

Managerial Considerations for Laser Cataract Surgery

Important questions about reimbursement are engendered by this new technology.



By Kevin J. Corcoran, COE, CPC, FNAO

During the past 50 years, technological advances have allowed ophthalmic surgeons to perform better cataract surgery. Like phaco technology before it, the femtosecond laser represents another advance but one with a very high price tag—a kind of golden scalpel. If this controversial technology is to succeed, all of the interested parties must be satisfied.

THE PROCEDURES

Diagnostic Testing

Most items and services associated with routine cataract surgery are covered under Medicare's national policy (NCD 10.1).¹ In addition, specular microscopy prior to cataract surgery is covered under another Medicare national policy (NCD 80.8).² Some things are not covered, and the beneficiary is financially responsible for payment.³ For example, refraction is not covered by the Medicare law.⁴⁻⁶ Corneal topography is very helpful for assessing corneal astigmatism hinted at by lensometry, subjective or objective refraction, or detected by keratometry prior to cataract surgery. Corneal topography is considered a covered test for indications such as post-penetrating keratoplasty, keratoconus, corneal dystrophy, or keratopathy but not for preoperative cataracts.⁷ Screening for potential disease, such as macular degeneration or epiretinal membrane, using scanning computerized ophthalmic diagnostic imaging of the retina also is not covered. This is because prophylactic testing is not a Medicare benefit unless specifically authorized by Congress.^{8,9}

Taken together, the purpose of these optional, noncovered tests is to allow the surgeon to minimize residual refractive errors after cataract surgery and obtain the best possible UCVA or the desired ametropia as planned for in pseudophakic monovision.

LATE-BREAKING NEWS

The AAO and the ASCRS have released a joint statement providing Medicare billing guidance to surgeons for laser technology used in cataract procedures. For more, please see page 7.

Laser Capsulorhexis

The image-guided femtosecond laser creates a precise capsulorhexis¹⁰⁻¹² in the preferred shape and location. The fenestrated capsule remains in place atop the lens until it can be removed in the OR.

Laser Lens Fragmentation

The femtosecond laser creates a series of intersecting vertical and horizontal planes, which facilitate the (later) phacoemulsification by breaking the lens into many small pieces (Figure 1). These small pieces require less time and energy to remove.

Corneal Incision

The femtosecond laser can be programmed to create a nonpenetrating, self-sealing, stepped corneal incision with the corneal epithelium still intact. The femtosecond laser is only applied to the inner layers of the cornea. Later, in the OR, the eye is readily opened at the locus of the partial corneal incision.

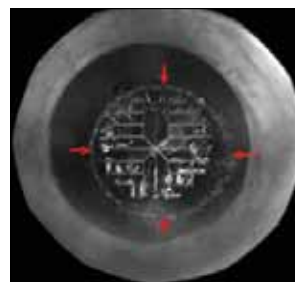


Figure 1. Laser lens fragmentation may result in the need for less phaco energy during cataract surgery.

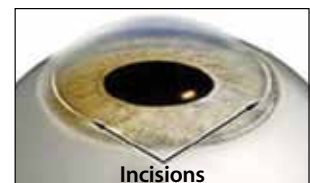


Figure 2. Surgical correction of astigmatism, with or without a femtosecond laser, is not eligible for Medicare reimbursement unless it is used to correct a surgical complication.

TABLE. COVERED AND NONCOVERED SERVICES

	Facility	Surgeon
Eye examination	—	Covered
Biometry ^a	—	Covered
Refractive testing ^b	—	Not covered
Corneal topography ^c	—	Rarely covered
Specular microscopy ^d	—	Covered
Screening ^e	—	Not covered
Laser capsulorhexis ^f	Covered	Covered
Laser lens fragmentation ^f	Covered	Covered
Phacoemulsification	Covered	Covered
Postoperative care	—	Covered
Refractive surgery ^g	Not covered	Not covered

^a NCD 10.1 A-scan or optical coherence biometry (only one).²²

^b Testing for refractive errors, including refraction (sphere, cylinder, add, prism), corneal topography (cylinder), or wavefront aberrometry (higher-order aberrations) is a noncovered service in Medicare.²³ Beneficiaries with supplemental insurance that includes a vision care benefit may have separate coverage.

^c Regular astigmatism is not a covered indication for Medicare. Corneal pathology may be covered.²⁴

^d NCD 80.8 states: "When a presurgical examination for cataract surgery is performed and the conditions of this section are met, if the only visual problem is cataracts, endothelial cell photography is covered as part of the presurgical comprehensive eye examination or combination brief/intermediate examination provided prior to cataract surgery, and not in addition to it."²⁵

^e Prophylactic testing (eg, scanning computerized ophthalmic diagnostic imaging) is not a Medicare benefit, unless specifically authorized by Congress.

