

Elective Intraocular Lens Reimbursement Guide

ACRY *Sof* IQ[®]
ASPHERIC IOL

ACRY *Sof* IQ[®]
ReSTOR[®]
MULTIFOCAL IOL

ACRY *Sof* IQ[®]
TORIC
ASTIGMATISM IOL

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Alcon Reimbursement Services has developed this guide as part of the various support programs offered to help ensure understanding of the basic reimbursement concepts related to Alcon's elective intraocular lenses.

This document will provide general information for navigating through some of the complicated and ambiguous issues being raised about the purchasing of elective intraocular lenses (IOLs), billing and coding for their implantation, advertising the availability of these IOLs, and the co-management of patients who choose to have an elective IOL inserted at the time of cataract surgery. This guide is not exhaustive of all questions or nuances that may arise and is not intended to be legal advice. If you have questions about the information in this guide, please contact Alcon Reimbursement Services.

We hope you find this manual useful.



SECTION I IOL Reimbursement Background

History

For many years, payers - both Medicare and most commercial insurers - have bundled reimbursement for intraocular lenses (IOLs) implanted at the time of cataract removal surgery in the payment for the cataract surgical procedure. Therefore, payments attributable to IOLs are not readily identifiable. As a result, it is difficult to assert that payments for IOLs have not kept pace with the cost of new technology when you cannot decipher the actual payment rate for the IOL as opposed to the physician service.

The rapid development of new IOL technology is unprecedented. It is hard to find any other category of medical devices that evolves and improves almost annually. The past several years have proven to be some of the most progressive with the introduction of IOLs that address not only post-cataract removal aphakia, but also refractive problems such as presbyopia or astigmatism. These lenses have been coined by the industry as “elective IOLs.” Prior to elective IOLs that correct two separate medical conditions, there have been many IOLs developed that corrected aphakia better or with fewer complications than earlier models. For example, lenses have been developed that reduce spherical aberration.

Ambulatory Surgery Centers – New Technology Intraocular Lens (NTIOL)

Payment System

NOTE: The NTIOL category for reduced spherical aberration expired on February 26, 2011.

Medicare has recognized the importance of continued advancements of IOL research and development, and has attempted to set up systems whereby truly new technology IOLs offering patients improved clinical outcomes are reimbursed more than the typical payment bundled into the reimbursement for cataract surgery with IOL. IOLs entitled to a payment adjustment under the ambulatory surgery centers (ASCs) reimbursement methodology are called New Technology IOLs (NTIOLs). Each year, Medicare accepts requests from manufacturers, physicians, medical societies, and from the public at large to have a new IOL classified as an NTIOL. To be granted this status by Medicare, the IOL must be determined by CMS to be FDA approved and have a new characteristic that provides **meaningful and superior clinical improvements** in patient outcomes as compared to existing IOLs. Examples of such superior outcomes include accelerated post-operative recovery, more stable post-operative visual acuity, or a decreased need for diagnostic or therapeutic interventions post-surgery. Medicare pays ASCs an additional \$50 for IOLs deemed to be NTIOLs for up to five years. Patients may not be charged any additional amounts for the IOL or the physician services.

- On May 19, 2006, the AcrySof® IQ IOL (model SN60WF) was included in the NTIOL (New Technology Intraocular Lenses) category of “Reduced Spherical Aberration” established by CMS on Feb. 2, 2006.
- AcrySof® IQ IOL in AcrySert® Delivery System (model SN60WS) was included in the NTIOL ruling on June 25, 2007.
- NTIOL only applies to Medicare claims in the ASC setting of care.
- Patients may not be charged any additional amounts for the IOL or the physician services.
- AcrySof® IQ Toric IOL (models SN6AT3, SN6AT4, SN6AT5) was included in the NTIOL ruling for dates of service on or after July 31, 2009.

