary surveys, this will be the first one specifically designed for ophthalmic ASCs and in parallel with the AAOE practice salary survey,” says Member Services Consultant Albert Castillo. “The AAOE will handle the practice aspects of the survey. OOSS will contribute on the ASC side, and BSM Consulting will provide the platform. The Allergan organization has provided generous financial support to develop the program.”

According to Mr. Castillo, this new platform will place your practice or ASC in the 25th, 75th or 95th percentiles. Depending on the number of participants, the results may also be reported by region.
The goals of the Affordable Care Act (ACA) are to increase access to care, ensure better outcomes and meet quality standards while controlling the cost of health care. Because ambulatory surgery centers (ASCs) can meet all of these goals very effectively, the ACA is giving ASCs an opportunity to capture new business. Below are several ways ASC owners can benefit from the ACA.

ASCs Meet Economic Goals
When it comes to expectations under the ACA, we routinely hear the expression “do more for less,” and the ASC is much better positioned to “do more for less” than the hospital setting.

ASCs pass along savings to patients and payers by providing services at a lower price than full-service hospitals due to specialization and scale of operations. For example, on average, procedures performed at ASCs cost 40% less than those performed in the institutional environment. For Medicare, that low-cost delivery model translates into a savings of more than $2.5 billion a year when procedures are moved from the hospital to the ASC.

As a result, CMS and private insurers will increasingly incentivize outpatient surgery over the hospital setting. Hospitals will push procedures to their ASCs, and physician-owned ASCs will get busier. At the same time, the ACA is expanding the patient pool for every ASC by greatly increasing the number of people with health care coverage.

The move from hospital to ASC and the increase in insured patients are making us take a hard look at just how much ASC space is available. We’re seeing an important increase in the number of individuals who can access ASCs, but the number of ASC locations is flat. Thus, we can assume that in the ACA environment of increased reimbursement and demand, more ASCs will open to meet this growing patient population.

Retina Boosts Revenue
To multiply the positive effects of the ACA, ophthalmic ASCs might consider adding retina procedures, which are already rising in both volume and reimbursement in the ASC. In the last 5 years, there has been a dramatic increase in the number of retina cases performed in ASCs and this has been driven by rising reimbursements.

In 2007, retina procedures were reimbursed for $630. We couldn't bill heavy liquids and silicone separately, so their use would often result in a loss for the center. In 2008, Medicare significantly improved reimbursement and the number of procedures grew to 44,381, with billings growing 71% to $39.8 million. In 2009, ASCs performed more than 50,000 retina procedures and billings jumped another 23% to $48 million.

As an example, let’s consider the most common retina procedure, standard pars plana vitrectomy, for which the increase is clear:

- **2007**: $630 (9 ASC payment groups)
- **2008**: $857 (first year of the new ASC payment system)
2011: $1,540 (changes to payment system fully implemented)

Of course, there are initial and ongoing costs when an ASC takes on retina as a specialty. To get started, the ASC will need vitrectomy and cryotherapy equipment, an argon laser and some handheld instruments. In terms of ongoing costs, retina cases take longer, cost more per procedure and require a higher level of staff training.

One way to reduce the retina investment is to minimize supplies and equipment. Equipping a retina room with a vitrectomy machine, microscope and instruments costs $250,000-$350,000. When possible, ASCs should select equipment that can perform both anterior and posterior procedures in one combined surgical platform such as the Stellaris® PC, Vision enhancement system, with Integrated laser from Bausch+Lomb (Rochester, NY). It also helps if retina physicians are willing to use the same supplies and equipment to reduce inventory costs. And ASCs should join a buying group because they can help you secure better prices on surgical supplies.

From the retina surgeon’s perspective, there are many advantages to moving to the ASC. ASCs generally experience less personnel turnover than hospitals and they have more staff members who are familiar with specific procedures. ASCs also offer greater efficiency and turnover, and better potential for ancillary income, including access to uninsured patients who can afford to pay out of pocket.

If you’re considering adding retina surgeons to your ASC, choose wisely. Get a clear picture of a prospective surgeon’s skill, speed and preferences. Seek out efficient surgeons who take less than 45 minutes per case. Watch for red flags such as late start times, unpredictable OR times, high resource use, or opening supplies that aren’t used. The key is to ensure that you’re maximizing your margin per procedure for every procedure performed. Using the surgeon’s case volume and other retrospective data, try to predict the total cost per case for the surgeon.

GROWING PAINS SIGNAL GROWTH

The new ACA environment may bring about some negative experiences as well. ACA changes in reimbursement will create some stress in our ASCs. ACA compliance will increase operating costs, most likely with a set of quality outcome measures that will require extra steps and administrative costs for compliance. We’ll need to record and maintain more data to track outcomes and support reimbursements.

At the same time, we’ll find opportunities for ASCs to capture new business.

We all need to re-evaluate our business models to ensure that they’re in line with the changes in our markets. We have to prepare for more patients. And we should explore the role of increased reimbursements for retina surgery in our ASCs. As we respond and adapt to the ACA environment, we should be able to find ways to be profitable in this new environment.

REFERENCES

1. ASCA. What is an ASC? 2013. Available at: ascassociation.org/AdvancingSurgicalCare/aboutascs/industryoverview; last accessed March 31, 2014.

Should You Consolidate, Merge or Stay the Course?

Many people ask, “Is it worthwhile to consolidate our surgical center?” The answer varies. If merging with a hospital will increase your revenues without being detrimental to your ASC, then do it. But if a hospital doesn’t have an Accountable Care Organization (ACO) and there’s a separate ACO, then that relationship might not be beneficial.