^f Laser capsulorhexis and lens fragmentation are an integral part of cataract surgery, so there is no merit for a separate professional charge.

^g NCD 80.7 states: "The use of radial keratotomy and/or keratoplasty for the purpose of refractive error compensation is considered a substitute or alternative to eyeglasses or contact lenses, which are specifically excluded by §1862(a)(7) of the Act (except in certain cases in connection with cataract surgery). In addition, many in the medical community consider such procedures cosmetic surgery, which is excluded by section §1862(a)(10) of the Act. Therefore, radial keratotomy and keratoplasty to treat refractive defects are not covered."²⁶

Cataract Surgery

In the OR, all of the expected steps of cataract surgery with the implantation of an IOL are performed. Although pretreatment of the eye with the femtosecond laser affords some advantages for the patient and the surgeon, intraocular surgery is essentially the same.

Refractive Surgery

By virtue of its extreme precision, the femtosecond laser is ideally suited to making corneal relaxing incisions (Figure 2) to ameliorate regular astigmatism.^{13,14} This procedure may be performed at the time of cataract surgery or later, once the eye has stabilized and a final refraction has been obtained. Then, any clinically significant residual refractive error can be addressed.

REIMBURSEMENT

Medicare

The economic hallmark of cataract surgery combined with an additional procedure is the provider's expectation of additional payment beyond the customary contracted amount. Under most circumstances, such expectations are frustrated by potent restrictions placed on balance billing by all third-party payers, including Medicare.

Balance billing is the practice of asking a beneficiary to pay the difference between the nominal charge and the assigned benefit amount that the provider has contractually accepted as payment in full. The term does not refer to the collection of copayments and deductibles. At the very least, the provider who balance bills beneficiaries has breached his or her preexisting agreement with the payer, which could result in civil

sanctions. The provider may also be guilty of a crime in some states. Federal regulators are so concerned about this issue that a special whistleblowers' Web site¹⁵ exists, with lawyers available 24 hours a day to accept reports of allegedly fraudulent activity.

In the context of the use of the femtosecond laser for cataract surgery, Medicare and other third-party payers would assert that a laser capsulorhexis and laser lens fragmentation are elements of cataract surgery and not separately chargeable to beneficiaries (confidential legal opinion and private discussion with Centers for Medicare & Medicaid Services official). This viewpoint is true whether the procedure occurs in one or two stages. Corcoran Consulting Group's prior experience with femtosecond laser-assisted keratoplasty demonstrated that Medicare reimburses a staged corneal transplant procedure (ie, done in two steps) at the same payment rate as a traditional penetrating keratoplasty and prohibits balance billing beneficiaries for the use of a golden scalpel.¹⁶

Medicare beneficiaries are entitled to "one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens."^{17,18} The patient may, however, choose cosmetic corneal refractive surgery to reduce his or her dependency on eyeglasses. Medicare and other third-party payers treat the surgical correction of corneal astigmatism as a noncovered service, when it is not a surgically induced complication, whether or not a femtosecond laser or some other surgical instrument is used.¹⁹ Then, a charge to the beneficiary for the noncovered refractive service is permitted.

Despite the powerful deterrents to balance billing, there is no prohibition against billing beneficiaries for noncovered services (eg, cosmetic and refractive procedures). In this context, it is useful to define and separate covered from noncovered services and to obtain the patient's voluntary acceptance of financial responsibility for the latter.

Prior to surgery and in addition to informed consent, beneficiaries should be educated that refractive cataract surgery using a femtosecond laser encompasses both covered and noncovered items and services (Table).

Other Third-Party Payers

Other third-party payers are not obliged to agree with Medicare's rules on coverage and payment, although many do. Consequently, surgeons should not assume that the familiar rules of the Medicare program are universally applicable.

