



Best Practices for Laser-Assisted Cataract Surgery

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SUMMARY: A femtosecond (FS) laser is exciting new technology, but it requires consideration of some important governance and compliance issues. Best practices require the surgeon and the facility (ASC or Hospital) to identify covered and non-covered services, create formal arrangements between the two, develop suitable financial waiver forms, and ensure that patients are clearly informed about their financial responsibility.

The addition of a femtosecond (FS) laser excites ophthalmic surgeons like few other new technologies. Excitement aside, some consideration must also be given to the associated implementation and compliance issues.¹ In particular, when it comes to charging for the FS laser, there are several things to consider. Have third party payers, specifically Medicare (CMS), taken any positions? What have the major professional societies, like AAO and ASCRS published? Who owns the FS laser? Can a patient be charged for items and services associated with cataract surgery? Who can charge the patient for services rendered with the FS laser? And finally, what administrative forms are needed?

GUIDANCE FROM CMS AND THE SOCIETIES

On November 16, 2012, CMS released the [document](#) "Laser-Assisted Cataract Surgery and CMS Rulings 05-01 and 1536-R".² In this document, CMS discusses what has become known as the *two-aspect rule*, where Medicare recognizes that a single procedure (cataract surgery) and a single device (IOL) can provide both a covered and a non-covered service³, and the possible areas where/when charges can be levied on patients for non-covered and/or refractive services associated with premium or deluxe intraocular lenses (*i.e.*, Presbyopia-Correcting (PC) IOLs and Astigmatism-Correcting (AC) IOLs). To summarize the CMS document, a beneficiary may pay both the ASC and surgeon an additional charge for their respective non-covered services like an astigmatic keratotomy (AK) or other services related to a PC-IOL or an AC-IOL. However, "[s]ervices that are part of cataract surgery with a conventional lens, including but not necessarily limited to the incision by whatever method, capsulotomy by whatever method, and lens fragmentation by whatever method, may not be charged to the patient."⁴ That is, the allowable Medicare reimbursement for cataract surgery does not change according to the surgical method or technology used. For example, when the ASC provides the PC-IOL, the patient pays the ASC for the non-covered portion of the PC-IOL.⁵ When the surgeon provides an additional screening test, like an optical coherence tomography (OCT), the surgeon collects for the non-covered screening test. It is recommended that each party charge the patient separately for their respective non-covered services. To do otherwise (*e.g.*, the surgeon collects payment in full and pays the ASC for his or her services, or vice versa), results in a payment between referral sources which then must be analyzed under federal, and if applicable, state anti-kickback laws to ensure that the payment is fair market value and commercially reasonable.

CMS also describes non-covered charges when using the FS laser imaging to implant PC-IOL or AC-IOL. If the surgeon includes premium IOL placement with the laser system, as part of his or her non-covered charges, we have to ask the question, did the surgeon use the laser imaging system to make corneal

arcuate incisions and/or to verify placement of the AC-IOL or PC-IOL? If the answer is yes, the surgeon can charge the patient a commercially reasonable fee for the additional, non-covered professional service provided by the surgeon with the FS laser.

In December 2012, the AAO and ASCRS published a [joint paper](#) providing further clarification regarding Medicare guidelines for charging beneficiaries when using a FS laser and provided specific examples of services that can and cannot be charged.⁶ For example, a refractive lens exchange or an AK are non-covered refractive services charged directly to the beneficiary. In some cases, the AK is performed in conjunction with cataract surgery, however it remains refractive and non-covered.