Hospital Outpatient—Pass-Through Payment System

The Medicare hospital outpatient prospective payment system (“HOPPS”) also includes a method for the program to pay additional amounts for two to three years for categories of new and innovative medical devices that are shown to improve patient outcomes and which cost hospitals a “not insignificant” amount in relation to the hospital outpatient prospective APC payment. This program is referred to as transitional pass-through payments. A pass-through category for NTIOLs was in place from August 2000 through the end of 2002, when it was sunset. At the time of sunset, the ophthalmic industry argued that the IOL pass-through category should not be eliminated or that it should be narrowly described (like the current NTIOL categories for ASCs) such that the possibility for pass-through payments would not forever be eliminated for new innovative IOLs. Medicare rejected this argument at the time, but it is unclear what would happen if the government’s position was challenged today.

Two-Aspect Payment System

Both the ASC NTIOL and the HOPPS pass-through payment methodologies necessarily are grounded in the fact that the additional payments are made for IOLs considered to be reasonable and medically necessary. By law, Medicare only may pay for items and services that fall within a coverage benefit category and that are reasonable and necessary based on the current standard of medical care.


In 2004, Medicare was presented with a unique situation when it was faced with the question of how it would pay for a new class of IOLs – the presbyopia-correcting IOLs – that provided patients with both a covered treatment (the correction of aphakia post-cataract extraction), and a non-covered-treatment (the correction of primary presbyopia). After more than a year of consideration, Medicare took a giant leap forward when it adopted a policy where the presbyopia-correcting IOLs were, for payment purposes, separated conceptually into two clinical functions, the function/aspect which is covered by Medicare, and the function/aspect that is not. By recognizing these two distinct functions, Medicare made it possible for the payment of the IOL to also be divided.

CMS Ruling Summary

Ruling	Issued	Description
CMS 05-01	May 3, 2005	Sets forth CMS policy concerning requirements for determining payment for insertion of presbyopia-correcting intraocular lenses (PCIOLs) following cataract surgery. http://www.cms.hhs.gov/Rulings/downloads/CMSR0501.pdf
CMS-1536-R	January 22, 2007	Sets forth CMS policy concerning requirements for determining payment for insertion of astigmatism-correcting intraocular lenses (ACIOLs) following cataract surgery. http://www.cms.hhs.gov/Rulings/downloads/CMS1536R.pdf

Covered vs. Non-covered

Accordingly, Medicare set a policy whereby the federal program would pay for the medically necessary aspect of the IOL and patients would be responsible for the cosmetic, presbyopia-correcting aspect. Medicare has applied this same logic to the class of IOLs that provide correction of astigmatism that exists pre-operatively. Thus, if a patient chooses an ACIOL or a PCIOL, then the patient will be responsible for payment of the presbyopia- or astigmatism-correcting aspect of the elective IOL and any additional physician services that are related **solely** to the refractive correction aspect of the IOL.

 If a patient chooses an ACIOL or a PCIOL, the patient will be responsible for payment of the presbyopia- or astigmatism-correcting aspect of the elective IOL, and any additional physician services that are related solely to the refractive correction aspect of the IOL.

The Medicare policy is exciting not only for Medicare beneficiaries, but also for enrollees in commercial plans since many insurers have opted to follow the Medicare payment rule. However, not all commercial insurers' payment policies mirror the Medicare ruling exactly. Thus, it is imperative that physicians and facilities who are unsure how a particular payer handles elective IOLs seek guidance from the payer before charging the patient. As discussed later in this document, the charging of patients' amounts beyond their applicable deductible and co-payment may be a violation of the law and most payer provider contracts.

SECTION I IOL Reimbursement Background

Both Ruling CMS 05-01 and Ruling CMS-1536-R indicate that a single device can have two clinical functions: 1) one which provides a covered benefit, and 2) one which provides a non-covered benefit. The following is an overview of the application of the two-aspect payment model:

	COVERED	NON-COVERED
FACILITY	Cataract Surgery CPT Codes 66984, 66982 Fee Schedule	Facility charge for surgery w/elective IOL minus facility charge for surgery with conventional IOL equals patient payment
PHYSICIAN	Cataract Surgery CPT Codes 66984, 66982 Fee Schedule	Customary charges for non-covered services equals patient payment

66984 - Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification)

66982 - Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage

Fee schedule - A complete listing of fees used by health plans to pay doctors or other providers.