Merging also depends on your environment. As we are all rethinking our business models, opportunities for new partnerships could arise. Insurers are looking for not only good processes, but also for associated outcomes. If an ASC can help a hospital achieve those outcomes, then it makes sense to partner.
Stellaris® PC: Premium Precision Precise Control

With fully integrated laser

Introducing the next generation Stellaris PC. The ideal choice for cataract, VR and combined procedures, evolution driven by surgeon feedback.

Stellaris PC now features fully integrated laser. Upgrade compatible with existing Stellaris PC models.
Indication and Usage

Visudyne® (verteporfin for injection) is indicated for the treatment of predominantly classic subfoveal choroidal neovascularization due to age-related macular degeneration, pathologic myopia, or presumed ocular histoplasmosis.

Important Safety Information

• Visudyne® (verteporfin for injection) is contraindicated for patients with porphyria or known hypersensitivity to any of its components.
• Avoid exposure of skin and eyes to direct sunlight or bright indoor light for 5 days. If extravasation occurs during infusion, the extravasation area must be thoroughly protected from direct light until swelling and discoloration have faded in order to prevent the occurrence of a local burn which could be severe. If emergency surgery is necessary within 48 hours after treatment, as much of the internal tissue as possible should be protected from intense light.
• Patients who experience severe vision decrease (≥4 lines within 1 week) should not be retreated until their vision completely recovers to pretreatment levels and potential benefits and risks of subsequent treatment are carefully considered.
• Use of incompatible lasers that do not provide the required characteristics of light for photoactivation of Visudyne® could result in incomplete treatment due to partial photoactivation or overtreatment due to overactivation, or damage to surrounding normal tissue.
• For injection of Visudyne®, avoid small hand veins in favor of the largest possible arm vein, preferably the antecubital vein.
• The most frequently reported adverse events (10% to 30% incidence) were injection site reactions (including pain, edema, inflammation, extravasation, rashes, hemorrhage, and discoloration), and visual disturbances (including blurred vision, flashes of light, decreased visual acuity, and visual field defects, including scotoma).

When Anti-VEGF Therapy Isn’t Enough

Indocyanine green-directed photodynamic therapy helps AMD patients with persistent disease activity.

Sometimes AMD cases are straightforward. A patient presents with classic neovascularization, receives a few injections of anti-VEGF therapy and has no more leakage. With standard treatment, the patient can do very well over time.

Sometimes AMD cases aren’t so simple. Some eyes respond poorly to anti-VEGF therapy, and we observe the presence of persistent leakage, increased lesion growth, progressive fibrosis or new hemorrhage. We call this persistent disease activity (PDA).

How common is PDA? What causes it? And how should we treat AMD when anti-VEGF therapy isn’t enough?

Is PDA Common?

Consider these examples of PDA. A patient presents with persistent subretinal fluid that doesn’t improve after six doses of anti-VEGF therapy. Or, a case of classic neovascularization that actually gets larger while the patient is on therapy. Or, the classic CNV patient who demonstrates good drying of leakage and blood, but fibrosis continues to progress.

These are all cases of PDA. How common is this problem?

Published trials suggest a high frequency of PDA — 20% to 80% of patients after a year of anti-VEGF therapy — depending on the drug, frequency of injection and the criteria used to evaluate PDA.1,4

Using a severity scale we developed at Duke that classifies PDA as mild, moderate or severe based on a point system reflecting OCT, fluorescein and clinical findings, we evaluated a series of cases in our practice. About 25% of patients with classic neovascular AMD showed moderate or severe persistence (enlargement of the lesion or persistent leakage with or without fibrosis) after a year of anti-VEGF therapy.

What Causes It?

PDA in classic neovascularization is usually caused by arteriolarization of the new vessel complex during which nascent new capillaries acquire a vascular smooth muscle sheath, turning them into arterioles. To identify this process, we perform video indocyanine green chorioangiography (ICGA), also called high speed ICGA, using the Spectralis system (Heidelberg).

Using video ICGA, it is possible to identify examples of patients with classic neovascularization who demonstrate
different stages of vessel maturation and arteriolarization. At Duke, we have developed a classification system to identify different stages of vessel maturation. The most immature vessels are termed “capillary-dominated,” while the most mature and remodeled vessels are termed “arteriolarized vascular complexes.”

Capillary-dominated lesions are mostly endothelial tubes with pericytes. The biology is predominantly VEGF-mediated, which is why they seem to respond well to anti-VEGF injections. Arteriolarized lesions manifest vascular smooth muscle cells with perivascular fibrosis. Not surprisingly, other growth factors beyond VEGF mediate arteriolarized vascular complex formation, which is why anti-VEGF therapy is often less effective in these cases.

At Duke, we compared the ICGA morphology at presentation and in the subset demonstrating PDA. At presentation, 60% of all cases of classic neovascularization demonstrated capillary or mixed lesions, while 30% were arteriolarized. However, among cases with PDA, no cases were capillary or mixed, and 70% were arteriolarized. Clearly, when we address PDA cases, we’re addressing arteriolarized lesions, which rely on non-VEGF growth factors and require an alternative treatment to anti-VEGF therapy.

How Can We Treat AMD with PDA?

We initiate treatment of predominantly classic neovascularization with anti-VEGF therapy. If the neovascularization shows incomplete response after a trial of monthly anti-VEGF therapy (3–5 injections), then, we use ICGA to determine if there are arteriolarized vessels causing PDA. In this case, my colleagues and I have been using Visudyne® (verteporfin for injection), directing treatment at the large caliber feeder vessels shown with ICGA rather than the entire area of leakage as shown with fluorescein. By closing off the feeding artery and the central branching arterioles, there is dramatic occlusion of the flow through the rest of the lesion (Figure 1). Our preliminary results suggest about 75% of eyes will show less leakage and new vessel perfusion after a single treatment with Visudyne. Most of the remainder will respond to retreatment.