Figure 1 **Covered and Non-Covered Services**

	7° #001	SURGEON
Eye exam	----	Covered
Biometry (A)	----	Covered
Refractive testing (B)	----	Not covered
Corneal topography (C)	----	Rarely covered
Specular microscopy (D)	----	Covered
Screening (E)	----	Not covered
Laser capsulorrhexis(F)	Covered	Covered
Laser lens fragmentation (F)	Covered	Covered
Phacoemulsification	Covered	Covered
Postop care	----	Covered
Refractive surgery(G)	Not covered	Not covered

- A. [NCD 10.1](#)⁷ A-scan or Optical Coherence Biometry (only one)
- B. Testing for refractive errors including [refraction](#) (sphere, cylinder, add, prism), corneal topography (cylinder), or wavefront aberrometry (higher order aberrations) are non-covered services in Medicare.⁸ Beneficiaries with supplemental insurance that includes a vision benefit may have separate coverage.
- C. Regular astigmatism is not a covered indication for Medicare. Corneal pathology may be covered.⁹

- D. [NCD 80.8](#)¹⁰ 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.”*
- E. Prophylactic testing (e.g., scanning computerized ophthalmic diagnostic imaging) is not a Medicare benefit, unless specifically authorized by Congress.
- F. Laser capsulorrhexis and lens fragmentation are an integral part of cataract surgery, so there is no merit for a separate professional charge.
- G. [NCD 80.7](#)¹¹ 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.”*

WHO OWNS THE FS LASER?

In most cases, the laser is purchased by the facility, either ASCs or hospitals, with a small percentage of units owned by surgeon(s). In this context, the ownership aspect of the laser is a key consideration when charging a patient for non-covered FS laser services.

ASC owns the FS laser

In a recent case, we learned that an ASC purchased an FS laser and routinely requested a per case payment from the surgeon (not the patient) for the use of the FS laser. The surgeon included a fee for the FS laser in the non-covered refractive package to the patient. Due to several variables, including an increased volume of procedures beyond original projections, the ASC lowered the FS laser fee it charged the surgeon. The surgeon, in this case, did not reduce the charge for the non-covered services, thereby realizing a “profit” by keeping the difference in the ASC original charge for the FS laser and the new, lower charge. Since the surgeon refers Medicare patients to the ASC, this arrangement potentially implicates the federal Anti-kickback Statute, 42 U.S.C. § 1320a-7(b), which prohibits providers of services or goods covered by a federal healthcare program (including Medicare and Medicaid) from knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service for which payment may be made under a federal healthcare program.¹² The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to obtain money for the referral of services or to induce further referrals.¹³

This arrangement posed another serious problem for the ASC and surgeon since every use of the FS laser was billed to the surgeon, even when a conventional IOL was used and no corneal arcuate incisions were performed. The Medicare participation agreement of the ASC does not permit an additional charge, directly or indirectly, to the beneficiary for covered services such as the use of the FS laser to perform capsulorrhexis, lens fragmentation, or to make a corneal incision to facilitate entry of surgical instruments into the anterior chamber. In a similar vein, by virtue of its reimbursement from Medicare or other third party payer, the ASC cannot ask the surgeon to pay for access to the FS laser; the cost of the FS laser in routine cataract surgery is solely the responsibility of the ASC.

Surgeon(s) leases FS laser to ASC

In this scenario, the surgeon(s) owns the FS laser and make it available to the ASC. Since the surgeon is incurring the cost of the FS laser, the ASC should reimburse the surgeon for use of the FS laser. To do otherwise, the ASC would be using “free” equipment from a referral source to generate ASC revenue which can implicate the federal Anti-kickback Statute. The lease arrangement between the surgeon(s) lessor and the ASC should structure the arrangement in compliance with the equipment lease Anti-kickback Statute “safe harbor”.¹⁴ Safe harbors describe business arrangements between referral sources (e.g., an ASC and a surgeon) that if satisfied will not run afoul of the federal Anti-kickback Statute. The equipment lease safe harbor protects equipment rental payments if:

- there is a written lease signed by the parties;
- the lease specifies the equipment covered by the lease;
- where the lease is intended to provide the lessee with the use of the equipment for periodic intervals, rather than full-time for the term of the lease, the lease specifies the exact schedule, length, and rent for the intervals;
- the term of the lease is for at least one year; and
- the aggregate rental charge is set in advance, consistent with fair market value in an arms-length transaction, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.