The basic concept of Medicare Rulings CMS 05-01 and CMS-1536-R (the Rulings) is that Medicare will continue to pay as it always has for the physician and facility services required to perform a medically necessary cataract surgical procedure. But, Medicare will not pay for the additional cost of an elective IOL or the physician/facility services related to the non-covered aspect of the surgery and pre- and post-operative care. While the Rulings set forth a clear rule, it is extremely difficult to create a bright-line rule as to what physician/facility services may be charged to a Medicare beneficiary. Physicians vary in opinion as to what additional services are required to treat a patient who receives a presbyopia-correcting IOL (PCIOL) or an astigmatism-correcting (ACIOL). Further, local Medicare carriers have different rules as to what services are bundled into the payment for cataract surgery with IOL implantation.

Services That May be Billed to the Patient

When a physician or facility provide clearly identifiable, medically appropriate¹ services that are not otherwise included in the physician payment or facility reimbursement for a conventional IOL implant, then the physician and facility may charge the patient for those additional services. The Rulings provide that a physician may “take into account the additional physician work and resources for insertion, fitting, and vision acuity testing of the astigmatism-, or presbyopia-correcting IOL compared to insertion of a conventional IOL” when determining the charge for those services.

Medicare will not pay for the additional cost of an elective IOL or the physician/facility services related to the non-covered aspect of the surgery and pre- and post-operative care.

The physician and facility should accurately document the additional time and resources expended in providing beneficiaries with a PCIOL or ACIOL and establish patient charges at a level reasonably related to the increased time and resources involved. Some ophthalmologists are offering patients the opportunity to pay a single, upfront amount for a package of all the physician services that are required to achieve correction of astigmatism or presbyopia but not required for the treatment of cataract. Provided that patients are informed clearly and realistically about the probability that they may need each of the services in the package, that they are given this information prior to being asked to pay this additional amount, and that there is a reasonable likelihood that such services will be needed by the patient, then this package approach for additional physician charges should not raise any significant problem.

Determining Charges for Non-Covered Services

While neither the Rulings nor commercial payer policies have instituted a dollar limitation on the amount that may be charged for the non-covered services, physicians and facilities must be cautious to avoid allegations that the amount charged for the non-covered service is inflated and designed, in part, to supplement the reimbursement for the covered service. Reimbursement for the covered cataract surgery procedure is subject to the assignment rule, or, for those physicians who do not accept assignment, to the limiting charge rule, and violation of either of these provisions may subject a physician to civil money penalties.

Consequently, aggressive pricing may be viewed as violating the Medicare assignment or limiting charge rule and similar provisions contained in most commercial insurance plans. Any mark-up of the IOL should not differ significantly from a facility's mark-up of

The physician and facility may charge the patient for the additional services which are clearly identifiable as medically appropriate.¹

The physician and facility should accurately document the additional time and resources expended in providing beneficiaries with a PCIOL or ACIOL and establish patient charges at a level reasonably related to the increased time and resources involved.

¹ The term “medically appropriate” is used as distinguished from “medically necessary,” recognizing that the non-covered portion of the astigmatism-correcting IOL implant is not a medically necessary service.


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other services that are separately billed to patients, and physician charges should be in line with the usual and customary charges a practice has in place.

Laws and Regulations

Aggressive charges may also implicate state laws meant to protect patients. For example, Illinois state law considers it unprofessional conduct for a physician to grossly, willfully, and continually overcharge for professional services. Violation of that provision is punishable by administrative sanctions up to and including suspension and revocation of the physician's license to practice medicine. The Illinois Department of Professional Regulation previously has sanctioned a surgeon for grossly overcharging for surgical procedures that required very little expenditure of his time and resources. Most states have similar provisions in their licensing statutes.