Added Insights

Knowing that in some cases, on-label verteporfin photodynamic therapy can help AMD patients with PDA by occluding large-caliber vessels, it is helpful to understand how many patients fit that treatment group.

References


FIGURE 1. Classic AMD with Arteriolarized Vascular Complex Neovessel closure with PDT

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Based on a live B+L event held during the 2014 Royal Hawaiian Eye Meeting

US/VID/14/0010
Visudyne®
(verteporfin for injection)
Rx only

BRIEF SUMMARY: Please see package insert for full prescribing information.

INDICATIONS AND USAGE
Visudyne® (verteporfin for injection) therapy is indicated for the treatment of patients with predominantly classic subfoveal choroidal neovascularization due to age-related macular degeneration, pathologic myopia or presumed ocular histoplasmosis.

There is insufficient evidence to indicate Visudyne for the treatment of predominantly occult subfoveal choroidal neovascularization.

CONTRAINDICATIONS
Visudyne® (verteporfin for injection) is contraindicated for patients with porphyria or a known hypersensitivity to any component of this preparation.

WARNINGS
Following injection with Visudyne® (verteporfin for injection), care should be taken to avoid exposure of skin or eyes to direct sunlight or bright indoor light for 5 days. In the event of exposure, the extravasation area must be thoroughly protected from direct light until the swelling and discoloration have faded in order to prevent the occurrence of a local burn which could be severe. If emergency surgery is necessary within 48 hours after treatment, as much of the internal tissue as possible should be protected from intense light.

Patients who experience severe decrease of vision of 2 or more lines within 1 week after treatment should not be retreated at least 6 months after the initial injection site. In patients treated with multiple injections, the pretreatment levels and the potential benefits and risks of subsequent treatment are carefully considered by the treating physician.

Use of ultraviolet C (UV-C) compatible lasers that do not provide the required characteristics of light for the photoactivation of Visudyne could result in the incomplete treatment due to partial photoactivation of Visudyne, or treatment due to overactivation of Visudyne, or damage to surrounding normal tissue.

PRECAUTIONS
General
Standard precautions should be taken during infusion of Visudyne® (verteporfin for injection) to avoid extravasation.

Examples of standard precautions include, but are not limited to:

- A free-flowing intravenous (IV) line should be established before starting Visudyne infusion and the line should be carefully monitored.
- Due to the possible fragility of vein walls of some elderly patients, it is strongly recommended that the largest arm vein possible, preferably antecubital, be used for infusion.
- Small veins in the back of the hand should be avoided.

Extravasation of Visudyne, especially if the affected area is exposed to light, can cause severe pain, inflammation, swelling and discoloration.

If extravasation does occur, the infusion should be stopped immediately. The extravasation area must be thoroughly protected from direct light until swelling and discoloration have faded in order to prevent the occurrence of a local burn, which could be severe. Cold compresses should be applied to the injection site (see WARNING). Oral medications for pain relief may be administered.

Visudyne therapy should be considered carefully in patients with moderate to severe hepatic impairment or biliary obstruction since there is no clinical experience with verteporfin in such patients.

There is no clinical data related to the use of Visudyne in anesthetized patients. Patients with age >10 years have been given by bolus injection to sedated or anesthetized pigs, verteporfin caused severe hemodynamic effects, including death, probably as a result of complement activation. These effects were dose related and prevented by priming with antihistamine and they were not seen in conscious, nonsedated pigs. Visudyne resulted in a concentration-dependent increase in complement activation in human blood in vitro. At 10 mg/mL (approximately 5 times the expected plasma concentration in human patients), there was mild to moderate complement activation. At 100 mg/mL, there was significant complement activation. Signs (chest pain, syncope, dyspnea, and flushing) consistent with complement activation have been observed in <1% of patients in clinical trials with Visudyne. Patients should be supervised during Visudyne infusion.

Information for Patients
Patients who receive Visudyne will become temporarily photosensitive after injection. Patients should wear a wristband to remind them to avoid direct sunlight for 5 days. During that period, patients should avoid exposure of the eyes or skin to bright light. For those patients who do not go outdoors in daylight during the first 5 days after treatment, they should protect all of their skin and their eyes by wearing protective clothing and dark sunglasses. UV screens are not effective in protecting against angiography because photoactivation of the residual drug in the skin can be caused by visible light.

Patients should not stay in the dark and should be encouraged to expose their skin to indoor light, as it will help inactivate the drug in the skin through a process called photobleaching.

Following Visudyne treatment, patients may develop visual disturbances such as abnormal vision, vision decrease, or visual field defects that may interfere with their ability to drive or use machines. Patients should not drive or use machines as these symptoms persist.

Drug Interactions
Drug interaction studies in humans have not been conducted.

Verteporfin is rapidly eliminated by the liver, mainly unchanged drug. Metabolism is limited and occurs by liver and plasma esterases. Microsomal cytochrome P450 does not appear to play a role in verteporfin metabolism.

Based on the mechanism of action of verteporfin, many drugs used concomitantly could influence the effect of Visudyne. The following drugs are recommended to be avoided:

- Calcium channel blockers, polymyxin B or radiation therapy could enhance the rate of Visudyne uptake by the vascular endothelium. Other photosensitizing agents (e.g., tetracyclines, tetrahydroaminoacridine, sulfonamides, hypoglycemic agents, thiazide diuretics and griseofulvin) could increase the potential for skin photosensitivity reactions. Compounds that quench active oxygen species or scavenge radicals, such as dimethyl sulfoxide, b-carotene, ethanol, formamide, and mannitol, would be expected to decrease Visudyne activity. Drugs that decrease clotting, vasoconstriction or platelet aggregation, e.g., thromboxane A2 inhibitors, could also decrease the efficacy of Visudyne therapy.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No studies have been conducted to evaluate the carcinogenic potential of verteporfin.