FINANCIAL WAIVERS

Although payment for noncovered services is the beneficiary's obligation, the Medicare law contains a

TIPS ON MANAGEMENT

- The surgeon may not charge "extra" for cataract surgery performed with a femtosecond laser. The surgeon's reimbursement for cataract surgery is unchanged by the election to use a femtosecond laser.
- Laser cataract surgery is unaffected by the type of IOL used. A premium IOL is not required in the business model.
- Medicare beneficiaries may not be compelled to pay for elective services as a precondition for obtaining covered services.
- The treatment of surgical complications of cataract surgery, with or without the femtosecond laser, is a covered service. For example, treatment of infection or inflammation after surgery is covered.
- Refractive surgery (eg, limbal relaxing incisions, LASIK, PRK) to minimize residual refractive errors after cataract surgery is not usually a covered service.
- With appropriate consent from the patient and a signed Advance Beneficiary Notice, the beneficiary is responsible for all noncovered professional services to address refractive errors.
- Surgeons should not assume that all third-party payers follow Medicare's precepts.

provision that waives that liability if the beneficiary is not likely to know and did not have a reason to know that the services would not be covered.²⁰ Without proof of the Medicare beneficiary's advance acceptance of financial responsibility, the surgeon is required to refund any payment collected. To adequately address the economic considerations of refractive cataract surgery using the femtosecond laser, the patient's financial responsibility for the noncovered services must be carefully delineated and agreed upon. An Advance Beneficiary Notice (CMS-R-131)²¹ or similar financial waiver is used to document that the Medicare beneficiary acknowledges that he or she has been advised that Medicare will not pay and that he or she agrees to be responsible for payment, either personally or through another insurance plan. For an Advance Beneficiary Notice to have any utility, it must be signed before provision of the item or service.

CONCLUSION

The use of a femtosecond laser during cataract surgery is a new and exciting option but an extremely

expensive one. It raises important questions about reimbursement as well as the technology's potential. Because Medicare and other third-party payers reimburse ophthalmologists for cataract surgery, an extra charge for the use of the femtosecond laser is only warranted for concurrent refractive surgery to ameliorate corneal astigmatism; otherwise there are limitations on billing beneficiaries out of pocket for the use of a femtosecond laser to perform parts of the cataract surgery. Surgeons would be well served to remember the information included in the sidebar *Tips on Management*.

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The use of the laser enhances the refractive result of the surgery. Because a refractive procedure is not covered under Medicare, is it appropriate to bill the patient?



By Alan E. Reider, JD, MPH, and Allison Weber Shuren, MSN, JD
We have all heard the adage, “Medicare does not pay for a golden scalpel.” The unstated

but understood corollary of that saying is that you may not charge the patient, either. The question of whether this concept applies to the femtosecond laser has generated considerable debate within the medical community as well as the device industry. As of this writing, there is no clear guidance from the government relating to the question of when—or if—it is appropriate to bill patients in connection with the use of the femtosecond laser. As a result, this article does not provide answers. Instead, the authors attempt to describe some of the key issues from both the legal and the policy perspectives that contribute to the current state of uncertainty.

THE DEBATE

There appears to be consensus that the correction of corneal astigmatism generally is not a covered procedure and, therefore, the patient may be billed for the use of the femtosecond laser in connection with the creation of a corneal relaxing incision to correct astigmatism. Current debate surrounds the use of the femtosecond laser in connection with cataract surgery and the implantation of an IOL. Complicating matters, three perspectives are being advanced by a variety of stakeholders:

(1) It is appropriate to charge a patient in connection with the use of the laser during cataract surgery, regardless of the type of IOL that is implanted.

(2) It is appropriate to charge a patient for the use of the laser during cataract surgery but only in connection with implantation of a premium IOL.

(3) It is not appropriate to charge a patient for the use of the laser in connection with any cataract procedure, regardless of the type of IOL that is implanted.

Those who maintain that it is appropriate to charge a patient regardless of the type of lens implanted argue that the use of the laser enhances the refractive result of the surgery and, because a refractive procedure is not covered under Medicare, it is appropriate to bill the patient. Proponents of charging the patient in connection with the implantation of a premium IOL argue that the three-dimensional imaging component of the laser is used to ensure the precise shape, size, and position of the premium IOL in the capsular bag. Proper tilt and centration of a premium lens are critical to its maximum functionality, as distinguished from monofocal IOLs. Finally, those who reject the propriety of billing the patient for the use of the laser in any cataract surgery argue that the procedure is a covered service, regardless of what instrument or equipment is used. In other words, they argue that the femtosecond laser is essentially a golden scalpel.

THE FOCUS OF THE DEBATE

The Centers for Medicare & Medicaid Services (CMS) Ruling 05-01 and its companion Ruling 1536-R^{1,2} serve as the foundation for the arguments both in favor of and opposed to charging patients for the use of the laser. These rulings, which were published in 2005 and 2007, respectively, enabled physicians and facilities to bill patients for the noncovered portion of implanting presbyopia-correcting and toric IOLs. These rulings created what has become known as the *two-aspect rule*, in which Medicare recognizes that a single procedure and a single device provide both a covered and a noncovered service.