In addition, state consumer protection laws, which are designed to ensure that sellers do not take advantage of unknowing buyers of products and services, also may be implicated. Texas, for example, considers any act or practice that takes advantage of the consumer's lack of knowledge or experience to a grossly unfair degree to be an unconscionable action in violation of its consumer protection laws.

 If the charges are packaged, the ophthalmologist should maintain a list of individual charges applicable to each item in the billed package and provide that information to the patient.

Physicians and facilities should be prepared to justify each non-covered service performed and charged to the beneficiary, whether billed separately or packaged. If the charges are packaged, the ophthalmologist should maintain a list of individual charges applicable to each item in the billed package and provide that information to the patient.

Why Backsolving is not a Recommended Method for Calculating Charges

We advise caution if the physician proposes to establish the non-covered fee by taking an aggregate total revenue target and then subtracting the reimbursement amount for cataract surgery. (This is sometimes referred to as the "backsolving" method.) For example, presume a physician implants astigmatism-correcting IOLs in patients with incipient cataracts. (There will be no payment from an insurer because it is not medically necessary to treat the cataract.) Presume further that the physician's global professional charge for this procedure is \$2,500 per eye, exclusive of the facility and lens fee, and that this charge covers all of the pre-, intra-, and post-operative services of the surgeon. Presume still further that for patients who present with visually significant (covered) cataracts, the Medicare payment rate to the physician is \$700 per eye for cataract extraction with insertion of an IOL, and this amount includes payment for pre-, intra-, and post-operative services for treating the cataract.

If this physician determines the professional charge to the Medicare patient for non-covered services simply by subtracting the \$700 Medicare payment from the physician's global charge of \$2,500 (thus charging the patient an additional \$1,800), then there is a risk that such a practice could run afoul of the Medicare assignment or limiting charge rule unless the \$1,800 represents payment for only non-covered services and not payment for the same pre-, intra-, and post-operative services that are already paid for in the \$700 Medicare reimbursement. The most costly item in the \$2,500 global fee likely is the surgery itself, yet the \$700 Medicare payment covers the surgery as well as many of the other pre- and post-operative services bundled in the \$2,500 charge. Thus, the \$1,800 charge to the patient could very well include charges for services that Medicare already paid for as part of cataract surgery.

Further, to the extent that a physician has established customary charges for the same services billed to the patient as non-covered, it would be difficult to justify charging an amount in excess of those customary charges. Figure 1 illustrates how the ill-advised “backsolving” approach described previously can yield a patient charge that is not consistent with the reasonable charges for the various physician services that are encompassed in the \$1,800.

Determining Charges for Non-Covered Refractive Services Related to a Medicare Covered Cataract Surgery Customary Charges vs. “Backsolving” Method

Customary Charge Method		Backsolving Method	
Non-covered refractive services	Customary Charge	\$2,500	Global Charge
Service A	\$100	-\$700	Less Medicare physician reimbursement for surgery (includes payment for pre-, intra-, and post-operative work)
Service B	\$400		
Service C	\$50		
Service D	\$500		
Service E	\$30		
Service F	\$20		
Charge to patient for non-covered services	\$1,100*	\$1,800*	Charge to patient for non-covered services

*Note the inconsistency in these two amounts; both are charges for the same non-covered, non-surgical refractive services. The backsolving approach yields a charge that is higher than the sum of the customary charges for the non-covered services. The difference could be viewed as a subsidy for the cataract surgery payment, thus raising concerns about balance billing.

Commercial Payers

A similar analysis as discussed with respect to the Medicare program applies to commercial payers. Each payer has different rules regarding covered and non-covered services and what services are bundled into their payment for cataract surgery. It is the physician’s responsibility to determine whether the services are medically appropriate and not otherwise included in the reimbursement rate.

