ARS
ALCON REIMBURSEMENT SERVICES

Alcon®

Reimbursement Guide for Advanced Technology Intraocular Lenses

a Novartis company

Alcon Reimbursement Services has developed this guide to provide an understanding of the basic reimbursement concepts related to Alcon's Advanced Technology Intraocular Lenses (ATIOLs).

This document will provide general information for navigating through some of the complicated and ambiguous issues about the purchasing of ATIOLs, billing and coding for their implantation, and the co-management of patients who choose to have an ATIOL 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 or your healthcare attorney.

We hope you will find this manual useful.

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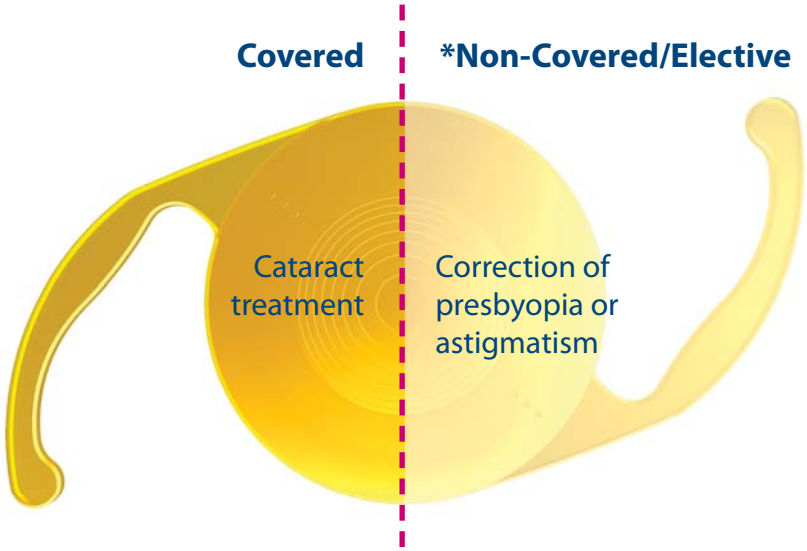
Cataract and Intraocular Lens Reimbursement: Then and Now

Historically, Medicare and most commercial insurers have packaged the reimbursement of a conventional intraocular lens (IOL) implanted during cataract removal surgery with the cataract surgical procedure. In recent years, with the introduction of advanced technology intraocular lenses (ATIOLs) like those that correct refractive problems (e.g., presbyopia and astigmatism), the reimbursement methodology for cataract surgery has evolved.

In 2005 and 2007, The Centers for Medicare and Medicaid Services (CMS) issued landmark Rulings that provide Medicare beneficiaries a choice between cataract surgery with a conventional IOL (a covered service and supply), or cataract surgery with an ATIOL (a partially-covered service and partially-covered supply).

This guide is intended to provide direction for providers whose patients elect insertion of an ATIOL, and guidance on how to properly bill for both the covered and non-covered items and services.

ATIOLs: One lens, two components (covered and non-covered).



*Patient's responsibility

Medicare's Payment Methodology for ATIOLs

By law, Medicare can only 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 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 covered*. By recognizing these two distinct functions, Medicare made it possible for the payment of the IOL to also be separated. The original Ruling regarding presbyopia-correcting IOLs in 2005 was followed in 2007 by a Ruling of the same type for astigmatism-correcting IOLs.

The payment methodology recognizing both a covered and non-covered component of one device is commonly referred to as the two-aspect payment model.

Summary of the CMS Rulings for presbyopia- and astigmatism-correcting intraocular lenses:

CMS Ruling	Date	Purpose
CMS 05-01	May 3, 2005	Set forth the CMS policy regarding the covered and non-covered aspect of **presbyopia**-correcting lenses and outlined the Medicare beneficiary's responsibility for the non-covered item/services.
CMS 1536-R	January 22, 2007	Set forth the CMS policy regarding the covered and non-covered aspect of **astigmatism**-correcting lenses and outlined the Medicare beneficiary's responsibility for the non-covered item/services.

Centers for Medicare and Medicaid Services, Ruling 05-01: https://www.cms.gov/Rulings/downloads/CMSR0501.pdf
Centers for Medicare and Medicaid Services, Ruling CMS 1536-R: https://www.cms.gov/Rulings/downloads/CMS1536R.pdf

The Medicare Rulings are positive not only for Medicare beneficiaries, but also for enrollees in commercial plans because most insurers follow the Medicare two-aspect payment rule. However, not all commercial insurers' payment policies mirror the Medicare Ruling exactly. For this reason, it is imperative that physicians and facilities who are unsure how a particular payor views billing for ATIOLs seek guidance from the payor before charging the patient. As discussed later in this document, charging patients amounts beyond their applicable deductible and co-payment may be a violation of the law and most payor/provider contracts.