In analyzing the potential application of the two-aspect rule to the use of the femtosecond laser, it is important to understand why and how CMS issued this extraordinary policy. One significant motivator was the concern that, if a Medicare patient were not allowed to pay for a portion of the service, he or she would be denied access to this new technology. The only other option would be for Medicare to pay for the premium lenses, which was neither practical nor realistic and was outside the Medicare benefits.

With the policy motivation clear, the question arose as to how the femtosecond laser fits within the policy articulated in the Rulings. After all, cataract surgery with IOL implantation is a covered service, and Medicare patients may not be charged an additional amount for a covered service beyond any applicable deductible and copayment. The language of CMS Ruling 05-01 provides a relatively simple and straightforward answer. In reviewing the func-

tionality of the premium lens, CMS found:

“A conventional intraocular lens (IOL) is covered when implanted following cataract surgery ... a conventional IOL is a small, lightweight, clear disk that replaces the distance focusing power of the eye’s natural crystalline lens. ... Medicare ... does not cover the accommodative change in eyeglass or contact lens power that is required to compensate for the gradual loss of near vision as presbyopia progresses. Therefore, the presbyopia-correcting functionality of an IOL does not fall within the benefit category and is not covered.”

Thus, the CMS Rulings took a single procedure using a single device and recognized that it performed two distinct functions: (1) removal of a cataract with implantation of a prosthetic lens (covered service) and (2) implantation of a lens that provides a presbyopia- or astigmatism-correcting functionality (noncovered service). Based on this distinction, the ruling provided for the following mechanism to implement the two-aspect concept:

“The beneficiary is responsible for payment of facility charges and resources required for fitting and vision acuity testing of a presbyopia-correcting IOL that exceed the facility charges for resources furnished for a conventional IOL following cataract surgery. The physician may take into account the additional physician work and resources required for insertion, fitting, and vision acuity testing of the presbyopia-correcting IOL compared to insertion of a conventional IOL.”

As stated, patients are therefore responsible for paying the facility and the physician for the resources required for fitting and visual acuity testing associated with the implantation of a premium IOL not otherwise required for the implantation of a conventional IOL.

CMS RULING 05-01 AND THE FEMTOSECOND LASER

By its terms, CMS Ruling 05-01 applies to a very specific scenario: charging patients for the noncovered component of cataract surgery when a presbyopia-correcting IOL is implanted. Nevertheless, a close reading of CMS Ruling 05-01 may provide guidance on and insight into the question of charging patients for use of the femtosecond laser. Recall the language quoted previously in connection with the implantation of a conventional IOL: “A conventional IOL is a small, lightweight, clear disk that replaces the distance focusing power of the eye’s natural crystalline lens.”

Does this language suggest that because monofocal IOLs have advanced to not only replace the cloudy, natural cataractous lens but also are designed to achieve vision at a single point in the distance, refrac-

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tive correction is part of the covered service? If so, how does that affect the argument that the use of the femtosecond laser in connection with a monofocal IOL enhances the refractive result and should be considered a noncovered service?

With respect to the implantation of a premium lens, recall the language of the ruling that states that the patient is responsible for the payment of any resources required for fitting and visual acuity testing in connection with the implantation of a presbyopia- or toric IOL and not otherwise necessary with implantation of a monofocal implant. Applying this standard, is the use of the femtosecond laser part of the additional work and resources required for the insertion and fitting of the premium IOL beyond that of the conventional lens? Is the heightened need to ensure appropriate placement of the lens for proper tilt and centration, which is so critical in connection with premium implants compared with conventional IOL implants, a sufficient distinction?

CMS Ruling 05-01 does not provide a definitive answer to either of these questions. It does, however, provide some insight into how the regulators may address these issues if, or when, they are presented.

IS THERE ANOTHER OPTION?

Absent from the current debate is still another option for consideration: the development of a new code. If a new code were established to reflect the steps followed in use of the femtosecond laser prior to cataract surgery, the focus would be on whether this new code would be recognized as a covered procedure by Medicare or other third-party payers. A new code, however, would require further guidance concerning coverage and reimbursement.

THE NEED FOR GUIDANCE

The issue of billing for laser cataract surgery is complex, and existing guidance provided by the rulings for premium IOLs may suggest a reasonable basis on which to rely. Given the uncertainty regarding this position, and the ever-present threat of enforcement in this environment, there is a real need for productive interchange with Medicare regulators. ■

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