Similar to Medicare, commercial insurance plans generally include IOLs as part of a global facility fee paid to the ASC or hospital where a patient undergoes cataract surgery. Further, most commercial third party payers also restrict balance-billing of enrollees. In other words, a physician or facility may not ask a patient to pay the difference between the actual charge for a service and the assigned benefit amount for covered services that the provider has contractually accepted as payment in full. Physicians and facilities may, of course, collect any co-payments and deductibles due in accordance with a health plan’s rules.

In light of the Medicare Rulings, commercial payers have been re-examining their payment policies for refractive IOLs implanted following cataract surgery. While some commercial insurance plans have decided to follow the lead of Medicare, others continue to treat the elective IOLs as a conventional lens and not allow its enrollees to be billed for the non-covered aspect of the IOL and related services.

SECTION II

Billing For The Non-Covered Aspects Of Elective IOLs And The Related Physician And Facility Services

Given the known variation in policy across commercial payers, physicians and facilities are urged to seek guidance from the individual commercial insurance carriers with which they contract to determine how the plan will treat elective IOLs implanted as part of a cataract surgery before charging patients any additional fees.

- Commercial insurance plans generally include monofocal IOLs as part of a global facility fee paid to the ASC or hospital where a patient undergoes cataract surgery.
- Physicians and facilities are urged to seek guidance from the individual commercial insurance carriers with which they contract to determine how the plan will treat elective IOLs implanted as part of a cataract surgery before charging patients any additional fees.
- It is important to properly identify PC and ACIOLs in order for commercial payers to recognize them as non-covered. (See Coding for AcrySof® Intraocular Lenses on page 17.)

Under Medicare and most commercial insurance plans, IOLs are reimbursed as part of the facility fee paid to ambulatory surgery center and hospitals. Physicians cannot bill or be reimbursed by Medicare for the covered portion of elective IOLs. Nevertheless, the issue arises as to whether a physician may purchase elective IOLs from Alcon. Sometimes, a physician seeks to buy a elective IOL because the facility where he/she is credentialed to perform surgery is not willing to stock the elective IOLs. In other cases, the physician wants to own the lens so he/she may realize any profit on the IOL, rather than the facility. Both circumstances raise serious concerns. These issues are discussed below.

Sale of IOLs to Physicians

There are no statutes or regulations that prohibit an IOL manufacturer from selling IOLs directly to physicians. The Federal Food Drug and Cosmetic Act (enforced by U.S. Food and Drug Administration (FDA)) requires distributors of drugs and devices to register with the U.S. and to list the products they distribute. So long as the physician does not repackage, relabel, or process the IOLs in any manner when it resells the IOL to a facility, the physician should meet the definition of “wholesale distributor” and qualify for an exemption from the registration requirements.

In addition to the FDA requirements, many states have licensing laws that may require a physician who resells IOLs to an ASC or hospital to be licensed or registered as a distributor of drugs and devices. A physician should review the medical device and distributor licensing laws in the state in which he or she practices to determine whether a license or registration is required.

Thus, before a physician considers purchasing the elective IOL and reselling the device to a facility, they should realize that he/she is accepting the responsibility, and the related liability, to ensure that the IOLs are maintained and stored in a manner that is consistent with the IOL labeling. Moreover, the physician should check any relevant state law to determine whether he/she must register with the state as a distributor.

Physician Reimbursement for IOLs

Even if there is no state law that prohibits a physician from purchasing the IOLs, the physician should be made aware that there is no mechanism under Medicare or commercial insurance plans for the physician to submit a claim for an IOL implanted in a facility or for the ASC or hospital to bill and collect for the IOLs “on behalf” of the physician. It would be improper for an ASC or hospital to bill the Medicare program for an item which it did not supply or for which it did not incur a cost. In fact, the government could take the view that this conduct could result in a false claim. Even if it were possible for an ASC or hospital to bill for the IOLs on behalf of the physician, some states may prohibit any arrangement where the facility shares reimbursement (fee splits) for services it provides. Florida, for example, prohibits a hospital from entering into any split-fee arrangement in any form with a physician or a surgeon, either directly or indirectly, for patients referred to a hospital by the physician or surgeon.