Photodynamic therapy (PDT) as a class has been reported to result in DNA damage including DNA strand breaks, alkali-labile sites, DNA degradation, and DNA-protein cross links which may result in chromosomal aberrations, sister chromatid exchanges, and sister chromatid deletions. In addition, other photodynamic therapeutic agents have been shown to increase the incidence of SCE in Chinese hamster ovary (CHO) cells irradiated with visible light and in human lymphocytes exposed to visible light. These effects are not thought to be relevant to injury that could be seen in verteporfin was not evaluated in these latter systems. It is not known how the potential for DNA damage with PDT agents translates in vivo.

No effect on male or female fertility has been observed in rats following intravenous administration of verteporfin for injection up to 10 mg/kg/day (approximately 60-400-fold the human exposure at 8 mg/m² based on AUC₀₋₂₄ in male and female rats, respectively).

Pregnancy
Teratogenic Effects: Pregnancy Category C.

Rat fetuses of dams administered verteporfin for injection intravenously at ≥10 mg/kg/day during organogenesis (approximately 40-fold the human exposure at 6 mg/m² based on AUC₀₋₂₄ in female rats) exhibited an increase in the incidence of anophthalmia/microphthalmia. Rat fetuses of dams administered 25 mg/kg/day (approximately 125-fold the human exposure at 6 mg/m² based on AUC₀₋₂₄ in female rats) had an increased incidence of wavy ribs and anophthalmia/microphthalmia.

In pregnant rabbits, a decrease in body weight gain and food consumption was observed in animals that received verteporfin for injection intravenously at ≥10 mg/kg/day during organogenesis. The no observed adverse effect level (NOAEL) for effects on body weight was 3 mg/kg/day (approximately 7-fold the human exposure at 6 mg/m² based on body surface area). There were no teratogenic effects observed in rabbits at doses up to 10 mg/kg/day.

There are no adequate or well-controlled studies in pregnant women. Visudyne should be used during pregnancy only if the benefit justifies the potential risk to the fetus.

Nursing Mothers
Verteporfin and its diacid metabolite have been found in the breast milk of one woman after a 6 mg/m² infusion. The verteporfin breast milk levels were up to 46% of the corresponding plasma levels and declined below the limit of quantification (2 ng/mL) within 24 hours. The diacid metabolite had lower peak concentrations but persisted up to at least 48 hours.

Because of the potential for serious adverse reactions in nursing infants from Visudyne, 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.

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

Geriatric Use
Approximately 90% of patients treated with Visudyne in the clinical efficacy trials were over the age 65. A reduced treatment effect was seen with increasing age.

ADVERSE REACTIONS
Severe chink pain, vasovagal and hypersensitivity reactions have been reported. Vasovagal and hypersensitivity reaction on rare occasions can be severe. These reactions may include syncope, sweating, dizziness, rash, dyspnea, flushing and changes in blood pressure and heart rate. General symptoms can include headache, malaise, urticaaria, and pruritus.

The most frequently reported adverse events to Visudyne® (verteporfin for injection) are injection site reactions (including pain, edema, inflammation, extravasation, rashes, hemorrhage, and discoloration) and visual disturbances (including blurred vision, flashes of light, decreased visual acuity and visual field defects, including scotoma). These events occurred in approximately 10%-30% of patients. The following events, listed by Body System, were reported more frequently with Visudyne therapy than with placebo therapy and occurred in 1%-10% of patients:

- Ocular Treatment Site: Blurred vision, vision decrease, severe vision decrease with or without subretinal/retinal or vitreous hemorrhage
- Body as a Whole: Asthenia, fever, flu syndrome, infusion-related pain primarily presenting as back pain, photosensitivity reactions

- Cardiovascular: Atrial fibrillation, hypertension, peripheral vascular disorder, vericose veins

- Dermatologic: Eczema

- Digestive: Constipation, gastrointestinal cancers, nausea.

- Hemic and Lympohemic: Anemia, white blood cell count decreased, white blood cell count increased

- Hepatic: Elevated liver function tests

- Metabolic/Nutritional: Albinism, creatinine increased

- Musculoskeletal: Arthritis, arthrosis, myasthenia

- Nervous System: Hypersensitivity, sleep disorder, vertigo

- Respiratory: Cough, pharyngitis, pneumonia

- Special Senses: Cataracts, decreased hearing, diplodia, lacrimation disorder

- Urogenital: Prostatic disorder

- Severe vision decrease, equivalent of ≥4 lines, within 7 days after treatment has been reported in 1%-5% of patients. Partial recovery of vision was observed in some patients. Photosensitivity reaction usually occurred in the form of skin reactions which, in severe cases, can lead to more serious skin reactions. The higher incidence of back pain in the Visudyne group occurred primarily during infusion.

The following events have occurred either at low incidence (<1%) during clinical trials or have been reported during the use of Visudyne in clinical practice where these events were reported voluntarily from a population of unknown size and frequency of occurrence cannot be determined precisely. They have been chosen for inclusion based on factors such as seriousness, frequency of reporting, potential for causal connection to Visudyne, or a combination of these factors:

- Ocular Treatment Site: Retinal detachment (nonhemorrhagic), retinal or choroidal vessel neperfusion, retinal perforation, retinal neovascularization

- Nonocular Events: Chest pain and other musculoskeletal pain during infusion

OVERDOSAGE
Overdose of drug and/or light in the treated eye may result in rupture of inner or outer retinal vessels with the possibility of severe decrease in vision that could be permanent. An overdose of drug will also result in the prolongation of the period of photosensitivity which the patient remains photosensitive to bright light. In such cases, it is recommended to extend the photosensitivity precautions for a time proportional to the overdose.

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US/VID/14/0011 [1]
In wet AMD patients with predominantly classic lesions...

