CMS Guidance on Femtosecond Laser Systems for Cataract Surgery—Frequently Asked Questions

Overview

The Centers for Medicare and Medicaid Services (CMS) released a guidance document on November 16, 2012 addressing use of a femtosecond laser system in cataract procedures performed on Medicare beneficiaries. We have included a copy of the guidance document at the end of this piece. The guidance applies the principles of CMS rulings for presbyopia-correcting IOLs (released in 2005) and astigmatism-correcting IOLs (released in 2007) to the use of certain functions of a femtosecond laser system (FLS) when used in cataract procedures with conventional or advanced technology IOLs (ATIOLs).

Guidance Clarification

• Facilities may include the imaging function of the FLS in their charge to ATIOL patients, if it is used to achieve precise alignment necessary for ATIOLs.

• Facilities may not charge ATIOL patients for using the laser to create a capsulotomy, primary or secondary cataract incisions, or fragmentation of the nucleus, because these are steps of covered cataract surgery.

• The guidance makes no changes to existing policy regarding non-covered services such as refractive keratoplasty (RK). (FDA has not approved or cleared any femtosecond laser system – including the LenSx® Laser* – specifically for refractive procedures. This statement does not state or imply that the LenSx® Laser is FDA-approved or cleared specifically for astigmatism correction.)

Frequently Asked Questions

1. How does the CMS guidance affect my practice?
   • Surgeons can include the imaging function of the FLS in their charge to ATIOL patients, if it is used to achieve precise alignment necessary for ATIOLs.

   • Surgeons may not charge ATIOL patients for using the laser to create a capsulotomy, primary or secondary cataract incisions, or fragmentation of the nucleus, because these are steps of covered cataract surgery.

   • There is no change to the existing policy that refractive keratoplasty performed with any device is a non-covered service, so an arcuate incision to correct astigmatism remains chargeable to the patient regardless of whether it is performed as a standalone procedure or performed in the same operative session as cataract surgery. (FDA has not approved or cleared any femtosecond laser system – including the LenSx® Laser – specifically for refractive procedures. This statement does not state or imply that the LenSx® Laser is FDA-approved or cleared specifically for astigmatism correction.)

*See last page for Important Safety Information.
2. **Can surgeons charge their ATIOL patients additional fees for using a LenSx® Laser?**
   - Yes, but the charge is related only to the additional service of imaging (and the integrated computations) that is used to determine the size, shape, and location of a capsulotomy.
   - Creating a capsulotomy, primary and secondary incision, and fragmenting the nucleus with the FLS are steps of cataract surgery, a covered procedure, and are not separately chargeable to cataract patients.

3. **Can surgeons charge a conventional IOL patient for the imaging provided by the LenSx® Laser without an arcuate incision?**
   - No, if a conventional IOL patient is not also undergoing an additional refractive procedure, such as refractive keratotomy (RK), then the patient should not be charged for the imaging function of the laser.
   - The patient may only be charged for the co-pay and deductible.

4. **Can a surgeon who routinely uses the LenSx® Laser for steps of cataract surgery with conventional IOLs still charge his/her ATIOL patients for use of the imaging function of the laser?**
   - No. The surgeon can use the LenSx® Laser in cataract surgery with conventional IOLs, but doing so routinely or on an unlimited basis will eliminate his/her ability to charge ATIOL patients for the use of the imaging function.
   - If a surgeon uses functions of a femtosecond laser on a limited, non-routine basis in conventional IOL cataract procedures, then that limited, non-routine circumstance does not prevent them from charging ATIOL patients for use of imaging.

5. **What do the terms “limited” and “non-routine” mean?**
   - Alcon cannot provide legal advice on the meaning of these terms. Surgeons who have questions regarding interpretation of verbiage from the CMS guidance document should contact their legal counsel.

The diagrams below illustrate which elements of each clinical scenario are parts of non-covered (patient pay) services:
November 16, 2012

Laser-Assisted Cataract Surgery and CMS Rulings 05-01 and 1536-R

Per CMS Ruling 05-01, issued May 3, 2005, Medicare will allow beneficiaries to pay additional charges (which are non-covered by Medicare as these additional charges are not part of a Medicare benefit category) associated with insertion of a presbyopia correcting intraocular lens (PC-IOL) following cataract surgery. Per CMS-Ruling 1536-R, effective for services on and after January 22, 2007, Medicare will allow beneficiaries to pay additional charges (which are non-covered by Medicare as these additional charges are not part of a Medicare benefit category) for insertion of an astigmatism correcting intraocular lens (AC-IOL). These rulings allow the beneficiary to pay additional charges for two specific categories of non-covered services:

- The portion of the facility or physician’s charge for the PC-IOL or AC-IOL that exceeds the facility or physician’s charge for insertion of a conventional intraocular lens (IOL) following cataract surgery.
- Facility or physician charges for resources required for fitting and vision acuity testing of a PC-IOL or AC-IOL that exceeds the facility or physician charges for resources furnished for a conventional IOL following cataract surgery.