- Many states have licensing laws that may require a physician who resells IOLs to an ASC or hospital to be licensed or registered as a distributor of drugs and devices.
- Physicians should check any relevant state laws regarding the physician purchase of intraocular lenses.

- The facility must purchase the IOL in order to be reimbursed by Medicare for the covered portion of the lens.
- There is no mechanism under Medicare or commercial insurance plans for the physician to submit a claim for an IOL implanted in a facility or for the ASC or hospital to bill and collect for the IOLs “on behalf” of the physician.
- It would be improper for an ASC or hospital to bill the Medicare program for an item which it did not supply or for which it did not incur a cost.

SECTION III Physician Acquisition Of Elective Lenses

Questions have been raised as to whether a physician could bill for the non-covered portion of the elective IOL and the facility could submit a claim for the covered portion. There is no statute or regulation to date that affirmatively prohibits two parties from billing and collecting for portions of the same IOL. Nevertheless, payers and the government very likely would view this practice with great skepticism. The CMS Rulings suggest that CMS anticipates that it is the facility that will be responsible for charging the patient for the additional cost of the lens (except in the rare instances where a physician performs the cataract surgery in his/her office). Moreover, the facility must purchase the IOL in order to be reimbursed by Medicare for the covered portion of the lens (i.e., no mark-up). In this case, the physician purchaser would have to sell a portion of the IOL to the ASC or hospital in order for the facility to seek reimbursement for the covered portion of the IOL.

Cautions in Pricing the IOL to the Patient

If there are extenuating circumstances such that there is no alternative but for the physician to purchase the IOL, the physician should be extremely cautious about pricing the lens to the patient. Unlike the facility, physicians should seek to recover nothing more than the costs relating to the provision of the lens. In fact, if an ASC agrees to allow a physician to charge the patient for the lens so that the physician can profit by the sale, it could be alleged that the ASC and physician are engaged in a kickback arrangement, as the ASC is allowing the physician the opportunity to profit from the sale of the lens in exchange for the physician's referral of the patient to the surgery center for the Medicare portion of the service. So long as the physician does not profit from the sale of the IOLs, there should be little risk of a kickback allegation.

The same caution should be taken when dealing with commercial payers. Most states have "mini" false claims and anti-kickback statutes that are similar to the federal laws and apply to health care services paid for by commercial insurers and patients. Thus, the same concerns regarding a physician marking-up the cost of the lens applies equally to situations where the government, a commercial plan or the patient is the payer.

Finally, an ASC or hospital also could not submit a claim for cataract surgery without an IOL implant so that the physician could submit a claim for the IOL. Medicare, as well as most participating provider agreements for commercial payers, require physicians or facilities to submit claims that describe accurately what services were provided to a patient. Therefore, if the procedure performed was cataract surgery with the implantation of an IOL, the claim must reflect this procedure. Furthermore, because the standard of care for cataract surgery includes implantation of an IOL, Medicare and most commercial payers reimburse some amount for the IOL, and this amount generally is part of the facility reimbursement for cataract surgery. Consequently, submission of a claim for cataract extraction without an IOL implant could be viewed as improper unbundling as well as a false claim since the CPT code reported would not describe the procedure actually performed.

Both the federal government as well as the states regulate the advertising of health-related services. Regulators tend to be more critical of marketing related to medical products and services because most consumers do not have clinical backgrounds to decipher advertisement puffery. The government also regulates promotion of off-label uses of drugs and devices. In fact, the Office of Inspector General, the Department of Justice, and the State Attorney General are very focused on the off-label use of drugs and devices.

Physician Promotion of Off-Label

Physicians should not advertise the use of a lens for any off-label use. FDA has approved the elective lenses for use as an artificial lens for the correction of visual impairment due to aphakia after cataract surgery. Implanting the lens for any other treatment or procedure is an off-label use. As a matter of basic policy, FDA does not restrict an individual physician from using a device “off-label” and defers to a physician’s clinical decision. There is little doubt that FDA would allow physicians to offer a patient with astigmatism and no cataract the option of vision correction with the implantation of the IOL.