Covered vs. Non-covered Components of ATIOLs

Both Ruling CMS 05-01 and Ruling CMS-1536-R recognize 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.

In basic terms, the CMS Rulings state that if a patient chooses an ATIOL, then the patient will be responsible for payment of the cosmetic presbyopia- or astigmatism-correcting aspect of that IOL and any additional physician services that are related ***solely*** to the refractive correction aspect of the IOL.

The following is an overview of the covered and non-covered relevance of the two-aspect payment model for ATIOLs.

	Covered	Non-Covered	Patient's Responsibility
Physician	Surgery for treatment of cataract (e.g., CPT®[1] code 66982,or 66984)	Physician's services attributable to the non-covered functionality of the ATIOL (astigmatism or presbyopia correction). Additional physician work and resources required for insertion, fitting, and vision acuity testing.	Payment of charges for the physician services that exceed the physician charge for insertion of a conventional IOL.
Facility	Surgery for treatment of cataract (e.g., CPT® code 66982, or 66984)	Astigmatism- or presbyopia correcting function of an IOL 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.

66984 - *Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure),*
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 capsulorhexis) or performed on patients in the amblyogenic developmental stage manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification)*

[1] CPT is a registered trademark of the American Medical Association.

Non-Covered Services That May be Billed to the Patient

The fundamental concept of Medicare Rulings CMS 05-01 and CMS-1536-R 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 ATIOL or the physician and facility services related to the *non-covered aspect* of the surgery and pre- and post-operative care. While the Rulings set forth a clear regulation, 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 or an astigmatism-correcting IOL. Local Medicare carriers also have different rules as to what services are bundled into the payment for cataract surgery with IOL implantation.

Medicare pays for	Patient pays for
Medically necessary cataract surgical procedure	Services and items that are elective and not medically necessary (e.g., items and services related purely to the correction of presbyopia or astigmatism)

When a physician or facility provide *clearly identifiable, medically appropriate*[2] 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.

The physician and facility should accurately document the additional time and resources spent in providing beneficiaries with an ATIOL 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 problems.

[2] The term "medically appropriate" is used as distinguished from "medically necessary", recognizing that the non-covered portion of the ATIOL implant is not a medically necessary service.

Use of a Femtosecond Laser System (FLS) in ATIOL Cataract Surgery

CMS released a guidance document on November 16, 2012 addressing use of a femtosecond laser system (FLS) in cataract procedures performed on Medicare beneficiaries.[3] The guidance applies the principles of the CMS rulings to the use of certain functions of an FLS when used in cataract procedures with conventional or ATIOLs.

The guidance provides that

- 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.
- The surgeon may use an FLS in cataract surgery with a conventional IOL without charge to the patient, but doing so routinely or on an unlimited basis will eliminate the ability to charge ATIOL patients for the use of the imaging function.
- Use of an FLS to perform refractive keratoplasty for the purpose of correcting astigmatism is a non-covered service and not part of cataract surgery; consequently, patients may be charged for the use of an FLS to correct pre-existing astigmatism.

Please contact ARS for additional FLS billing guidance.

Determining the Amount Reimbursed for the Conventional Aspect of the ATIOL

In accordance with Rulings 05-01 and CMS 1536-R, facilities are permitted to seek payment from Medicare for the covered portion of the ATIOL, and from the patient for the non-covered portion. A facility is prohibited from asking the patient to pay for the covered portion of the ATIOL, except for the statutorily required co-payment and deductable amounts. Because seeking payment from the patient for a covered item or service is a violation of the Medicare assignment rule, the facility must take into account the fact that an amount designed to cover the covered portion of the lens is packaged with the facility's fee payment.

Medicare packages the covered portion of the lens with the facility's procedure payment (CPT® codes 66984 or 66982). Effective January 1, 2008, the ASC payment methodology transitioned to a system based on the relative weights and APC (groupings used in the OPPS (Outpatient Prospective Payment System). Prior to that change, the covered portion of the lens was easily identifiable because Medicare

[3] http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/Downloads/CMS-PC-AC-IOL-laser-guidance.pdf

added $150 to the ASC facility payment to cover the cost of a conventional IOL implanted at the time of cataract surgery. Prior to 2008, when an ATIOL was implanted, many facilities determined their charge for the non-covered portion by subtracting the $150 from the price of the ATIOL and then marking-up the remaining amount. This methodology also lent itself to a clear understanding that the portion of the lens paid by Medicare was taken into account when determining the charge to a patient for the non-covered portion.