Can induce vaso-occlusion of the arteriolarized neovessels that may be the cause of persistent activity^{1-5}

- Arteriolarized-type of neovascular AMD is not VEGF-mediated and may need vaso-occlusive therapy^{1-5}
- With branching arteriolarized vascular complex (AVC), lesions can increase in size while undergoing treatment with an anti-VEGF^{1-2,4}
- Evidence of neovessel remodeling and large caliber, branching AVC are reasons to select PDT for treatment^{1,4}

Make Visudyne® a part of your treatment loop

### Indications and Usage

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- Patients who experience severe vision decrease (≥4 lines within 1 week) should not be retreated until their vision completely recovers to pretreatment levels and potential benefits and risks of subsequent treatment are carefully considered.

- Use of incompatible lasers that do not provide the required characteristics of light for photoactivation of Visudyne® could result in incomplete treatment due to partial photoactivation or overtreatment due to overactivation, or damage to surrounding normal tissue.

- For injection of Visudyne®, avoid small hand veins in favor of the largest possible arm vein, preferably the antecubital vein.

- The most frequently reported adverse events (10% to 30% incidence) were injection site reactions (including pain, edema, inflammation, extravasation, rashes, hemorrhage, and discoloration), and visual disturbances (including blurred vision, flashes of light, decreased visual acuity, and visual field defects, including scotoma).

Please see Brief Summary of Prescribing Information on adjacent page.

References:  

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Should You Consider a Cataract Suite?

Several companies are bundling devices, IOLs and disposables with measurable benefits for ASCs.

Cataract surgery presents ASCs with a variety of purchasing decisions ranging from capital purchases to IOLs and disposables. When an ASC requires a new technology to provide the highest level of care to its patients, administrators must weigh the potential purchase’s capabilities and compatibility with existing technologies, as well as surgeon preferences and financial considerations to decide whether or not the purchase is a good fit for their center.

Today, administrators and surgeons have the option of purchasing a suite of cataract surgery products produced by one manufacturer. Is a cataract suite the right choice for your ASC?

What’s in It for the ASC?
Manufacturers of cataract suites promote three primary advantages for their customers: lower costs, efficiency and convenience.

Lower costs. Whenever an administrator is considering multiple purchases from a single manufacturer, it’s wise to ask about cost incentives. Companies that design and sell cataract suites do so with those incentives in mind.

“When we talk to people about purchasing more than one piece of equipment, along with IOLs and consumables such as phaco packs, we’re really talking about a long-term agreement that has to make sense to them in terms of both product performance and economic value,” says Becky Kirkwood, Bausch + Lomb’s U.S. marketing director for the Victus femtosecond laser. “We work with the customer, evaluating case volumes and procedural costs, to ensure that they earn cost advantages by purchasing a suite of products.”

Efficiency. When ASCs buy from a single
A suite of equipment with pieces optimally matched provides enhanced value for physicians because it offers true compatibility and interconnectivity that, in turn, help deliver greater efficiency and improved surgical precision.”

— Joseph Boorady, senior vice president of sales and service, Carl Zeiss Meditec.
Abbott Medical Optics (AMO)

“AMO’s product portfolio offers an array of options that allow surgeons to choose products based on their individual techniques and preferences. We focus on delivering a range of unique best-in-class products. Whether it’s IOLs, phaco devices, lasers or viscoelastics, each of our products has some attributes that only we offer,” Mr. Raney says. “For example, we have a disposable insertion device that’s preloaded with an IOL. Rather than loading the IOL, the technician simply fills the cartridge with viscoelastic to advance the lens. It’s faster and requires no reusable instruments.”

AMO’s full Micro-Implantation Suite covers the full range of products needed to perform surgery. Its Whitestar Signature phacoemulsification system makes both peristaltic and venturi pumps available to surgeons during a procedure. Elliptical movement of the phaco tip permits gentler fluidics and ease of removal for both soft and hard cataracts.

Also included in AMO’s suite is the Unfolder Platinum 1 implantation system series for the company’s Tecnis 1-Piece IOL. Finally, the Healon OVD series facilitates a number of procedures including cataract surgery, while a range of micro-implantation tools and accessories such as knives, tips and sleeves round out the cataract suite.

Alcon

The most recent innovations from Alcon Surgical are the Verion Image Guided System, the Centurion Vision System and the LuxOR LX3 Microscope. These three elements combined with the LenSx laser comprise the instrumentation portion of the Cataract Refractive Suite.

The Verion Image Guided System measures keratometry, pupillometry and other parameters for cataract surgery.
surgery, while capturing high-resolution reference images of the eye. The system’s digital marker feature helps surgeons optimize incision placement and IOL alignment.

“The Verion Image Guided System is unique because it delivers image driven guidance to the surgeon throughout the cataract procedure that the surgeon customizes for each patient,” says Mr. Bachmann.

Alcon’s LenSx Laser, the first femtosecond laser approved for cataract surgery, is upgraded regularly with the goals of improved speed and outcomes for cataract procedures. Alcon emphasized the large visual field and reduced need for focus adjustment with the LuxOR LX3 with Q-Vue Ophthalmic Microscope. Finally, the company’s Centurion Vision phacoemulsification system monitors and adjusts to conditions in the eye during surgery to ensure that the intraocular pressure is stable.

Although Alcon doesn’t group them into its Cataract Refractive Suite, the company also offers cataract surgeons its line of AcrySof IQ IOLS and DisCoVisc viscoelastics. According to Mr. Bachmann, “The suite of instrumentation combined with the AcrySof line of IOLS, and the high level of surgeon support provided by Alcon, is the unique offering in cataract surgery today.”