Nevertheless, while the FDA generally defers to an individual physician’s clinical decision of an off-label use of a medical device, FDA does restrict the promotion of off-label procedures by manufacturers. It also has taken action against a physician practice for the off-label advertisement outside the office setting, such as advertising a procedure on a practice web site. In October 2000, FDA issued a Warning Letter to a surgical practice threatening an enforcement action, in part, because the practice’s website referred to an off-label cosmetic use of a medical device. The Warning Letter stated, “[a]lthough physicians may use a legally marketed medical device to treat patients for any intended use that he/she desires within the bounds of his/her state licensing requirements, a licensed practitioner may not promote that medical device for use(s) that have not been approved by FDA.”


Moreover, a physician should be cautious in advertising any procedures using a refractive lens. Any aggressive advertising that creates unreasonable expectations about the clinical outcomes of procedures using a refractive lens may implicate federal and state laws that protect consumers from false and deceptive advertising.

Promotion of Free Services

The offer and advertisement of free services also raises certain issues. Some states have explicit rules regarding the offer of free services. These provisions often are found in the Medical Practice Act for the state. The offer of free services also raises concerns under federal law because the elective IOLs are implanted as part of a covered service, therefore the patient anti-inducement prohibition is applicable.

As part of the Health Insurance Portability and Accountability Act of 1996 (commonly known as HIPAA), the enforcement provisions of the Social Security Act were amended to add a new form of prohibited conduct: the provision of anything of value to a Medicare patient which likely would influence that patient to receive a service from a particular provider, practitioner, or supplier.

This rule does not prohibit providing services at no charge. Instead, surgeons may not promote the fact that they provide these services at no charge as a way to induce the patient to select them for the provision of cataract surgery. If a physician is not comfortable charging for these procedures, and prefers to offer them at no charge, such an offer should be made only after the patient has selected the physician to perform the cataract surgery. This should minimize the risk of an allegation that the provision of free services was designed to induce the patient to select the physician to perform cataract or other covered services.

 Some states have explicit rules regarding the offer of free services. These provisions often are found in the Medical Practice Act for the state.

SECTION V Co-Management And Physician Practice Guidelines

Co-management generally is thought of as the sharing of the post-operative care of a patient between the surgeon who performs a procedure and another qualified health care professional. In ophthalmology, the co-manager typically is a medical ophthalmologist or an optometrist. Co-management itself raises many questions, particularly related to the compensation of the co-manager. These questions are even more pronounced in instances where patients are paying out-of-pocket for a service. This section reviews some of the most common issues that should be considered when co-managing patients.

Payment for Services of a Co-Manager

If the post-operative care of a patient who received an elective IOL actually involves clearly identifiable, medically appropriate post-operative services that are not otherwise paid for as part of the standard post-operative care following cataract surgery with a conventional IOL implant, then the health care professional rendering the post-operative care may charge the patient a fair amount for the care. Yet, given the OIG's historical concern regarding inappropriate co-management arrangements between optometrists and ophthalmologists, and the considerable publicity regarding the Rulings, optometrists should exercise caution to ensure accuracy in billing the patient for non-covered services during the covered post-operative period. If non-covered services are furnished, the optometrist, like ophthalmologists, should document clearly the scope of the additional services and submit the invoice directly to the patient. The ophthalmologist should **not set or otherwise determine** the charges for the optometrist's services.

Ophthalmologists frequently ask whether it is permissible to present patients with a global fee that includes the co-managers fee and the surgeon's fee. While this type of combined billing is not recommended, there is no CMS policy that prohibits an ophthalmologist from charging a combined fee for all non-covered professional services rendered to a Medicare beneficiary. Nevertheless, it is not the most appropriate method of billing for the non-covered post-operative care. It is critical that the ophthalmologist provide patients with an itemized invoice that delineates the specific services from each provider for which the patient is paying and the amount the patient is paying each provider. The patient is entitled to know how much he or she is paying for each provider's services. The ophthalmologist may collect from the patient a single payment for the non-covered services; in doing so, however, the ophthalmologist should merely be acting as a collection agent for the optometrist and/or facility. The ophthalmologist should not be involved in setting the optometrist's fees or determining how much the co-managing optometrist is to be paid.