These rulings allow facilities and physicians to charge patients only for the non-covered portion of a service that is furnished at the same time as a covered service. Services 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. The beneficiary may only be charged for those non-covered services specified above.

We are providing this guidance because of a recent press release from an ophthalmology practice that described use of bladeless, computer-controlled laser surgery for cataract removal. The press release may imply a different Medicare policy regarding non-covered services that may be charged to the beneficiary if the cataract surgery is performed using a bladeless, computer-controlled laser. The press release states:

While traditional cataract surgery is fully covered by most private medical insurance and Medicare, bladeless cataract surgery requires patients to pay out-of-pocket for the portion of the procedure that insurance does not cover.

Medicare coverage and payment for cataract surgery is the same irrespective of whether the surgery is performed using conventional surgical techniques or a bladeless, computer controlled laser. Under either method, Medicare will cover and pay for the cataract removal and insertion of a conventional intraocular lens. If the bladeless, computer controlled laser cataract surgery includes implantation of a PC-IOL or AC-IOL, only charges for those non-covered services specified above may be charged to the beneficiary. These charges could possibly include charges for additional services, such as imaging, necessary to implant a PC-IOL or an AC-IOL but that are not performed when a conventional IOL is implanted. Performance of such additional services by a physician on a limited and non-routine basis in conventional IOL cataract surgery would not disqualify such services as non-covered services. This guidance does not apply to the use of technology for refractive keratoplasty.
# LenSx® Laser Important Safety Information

## Caution
United States Federal Law restricts this device to sale and use by or on the order of a physician or licensed eye care practitioner.

## Indication
The LenSx® Laser is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

## Restrictions
- Patients must be able to lie flat and motionless in a supine position.
- Patient must be able to understand and give an informed consent.
- Patients must be able to tolerate local or topical anesthesia.
- Patients with elevated IOP should use topical steroids only under close medical supervision.

## Contraindications
- Corneal disease that precludes applanation of the cornea or transmission of laser light at 1030 nm wavelength
- Descemetocoele with impending corneal rupture
- Presence of blood or other material in the anterior chamber
- Poorly dilating pupil, such that the iris is not peripheral to the intended diameter for the capsulotomy
- Conditions which would cause inadequate clearance between the intended capsulotomy depth and the endothelium (applicable to capsulotomy only)
- Previous corneal incisions that might provide a potential space into which the gas produced by the procedure can escape
- Corneal thickness requirements that are beyond the range of the system
- Corneal opacity that would interfere with the laser beam
- Hypotony or the presence of a corneal implant
- Residual, recurrent, active ocular or eyelid disease, including any corneal abnormality (for example, recurrent corneal erosion, severe basement membrane disease)
- History of lens or zonular instability
- Any contraindication to cataract or keratoplasty
- This device is not intended for use in pediatric surgery.

## Warnings
The LenSx® Laser System should only be operated by a physician trained in its use. The LenSx® Laser delivery system employs one sterile disposable LenSx® Laser Patient Interface consisting of an applanation lens and suction ring. The Patient Interface is intended for single use only. The disposables used in conjunction with ALCON® instrument products constitute a complete surgical system. Use of disposables other than those manufactured by Alcon may affect system performance and create potential hazards. The physician should base patient selection criteria on professional experience, published literature, and educational courses. Adult patients should be scheduled to undergo cataract extraction.

## Precautions
- Do not use cell phones or pagers of any kind in the same room as the LenSx® Laser.
- Discard used Patient Interfaces as medical waste.

## AEs/Complications
- Capsulotomy, phacofragmentation, or cut or incision decentration
- Incomplete or interrupted capsulotomy, fragmentation, or corneal incision procedure
- Capsular tear
- Corneal abrasion or defect
- Pain
- Infection
- Bleeding
- Damage to intraocular structures
- Anterior chamber fluid leakage, anterior chamber collapse
- Elevated pressure to the eye

## Attention
Refer to the LenSx® Laser Operator’s Manual for a complete listing of indications, warnings and precautions.

Information provided in this document is provided as a reference for providers in obtaining appropriate and accurate reimbursement. Content is for information purposes only and is not a guarantee that guidance will result in reimbursement to the provider. Providers may always consult with payers directly in regard to billing and reimbursement.