**Bausch + Lomb**

Bausch + Lomb doesn’t market a cataract suite per se, but the company does offer a comprehensive range of capital equipment, IOLs and disposables. Some equipment is designed to serve multiple specialties in the ASC.

“Our Victus femtosecond laser can be used for both cataract procedures and to create the LASIK flap for refractive surgery,” explains Ms. Kirkwood. “In ASCs that have both cataract and refractive surgery, that versatility makes sense. The facility amortizes costs and service fees on one platform instead of shouldering two.”

The range of Bausch + Lomb cataract products includes several devices and a range of supplies. The Victus femtosecond laser platform is flexible for ASCs, explains Ms. Kirkwood.

“The Victus platform’s bed now swivels 70 degrees, allowing surgeons to put a laser in the OR and swivel the bed far enough to perform a phaco procedure in the same room.”

Another cataract device is the Stellaris Vision Enhancement System, whose fluidics and incisions enable surgeons to perform surgery for lenses below 2 mm at insertion.

“In femtosecond procedures, it helps to have the ability to use a vacuum-based system, and our Stellaris platform has that precision,” Ms. Kirkwood says.

Bausch + Lomb’s Crystalens, SofPort,
Non-Contact, Ultra-widefield Angiography

Obtain high contrast, undistorted images of the far periphery with the simple exchange of a lens.

All SPECTRALIS and HRA2 angiography systems can be upgraded with the new Non-Contact Ultra-Widefield Angiography Module, a cost-effective alternative to stand alone widefield imaging devices.

See more at: heidelbergengineering.com/us/ultra-widefield
Akreos and enVista IOLs serve a variety of functions, including reducing aberrations, enabling microincision surgery and eliminating glistenings from patients’ vision. Finally, the Amvisc, Amsvic Plus and OcuCoat Viscoelastics give surgeons a range of choices for individual cataract cases.

**Carl Zeiss Meditec**

“The Zeiss Cataract Suite seamlessly integrates the gold standard IOLMaster biometer and OPMI Lumera 700 microscope with the Callisto Eye computer-assisted surgery system for biometry, visualization and toric IOL implantation,” Mr. Boorady says. “In this surgical platform for cataracts, the components are designed to work together for the benefit of the surgeon and the patient.”

The Zeiss Cataract Suite includes these three devices. The IOLMaster 500 helps surgeons select the right IOL for each patient with a system designed to be reliable, straightforward and easy to use. The Callisto Eye is an OR management system that enables surgeons to visualize incisions and IOL placement by superimposing them through the eyepiece of the OPMI Lumera 700 microscope. That microscope, the third element of this cataract suite, is designed for clear optics and ease of use with an “exhaustive range of customization options.”

Mr. Boorady adds, “Patented SCI stereo coaxial illumination in the OPMI Lumera line provides a brilliant red reflex without compromising the ability to resolve details.”

**A Suite or a Mix?**

Many ophthalmic ASCs already own devices from a variety of manufacturers, because purchases are made over time, and the need to replace or upgrade occurs at different time points for different machines. IOL choices depend on many factors, including surgeon preference and patient needs. And when there’s a significant advance in any product, an ASC might purchase it regardless of manufacturer. However, there are advantages to consolidating your purchases with a cataract suite, especially for those ASCs looking to purchase more than one device.
SC RAC audits on blepharoplasty are coming your way. This review gives background information and some tips on how to handle your defense.

What Is a RAC Audit?
The Recovery Auditor Contractor (RAC) was the original name of this Centers for Medicare and Medicaid Services (CMS) outsourced program, which was subsequently changed to the Recovery Auditor program. However, it continues to be known as “The RAC Audits.” The program was established to identify and correct improper Medicare payments. The auditing contractors are paid on a contingency basis and are supposed to identify both overpayments and underpayments by Medicare Administrative Contractors (MACs) who are your claims processors. The states are divided into areas, shifting at times, under the jurisdiction of the companies identified on the map (Figure 1).

There are three types of audits: automated, semi-automated and complex. The automated audits are mostly data mining audits. For example, audits on office encounters coded as a “New Patient” that are based on the physician’s National Provider Identification (NPI) number. Claims warranting recoupment are sent directly to the MAC for withholding from your paycheck.

A semi-automated audit may be initiated by data mining and then a request for medical records may be initiated as well. Complex audits request medical records from the outset and are reviewed by an auditor and a determination is made that may result in direct withholding from your Medicare payment.

What is the Blepharoplasty RAC About?
Each Recovery Auditor keeps a list of issues posted on their website that includes the class of

CONTINUED ON PAGE 30
We just changed the world of toric implant surgery — again. Haag-Streit’s connectivity pairs up LENSTAR and its ophthalmic surgical microscope for the ultimate precision and confidence.

Images obtained through LENSTAR transfer to the new integrated remote-viewing station on the Haag-Streit microscope.

LENSTAR, now with 6mm topo, is the ultimate tool for planning the entire procedure, from incision and IOL placement to cylinder power choice and more. And, all of this information is mapped over a high-resolution image of the eye.

Coupled with the microscope’s outstanding red reflex and superior optics that deliver a significant increase in depth of field, surgeons can operate with confidence.

Work with the best. Learn more about this exciting merger by calling 800-787-5426, or visit www.hs-surgical.com/topsecret.
provider being audited (physician, ASC, inpatient hospital, and so on). The blepharoplasty audits are listed as pertaining both to the physician and the ASC.

The current audits are complex and focus on blepharoplasty and ptosis surgery regarding whether it is cosmetic or functional. Criteria that the RAC uses will be listed in your MAC’s Local Coverage Determination (LCD). A typical description is shown from Performant Recovery: “Blepharoplasty is the plastic repair of the eyelid, and usually refers to an operation in which redundant skin, muscle and/or fat are excised. Functional blepharoplasty usually involves the excision of skin and orbicularis muscle. This procedure is done to correct a deficit in the upper or peripheral field of vision or as noted on forward gaze by skin resting on the upper eyelashes. When blepharoplasty repair is done for cosmetic purposes it does not meet the criteria of the functional visual impairment parameters and is considered not reasonable and medical necessary and therefore will denied [sic].”

