

Femtosecond Laser System for Cataract Surgery: Billing Guide

Overview

On November 16, 2012 the Centers for Medicare and Medicaid Services (CMS) released a guidance document addressing the use of a femtosecond laser system (FLS) in cataract procedures performed for Medicare beneficiaries¹.

The guidance applies the principles of CMS rulings for presbyopia-correcting intraocular lenses (IOLs) and astigmatism-correcting IOLs to the use of certain functions of a FLS when used in cataract procedures with conventional or advanced technology IOLs (AT-IOLs).

	COVERED	NON-COVERED	PATIENT'S RESPONSIBILITY
Physician	Surgery for treatment of <u>cataract</u> (66982 or 66984)	Physician's services attributable to the non-covered functionality of the <u>astigmatism correcting IOL (AC-IOL)</u> and <u>presbyopia correcting IOL (PC-IOL)</u> Additional physician work and resources required for insertion, fitting, and vision acuity testing	Payment of charges for the physician services that <u>exceed</u> the physician charge for insertion of a conventional IOL
Facility	Surgery for treatment of <u>cataract</u> (66982 or 66984)	<u>Astigmatism- or presbyopia correcting function of an IOL</u> and any additional resources required for insertion, fitting, and vision acuity testing	Payment of charges for the facility charges that exceed the facility charge for insertion of a conventional IOL

Established by CMS Ruling 05-01 (May 2005) and 1536-R (January 2007).

The American Academy of Ophthalmology (AAO) and the American Society of Cataract and Refractive Surgery (ASCRS) jointly issued guidelines for billing Medicare beneficiaries when using FLS in 2012. It indicated that "the allowable Medicare reimbursement for cataract surgery does not change according to the surgical methods used... Providers may not "balance bill" a Medicare patient or his/her secondary insurer for any additional fees to perform covered components of cataract surgery with an FLS."

References: 1. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/Downloads/CMS-PC-AC-IOL-laser-guidance.pdf>.
2. [http://ascrs.org/sites/default/files/resources/12-04-2012%20FS%20Laser%20Guidelines%20Document%20\(2\)_0.pdf](http://ascrs.org/sites/default/files/resources/12-04-2012%20FS%20Laser%20Guidelines%20Document%20(2)_0.pdf)

*See last page for Important Product Information.

Frequently Asked Questions

1. How does this CMS guidance affect my practice?

- Imaging performed as part of the FL surgery, which is necessary to implant premium refractive IOLs, is considered a non-covered service
- The Medicare beneficiary receiving AT-IOL may be charged for non-covered services (such as imaging), but not for using the FLS to perform covered steps of cataract surgery, such as the phaco incision, capsulotomy, and lens fragmentation

2. Can surgeons charge patients additional fees for using the LenSx® Laser?

- Yes, if the charge is related to the additional service of imaging (and the integrated computations) used to determine the size, shape, and location of a capsulotomy when implanting an AT-IOL
- 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 billable 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 astigmatic keratotomy, then the patient should not be charged for the imaging function of the laser
- The patient may only be billed for the co-pay and deductible for the cataract surgery

Patient Documentation & Advanced Beneficiary Notification (ABN)

The provider should fully educate and inform the patient about the out-of-pocket responsibility prior to treatment.

- Patients are responsible for the charges of tests, services, and items used for their refractive treatment that are considered not medically necessary for treatment of a cataract
- For Original (Fee-for-Service) Medicare Patients:
 - A voluntary ABN of Non-Coverage can be used by providers when Medicare payment is expected to be denied; this would include refraction services
 - When an ABN is used as a voluntary notice, the patient should not be asked to choose an option box or sign the notice
 - When a non-covered service is provided at the same time as a covered benefit (eg, cataract surgery) it is recommended that the patient's understanding of their financial responsibility be documented with an ABN
- For Medicare Advantage and Commercial Patients:
 - A pre-determination can be submitted to the payer to document non-covered services
 - Providers should review each individual plan contract and follow the appropriate process specific to that payer



CENTER FOR MEDICARE

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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 Product Information In Cataract Surgery

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 in the creation of corneal cuts/incisions (single-plane, multi-plane and arcuate), anterior capsulotomy and laser phacofragmentation during cataract surgery. Each of these procedures may be performed either individually or consecutively during the same surgery.
Restrictions	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Corneal disease that precludes appplanation 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 appplanation 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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.