With the 2008 change in ASC payment methodology, however, the Medicare payment for a standard IOL is now bundled as a part of the total OPPS and ASC payment rates for cataract surgery. We know that some portion of the facility payment is related to the IOL because hospitals include the cost of the IOL in charges for a cataract procedure, and this charge data underlies the OPPS and now the ASC payment methodologies. But, it is not possible to determine the amount that is attributed to the lens without a sophisticated analysis of the claims data submitted by hospitals. As a result, facilities no longer have an easily identifiable amount to reflect the payment received from Medicare for the covered portion of an IOL. This change does not mean that facilities now may charge patients for the covered portion. This would be problematic under the assignment rules and subject to civil monetary penalties. Instead, in establishing a charge for the non-covered portion of the ATIOL, each facility is advised to consider the fact that a portion of the facility fee is designed to pay for the covered portion of the lens. Unfortunately, there is no guidance from CMS relating to the appropriate methodology to determine the correct charge. The best ASCs or OPPS departments can is to determine their average cost for a standard monofocal lens and use that amount to represent the covered amount of the ATIOL.

To calculate the patient's non-covered responsibility for the ATIOL implant.

Add	+	Cost of ATIOL including reasonable mark-up
Subtract	–	Average cost to facility for conventional IOL
Total	=	Patient responsibility for non-covered component of ATIOL

Determining the Charges for Non-covered Services

While neither the Rulings nor commercial payor 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 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 Related to Charging the Patient for Non-covered Services

Aggressive charges may also involve 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.

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 Back-solving or Balance Billing is not a Recommended Method for Calculating Charges

The back-solving or balance-billing method is when a provider collects fees from the patient---other than copays and deductibles---for a covered service that exceed the reimbursement amount from a commercial or government payor in order to reach a targeted revenue.

Because the practice of balance-billing is generally a violation of payor/provider agreements, caution should be used in establishing the non-covered fee by taking a revenue target and then subtracting the reimbursement amount for cataract surgery. This method would represent back-solving or balance billing.

For example, presume a physician implants an astigmatism-correcting IOL in a patient with incipient cataracts. (There will be no payment from an insurer because it is not medically necessary to treat the incipient 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.

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. The following example illustrates how the ill-advised "back-solving" 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: Back-Solving Method vs. Customary Charges

Providers should maintain a list of clearly identifiable, medically appropriate services that are not included in the physician or facility reimbursement for cataract surgery with a conventional IOL.

Back-Solving Method (Not recommended)	
Global Charge	$2,500
Less Medicare physician reimbursement for surgery (includes payment for pre-, intra, and post-operative work)	-$700
Charge to patient for non-covered services	**$1,800**

Customary Charge Method (Recommended)	
Non-covered refractive services	**Customary charge**
Service A	$100
Service B	$400
Service C	$50
Service D	$500
Service E	$30
Service F	$20
Charge to patient for non-covered services	**$1,100**

Back-solving method may be viewed as a means to subsidize Medicare reimbursement amount.

*Note the inconsistency in these two amounts; both are charges for the same non-covered, non-surgical, refractive services. The back-solving 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, and consequently will raise concerns about balance billing.

Commercial Payor Considerations

Similar to Medicare, most commercial insurance plans include IOLs as part of a global facility fee paid to the ASC or hospital where a patient undergoes cataract surgery, and most commercial third party payors also restrict balance-billing of their members. 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 agreed to accept 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.

Each payor has different rules regarding covered and non-covered services and what services are bundled into their payment for cataract surgery. It is the provider's responsibility to determine whether the services are medically appropriate and not otherwise included in the payor's reimbursement.

Most commercial payor policies regarding ATIOLs mirror the Medicare Rulings allowing providers to collect the contracted covered benefit amount from the payor, and collect copays, deductibles, and the charges for non-covered services (correction of presbyopia or astigmatism) from the patient. Commercial payor policies and individual payor/provider contracts vary. It is imperative that providers consult individual commercial plans for specifics related to billing patients for non-covered services.

Physician Acquisition of ATIOLs

There are several reasons why it is recommended that the ***facility*** purchase and supply the IOL, as well as collect the non-covered charge for ATIOLs from the patient.

- Medicare reimbursement for the conventional aspect of the ATIOL is packaged with the facility reimbursement for cataract surgery.
- There is no mechanism for the physician to submit a claim for an IOL implanted in the facility, or for the facility to bill "on behalf" of the physician.
- It would be improper for the facility to bill the Medicare program for an item which it did not supply, or for which it did not incur a cost.
- Some states prohibit any "fee-splitting" arrangement between the facility and physician.
- Allowing the physician to realize a mark-up on the IOL (that is customarily supplied by the facility), could be viewed as a kickback arrangement.

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 ATIOLs. Nevertheless, the issue arises as to whether a physician may purchase ATIOLs from the IOL manufacturer. Sometimes, a physician seeks to buy an ATIOL because the facility where he/she is credentialed to perform surgery is not willing to stock the AT- 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.

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)) require 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, re-label, 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.