The lease between the surgeon(s) and the ASC should not stipulate who can or cannot use the FS laser; the ASC decides who uses the FS laser. Also, the lease payments cannot be conditioned on the ASC collections from the FS laser. The CMS guidance on applicable non-covered charges to beneficiaries applies independent of the lease. Finally, this approach is controversial because the lessor (i.e., surgeon) is typically the person using the FS laser thereby supporting the ASC’s lease payments through referrals. We don’t encourage this approach and would rather see the ASC buy the FS laser.

SETTING FEES

Guidance from both CMS and the AAO/ASCRS encourages financial transparency. Both the surgeon and the facility need to establish clear, reasonable and defensible charges for non-covered services. One physician client was advised by legal counsel, “...*(for non-covered services) the physician’s charge to the patient is not limited to the Medicare physician fee schedule. Nevertheless, the physician must be able to justify the charge to the patient. If the patient is charged for a series of diagnostic tests, the charge for those tests must be defensible. One way to assess the propriety of the charge is whether they are consistent with what the physician would otherwise charge a self-pay patient for the same services.*” The process of developing a package price for refractive services with a FS laser should be thorough, methodical, rational, and reasonable. It’s not a matter of pulling numbers out of the air. For more information on developing a suitable fee, CCG has published a \$99 monograph entitled, Management Considerations for Refractive Cataract Surgery Using Femtosecond Laser, which is available [here](#).

FINANCIAL WAIVERS

Medicare beneficiaries are obligated to pay for non-covered services, but the Medicare law contains a [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 by Medicare.¹⁵ Without proof of the Medicare beneficiary’s advance acceptance of financial responsibility, the surgeon and the ASC may be required to refund any payment by the patient for the non-covered service. Accordingly, to address the economic considerations

of refractive cataract surgery using the FS laser, the patient's financial responsibility for the non-covered services must be delineated and agreed upon before the procedure. An ABN ([CMS-R-131](#)) or similar financial waiver is a written notice a health care provider can give to a Medicare beneficiary when the provider believes that Medicare will not pay for items or services. By signing an ABN, the Medicare beneficiary acknowledges that he or she has been advised that Medicare will not pay for the service and agrees to be responsible for payment, either personally or through another insurance plan. For an ABN to have any utility, it must be signed before providing the item or service.

CONCLUSION

The use of an FS laser may provide some patient care advantages, and if structured properly can generate additional revenue for both the ASC and surgeon. It is important that any fee arrangement between referral sources comply with the federal, and if applicable state, anti-kickback laws. It is also important to set reasonable fees which reflect the value of the services provided with the FS laser and to discuss fee details with the patient in a transparent fashion. To avoid misunderstandings and recriminations, use ABNs or financial waivers for the surgeon and the facility to ensure that the patient understands his or her personal financial obligations before any services are rendered. In summary, be cautious, be transparent and be realistic.

MANAGEMENT TIPS

- The surgeon may not charge "extra" for cataract surgery performed with a FS laser. The surgeon's reimbursement for cataract surgery is unchanged by the election to use an FS laser.
- Laser cataract surgery is unaffected by the type of IOL. A premium IOL (*i.e.*, presbyopia-correcting or astigmatism-correcting) is not required in the business model.
- Medicare beneficiaries may not be compelled to pay for elective services as a pre-condition for obtaining covered services.
- Surgical complications of cataract surgery, with or without the FS laser, are a covered service. For example, treatment of infection or inflammation after surgery is covered.
- Refractive surgery (*e.g.*, LRI, LASIK, PRK) to minimize residual refractive error after cataract surgery is not usually a covered service.
- With appropriate patient consent and a signed ABN, the beneficiary is responsible for all non-covered professional services to address refractive errors.
- Don't assume that all third party payers follow Medicare precepts.

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