Consider this: How is the ASC going to prove that the case was functional? ASCs generally keep medical records and not medical necessity/chart documentation records.

What Chart Documentation Should the ASC Keep?

Many ASCs aren’t in the habit of keeping physician chart documentation as part of the ASC permanent chart documentation. Rather, they’re deeply concerned and occupied with meeting Medicare’s Conditions of Coverage.

Now is the time for a paradigm shift. As I write this, I’m receiving calls from clients who are preparing copies of their records to send off to a hospital or ASC to assist in their audit record requests. This after-the-fact gathering of information isn’t the same as the ASC having its own documentation preoperatively – otherwise, how could the ASC know if the case was cosmetic versus functional going forward? All the inherent billing issues, particularly charging the patient versus billing Medicare for the surgery, the facility fee and the anesthesia fees need to be decided before the surgery is performed, not afterward.

Suggested list of documents for the ASC chart

- Activities of Daily Living Form (ADL) (Figure 2)
- Blepharoplasty or Eyelid Ptosis or Brow Ptosis Checklist (Figure 3)
- Physician notes of the visit when surgery was scheduled and that document the patient’s problems that render the surgery functional

CONTINUED ON PAGE 32

Blepharoplasty, Eyelid Ptosis & Brow Ptosis

Patient Activities of Daily Living Questionnaire

Please check the YES or NO box for each question.

Please indicate each side that is affected.

SYMPTOMS/PROBLEMS

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>My upper or side peripheral vision is impaired.</td>
<td></td>
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<tr>
<td>My eyelid skin weighs heavily on my upper eyelids.</td>
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<tr>
<td>I have itching, scaling or a rash on my eyelids.</td>
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<tr>
<td>I am having difficulty with my artificial eye.</td>
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Patient Name _____________________________  Date _________________

Signature ________________________  Witness _______________________

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Figure 2
WELCOME TO THE ERA OF CENTURION®

Optimize every moment of your cataract removal procedure with the CENTURION® Vision System.

**Active Fluidics™**
Automatically optimizes chamber stability by allowing surgeons to customize and control IOP throughout the procedure.

**Balanced Energy™**
Enhances cataract emulsification efficiency using OZil® Intelligent Phaco and the INTREPID® Balanced Tip design.

**Applied Integration™**
Designed to work seamlessly with other Alcon technologies for an integrated cataract procedure experience.

Learn more about the era of cataract procedures. Visit MyAlcon.com.
IMPORTANT SAFETY INFORMATION FOR CENTURION® VISION SYSTEM

CAUTION: Federal (USA) law restricts this device to sale by, or on the order of, a physician.
As part of a properly maintained surgical environment, it is recommended that a backup IOL Injector be made available in the event the AutoSert® IOL Injector Handpiece does not perform as expected.

INDICATION: The CENTURION® Vision System is indicated for emulsification, separation, irrigation, and aspiration of cataracts, residual cortical material and lens epithelial cells, vitreous aspiration and cutting associated with anterior vitrectomy, bipolar coagulation, and intraocular lens injection. The AutoSert® IOL Injector Handpiece is intended to deliver qualified AcrySo® intraocular lenses into the eye following cataract removal.
The AutoSert® IOL Injector Handpiece achieves the functionality of injection of intraocular lenses. The AutoSert® IOL Injector Handpiece is indicated for use with the AcrySo® lenses SN60WF, SN6AD1, SN6AT3 through SN6AT9, as well as approved AcrySo® lenses that are specifically indicated for use with this inserter, as indicated in the approved labeling of those lenses.

WARNINGS: Appropriate use of CENTURION® Vision System parameters and accessories is important for successful procedures. Use of low vacuum limits, low flow rates, low bottle heights, high power settings, extended power usage, power usage during occlusion conditions (beeping tones), failure to sufficiently aspirate viscoelastic prior to using power, excessively tight incisions, and combinations of the above actions may result in significant temperature increases at incision site and inside the eye, and lead to severe thermal eye tissue damage.
Good clinical practice dictates the testing for adequate irrigation and aspiration flow prior to entering the eye. Ensure that tubings are not occluded or pinched during any phase of operation.
The consumables used in conjunction with ALCON® instrument products constitute a complete surgical system. Use of consumables and handpieces other than those manufactured by Alcon may affect system performance and create potential hazards.

AEs/COMPLICATIONS: Inadvertent actuation of Prime or Tune while a handpiece is in the eye can create a hazardous condition that may result in patient injury. During any ultrasonic procedure, metal particles may result from inadvertent touching of the ultrasonic tip with a second instrument. Another potential source of metal particles resulting from any ultrasonic handpiece may be the result of ultrasonic energy causing micro abrasion of the ultrasonic tip.

ATTENTION: Refer to the Directions for Use and Operator’s Manual for a complete listing of indications, warnings, cautions and notes.

CODING & COMPLIANCE

• Visual Fields showing a decrease with eyelids in normal position compared to position when taped up
• Photographs (as mandated by your MAC)

What Else Should We Do?
• Outside Help.