Caution: Before a physician considers purchasing the ATIOL 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.

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.

Note: 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.

Questions have been raised as to whether a physician could bill for the non-covered portion of the ATIOL 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, payors 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.

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 payors. 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 payor.

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 payors, requires 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 payors 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.

Co-Management and Physician Practice Guidelines

Co-management generally is 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.

If the post-operative care of a patient who received an ATIOL actually involves clearly identifiable, medically appropriate post-operative services that are not otherwise paid for as part of the standard postoperative 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 postoperative 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.

Co-Management and Commercial Payors

Ophthalmologists and optometrists that co-manage ATIOL patients should exercise caution in billing for non-covered post-operative services provided 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 guidance provided previously, 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 payors do not include optometrists on their provider panels or reimburse for optometric services. Therefore, 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. Additionally, 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 payor 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 payor, 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 ATIOL 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 the 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.

For more information on the co-management of ATIOL patients, please refer to the Co-management coding and reimbursement fact sheet provided by ARS.

New Technology Intraocular Lens (NTIOL) Payment System

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 a conventional 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 postoperative 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. At the end of the five years, the additional $50 payment expires. Other than the patient's customary co-pay responsibility, the patient cannot be charged additional for a NTIOL.

IOL models that qualify for payment adjustment by qualifying for new technology status are identified on the CMS website.

ARS will provide a separate FAQ for lenses that are included in an NTIOL category.

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 is encouraged to contact the payor 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 of those services. We recommend strongly that providers be prepared to explain their additional charges to patients on a per item basis.

ALCON REIMBURSEMENT SERVICES
(866) 457-0277
ARS.SupportUS@alcon.com

Important Safety Information for Alcon IOLs

If you have additional questions about billing for ATIOLs, please contact Alcon Reimbursement Services. Additional resources including coding guidance and sample forms are available at **http://ARS.alcon.com**

AcrySof® IQ ReSTOR® Intraocular Lenses

CAUTION:
Federal (USA) law restricts this device to the sale by or on the order of a physician.

INDICATIONS:
The AcrySof® IQ ReSTOR® Posterior Chamber Intraocular Lens (IOL) is intended for primary implantation for the visual correction of aphakia secondary to removal of a cataractous lens in adult patients with and without presbyopia, who desire near, intermediate and distance vision with increased spectacle independence. The lens is intended to be placed in the capsular bag.

WARNING/PRECAUTION:
Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. Physicians should target emmetropia, and ensure that IOL centration is achieved. Care should be taken to remove viscoelastic from the eye at the close of surgery.

Some patients may experience visual disturbances and/or discomfort due to multifocality, especially under dim light conditions. Clinical studies with the AcrySof® ReSTOR® lens indicated that posterior capsule opacification (PCO), when present, developed earlier into clinically significant PCO. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon for this product informing them of possible risks and benefits associated with the AcrySof® IQ ReSTOR® IOLs.

Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof® Natural IOL and normal color vision. The effect on vision of the AcrySof® Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g., glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optic nerve diseases) has not been studied. Do not resterilize; do not store over 45° C; use only sterile irrigating solutions such as BSS® or BSS PLUS® Sterile Intraocular Irrigating Solutions.

ATTENTION:
Reference the Directions for Use labeling for a complete listing of indications, warnings and precautions.

AcrySof® IQ Toric Intraocular Lenses

CAUTION:
Federal (USA) law restricts this device to the sale by or on the order of a physician.

INDICATIONS:
The AcrySof® IQ Toric posterior chamber intraocular lenses are intended for primary implantation in the capsular bag of the eye for visual correction of aphakia and pre-existing corneal astigmatism secondary to removal of a cataractous lens in adult patients with or without presbyopia, who desire improved uncorrected distance vision, reduction of residual refractive cylinder and increased spectacle independence for distance vision.

WARNING/PRECAUTION:
Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. Toric IOLs should not be implanted if the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned. Rotation can reduce astigmatic correction; if necessary lens repositioning should occur as early as possible prior to lens encapsulation. All viscoelastics should be removed from both the anterior and posterior sides of the lens; residual viscoelastics may allow the lens to rotate.

Optical theory suggest, that, high astigmatic patients (i.e. > 2.5 D) may experience spatial distortions. Possible toric IOL related factors may include residual cylindrical error or axis misalignments. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon for this product informing them of possible risks and benefits associated with the AcrySof® IQ Toric Cylinder Power IOLs.

Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof® Natural IOL and normal color vision. The effect on vision of the AcrySof® Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g., glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optic nerve diseases) has not been studied. Do not resterilize; do not store over 45° C; use only sterile irrigating solutions such as BSS® or BSS PLUS® Sterile Intraocular Irrigating Solutions.

ATTENTION:
Reference the Directions for Use labeling for a complete listing of indications, warnings and precautions.

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