- If non-covered services are furnished, the optometrist, like ophthalmologists, should document clearly the scope of the additional services and submit the invoice directly to the patient.
- The patient is entitled to know how much he or she is paying for each provider's services.
- The ophthalmologist should not be involved in setting the optometrist's fees or determining how much the co-managing optometrist is to be paid.
- The most appropriate method of billing for the post-operative care is to follow the Medicare guideline of having each provider bill for his or her own services as it minimizes the risk of a kickback allegation.

Billing to Commercial Payers

Ophthalmologists and optometrists also should exercise caution in billing for non-covered post-operative services rendered to private pay patients, as many states have anti-kickback statutes similar to the federal statute and many state licensing laws have ethical conduct requirements that prohibit economic considerations influencing postoperative care decisions. Similar to the analysis discussed above, the most appropriate method of billing for the post-operative care is to follow the Medicare guideline of having each provider bill for his or her own services as it minimizes the risk of a kickback allegation.

Another common problem in connection with co-management of enrollees in commercial plans is that many commercial payers do not include optometrists on their provider panels or reimburse for optometric services. Thus, an optometrist co-managing a patient enrolled in such a commercial plan has no method to submit a claim for payment for performing covered post-operative services. Moreover, if the services are provided in a state with a prohibition on splitting of professional fees, then the ophthalmologist could not share the fee received for post-operative care with the optometrist. In these cases, ophthalmologists and optometrists are advised to contact the commercial payer to determine whether the ophthalmologist may collect the co-management fee on behalf of the optometrist.

Regardless of whether a patient is covered by Medicare or a commercial payer, patients should be fully informed about the clinical aspects of the surgery, as well as the financial aspects. Patients should be educated that cataract surgery with insertion of an elective lens includes both covered and non-covered items and services, and regardless of whether a patient will be charged one all-inclusive amount for the non-covered services, the patient should be given an itemized list of the services for which the patient will be required to pay. If the surgeon has determined a patient's clinical status is such that transfer of care to a co-manager is medically acceptable, and the patient has expressed his/her desire to return to a primary care eye care professional for the postoperative care, then transfer is acceptable. It is critical to remember that it is the patient's choice as to whether he/she wants to return to an optometrist, and it should be documented by a signed consent form. It is not the optometrist's decision.

A copy of the signed co-management consent form should be retained in the medical record.

- Ophthalmologists and optometrists also should exercise caution in billing for non-covered post-operative services rendered to private pay patients, as many states have anti-kickback statutes.
- We recommend strongly that providers be prepared to explain their additional charges to patients on a per item basis.
- A copy of the signed co-management consent form should be retained in the medical record.
- It is the patient's choice as to whether he/she wants to return to an optometrist, and it should be documented by a signed consent form. It is not the optometrist's decision.

SECTION VI Conclusion And Summary

This Reimbursement Guide was developed to provide physicians and facilities with general guidance regarding the application of CMS Rulings CMS 05-01 and CMS-1536-R. CMS has issued MedLearn publications to explain the Rulings and to identify the various IOLs to which the Rulings apply. If a provider has questions regarding what services may be billed to a patient, the provider should contact the payor which is involved for specific guidance. Moreover, it is important for physicians and facilities to recognize that patients have a right to know what services they are paying for and the amount for the services. We recommend strongly that providers be prepared to explain their additional charges to patients on a per item basis.

If you have any additional questions about elective IOLs, feel free to contact your Alcon Surgical Sales Representative. Additional resources including sample forms can be found at <http://ARS.alcon.com>.

For reimbursement related questions, please contact:



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