Consider hiring an attorney or consultant to help you prepare a summary letter of defense. In any event, prepare a letter that’s clearly dated and succinctly and thoroughly presents your case and rationale.
• Use Checklists. Use the checklists provided here after the summary in your response package. It will show that the requirements of the LCD have been met. Use the checklists in the ASC as well, to make sure the case is properly documented as functional.
• ICD-10-CM. Start your preparations and training now so you’ll be ready for proper diagnosis billing (For functional cases, the diagnosis should be dermatochalasis).
• LCDs. Have your surgeons, as well as you and your staff, read your MAC’s LCD on blepharoplasty, ptosis and brow lift. Don’t have one? Use one from Wisconsin Physician Services or National Government Services, and be sure to read the new LCD from Novitas-Solutions if that’s your MAC. This is a drastic revision and I would continue to perform visual fields even though they may not require it, because it’s your first line of defense for establishing that the case was functional.
• Physician Protocols. Please make sure your surgeon is following the same documentation procedures as you.

BLEPHAROPLASTY, EYELID PTOSIS & BROW PTOSIS CHECKLIST (FIGURE 3) CONTINUED ON PAGE 34

Riva Lee Asbell is owner of Riva Lee Asbell Associates, an ophthalmic reimbursement firm specializing in Medicare reimbursement and compliance issues, with extensive experience in Academic Medical Centers and residency programs.
Our commitment to sight is our commitment to research, education and outreach.

LIGHT study:
A Moorfields Eye Hospital study will compare the SLT vs medication treatment outcomes of over 700 newly diagnosed glaucoma patients.

Glaucoma 360 Educational Program:
L. Jay Katz, MD, FACS, discusses SLT vs medication as a first line option for glaucoma.

SLT, Glaucoma, and St. Lucia:
Research published by Tony Realini, MD, demonstrates Lumenis SLT as a powerful tool for reducing glaucoma-related blindness.

To find out more about how our commitment will benefit you, call 877-LUMENIS, or visit us at ophthalmic.lumenis.com.
## Blepharoplasty, Eyelid Ptosis & Brow Ptosis
### Medical Necessity & Chart Documentation Checklist

### Blepharoplasty

<table>
<thead>
<tr>
<th>Medical Necessity</th>
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<tbody>
<tr>
<td>- Chart and/or ADL Questionnaire substantiates ADL problems and/or symptoms specific to redundant skin</td>
</tr>
<tr>
<td>- Peripheral visual field impairment</td>
</tr>
<tr>
<td>- Redundant skin resting on upper lashes</td>
</tr>
<tr>
<td>- Chronic dermatitis of upper eyelids</td>
</tr>
<tr>
<td>- Prosthesis difficulties in an anophthalmic socket</td>
</tr>
<tr>
<td>- Other ____________________________</td>
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<table>
<thead>
<tr>
<th>Diagnostic Tests</th>
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</thead>
<tbody>
<tr>
<td>- Taped and untaped visual fields shows intrusion into 15° into superior field</td>
</tr>
<tr>
<td>- Photographic series for blepharoplasty surgery</td>
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<table>
<thead>
<tr>
<th>Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Functional blepharoplasty</td>
</tr>
<tr>
<td>- RUL  LUL  RLL  LLL</td>
</tr>
<tr>
<td>- Date of Surgery ____________________________</td>
</tr>
<tr>
<td>- If bilateral, both sides to be performed at same session</td>
</tr>
<tr>
<td>- Diagnoses ____________________________</td>
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### Blepharoptosis

<table>
<thead>
<tr>
<th>Medical Necessity</th>
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<tbody>
<tr>
<td>- Chart and/or ADL Questionnaire substantiates ADL problems and/or symptoms specific to drooping eyelid(s)</td>
</tr>
<tr>
<td>- Peripheral visual field/vision impairment</td>
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<table>
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<tbody>
<tr>
<td>- Taped and untaped visual fields shows intrusion into 15° superior field</td>
</tr>
<tr>
<td>- Photographic series for ptosis surgery demonstrating intrusion into pupil</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Surgery</th>
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</thead>
<tbody>
<tr>
<td>- Functional ptosis surgery</td>
</tr>
<tr>
<td>- RUL  LUL</td>
</tr>
<tr>
<td>- Date of Surgery ____________________________</td>
</tr>
<tr>
<td>- If bilateral, both sides to be performed at same session</td>
</tr>
<tr>
<td>- Diagnoses ____________________________</td>
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### Brow Ptosis

<table>
<thead>
<tr>
<th>Medical Necessity</th>
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</thead>
<tbody>
<tr>
<td>- Chart and/or ADL Questionnaire substantiates ADL problems and/or symptoms specific to redundant skin</td>
</tr>
<tr>
<td>- Peripheral visual field impairment</td>
</tr>
<tr>
<td>- Redundant skin resting on upper lashes</td>
</tr>
<tr>
<td>- Chronic dermatitis of upper eyelids</td>
</tr>
<tr>
<td>- Prosthesis difficulties in an anophthalmic socket</td>
</tr>
<tr>
<td>- Ocular fatigue secondary to constant squinting or trying to raise eyelids</td>
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<tr>
<td>- Other ____________________________</td>
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<table>
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<tr>
<th>Diagnostic Tests</th>
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<tbody>
<tr>
<td>- Taped and untaped visual fields shows intrusion 15° into superior field</td>
</tr>
<tr>
<td>- Photographic series for brow ptosis surgery</td>
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<table>
<thead>
<tr>
<th>Surgery</th>
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</thead>
<tbody>
<tr>
<td>- Functional brow ptosis surgery</td>
</tr>
<tr>
<td>- RUL  LUL</td>
</tr>
<tr>
<td>- Date of Surgery ____________________________</td>
</tr>
<tr>
<td>- If bilateral, both sides to be performed at same session</td>
</tr>
<tr>
<td>- Diagnoses ____________________________</td>
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Actual slit-lamp photograph of glistenings in a competitive acrylic IOL.5

Glistenings do exist.

But not for enVista.®1,3

The new standard in acrylic IOL performance

- No glistenings were reported at any time in controlled clinical studies1-3
- Aberration-free aspheric Advanced Optics4-6
- Low rates of PCO7

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