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A Division of Ardare Corporation

# Reimbursement and the ReZoom™ IOL

*Prepared for*



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## Reimbursement and the ReZoom™ IOL

by

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**Objective:** *This report is provided as a general discussion of reimbursement for cataract surgery with a multifocal IOL and related issues. Local variations between carriers may occur which are not described here. The user is strongly encouraged to review official instructions promulgated by the Centers for Medicare and Medicaid (CMS), the agency formerly known as the Health Care Financing Administration (HCFA) and their Medicare carriers; this document is not an official source nor is it a complete guide on all matters pertaining to reimbursement. In addition, users should check with their local insurance carriers for approved diagnosis codes and usage guidelines for the services discussed.*

*This discussion is intended to assist the reader to better understand the rules and regulations regarding reimbursement for cataract surgery with implantation of a ReZoom™ IOL. However, the responsibility for appropriate usage, adequate documentation, and proper coding are always the physician's.*

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**Disclaimer:** *The reader is reminded that this information can and does change over time, and may be incorrect at any time following publication.*



## INTRODUCTION

With the recent advances of intraocular lenses, ophthalmic surgeons have new technology to help restore vision for patients with cataracts and to lessen their dependence on glasses following surgery. The AMO ReZoom™ intraocular lens (IOL) offers these attractive benefits to patients. It also poses some new challenges for billing and reimbursement.

This monograph examines how the ReZoom™ IOL fits within longstanding coverage and payment rules for cataract surgery. It addresses those IOL features and related professional services that are considered non-covered as described in the ground-breaking May 3, 2005 CMS<sup>1</sup> ruling, and the associated Transmittal dated August 5, 2005, concerning presbyopia-correcting IOLs. It also identifies the applicable CPT and HCPCS codes as well as ICD-9 codes that pertain to the professional and facility services related to cataract surgery and the implantation of the ReZoom™ IOL. Relevant modifiers are noted as well.

In the Appendix, there are several model forms for your use. These forms may be used to notify patients and third party payers and document the boundary between insurance payments and patient financial responsibility. Several sample letters are included to communicate with third party payers about cataract surgery including implantation of the ReZoom™ IOL.

## THE DEVICE

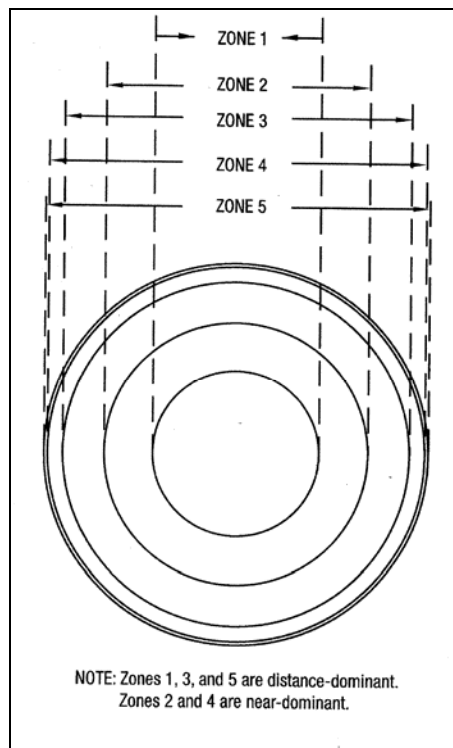
AMO's ReZoom™ Acrylic Multifocal Posterior Chamber Intraocular Lens (IOL) is intended for the visual correction of aphakia in persons 60 years of age or older in whom a cataractous lens has been removed, and who may benefit from useful near vision without reading add and increased spectacle independence across a range

of distances. The lens is intended to be placed in the capsular bag.

The ReZoom™ IOL is a new, second-generation acrylic multifocal IOL that has demonstrated the ability to predictably provide patients a full range of quality vision with increased freedom from reading glasses or bifocals. The lens features Balanced View Optics™ Technology, designed to provide patients a full range of vision in varying light conditions.

The ReZoom™ IOL optimally distributes 100% of transmitted light over five optic zones for enhanced restoration of visual function. It provides seamless distance, intermediate, and near vision and eliminates or reduces spectacle dependence in over 90% of patients implanted with the lens. Most adults over 50 years old require three or more diopters of near add correction. The ReZoom™ IOL provides up to +3.5 D of near add power at the IOL plane.

### ReZoom™ Acrylic Multifocal IOL



<sup>1</sup> Centers for Medicare and Medicaid Services

By comparison, traditional monofocal IOLs only correct vision at one focal point, usually distance, leaving most patients dependent upon spectacles for near and intermediate vision. The ReZoom™ IOL's proprietary multifocal design provides a range of vision that monofocals cannot match. ReZoom™ lenses are very effective, leaving 97% of all of its patients able to read J3 or better without spectacles.

Additionally, the Balanced View Optics™ Technology greatly minimizes the unwanted visual sensations seen in previous multifocal lenses through its proprietary modified anterior surface. This allows the lens to match its performance characteristics with the lifestyle demands of the patients under varying light conditions.

## PATIENT SELECTION

Careful patient selection is an integral part of any successful surgery. Historically, an individual has been considered an acceptable candidate for cataract surgery when the following characteristics exist<sup>2,3</sup>:

- Objective evidence of a cataract
- Reduced Snellen visual acuity
- Lifestyle complaints or visual symptoms
- Good prognosis for improvement
- Patient can tolerate the procedure
- Patient desires surgery

The optimal candidate for the ReZoom™ IOL should manifest all these criteria, and, in addition, must have the desire to be free of eyeglasses, particularly reading glasses, and must be willing to pay substantially more for a procedure and lens that provide this outcome. In

<sup>2</sup> Agency for Health Care Policy and Research, Division of the Public Health Service of the U.S. Department of Health and Human Services 1993

<sup>3</sup> Preferred Practice Patterns of the American Academy of Ophthalmology

fact, the patients most likely to opt for the ReZoom™ IOL will have much in common with the refractive surgery patient. This means that the patient likely will have high expectations and a lower tolerance for less than ideal outcomes.

Thus, the surgeon who hopes to satisfy these demanding patients should be prepared to consider selection criteria beyond those traditionally used for cataract patients, and be comfortable with excluding some patients who may not be ideal candidates for this procedure or may require additional intervention. For example, the surgeon should contemplate the potential impact of pupils that will not dilate, extraordinarily large pupils at rest, a propensity for posterior capsule opacity, astigmatism, very short or very long eyes, ophthalmic comorbidities, and some occupations that require extraordinary night-time vision.

Within the ophthalmic community, some surgeons advocate using the ReZoom™ IOL in conjunction with clear lensectomy solely for refractive purposes to correct presbyopia. This represents an unapproved, off-label use of the device that is not promoted in the United States by Advanced Medical Optics, and is not discussed in this monograph.

## REIMBURSEMENT

The economic hallmark of cataract surgery with a premium product such as the ReZoom™ IOL is the provider's expectation of additional payment beyond the fees collected for cataract surgery with IOLs that do not offer a chance at spectacle independence. Under most circumstances, such expectations are frustrated by limitations on balance billing. Most third party payers, including Medicare, restrict balance-billing beneficiaries. Balance billing is the practice of asking a beneficiary to pay the difference between the actual charge and the assigned

benefit amount<sup>4</sup> for covered services that the provider has contractually accepted as payment in full. It does not refer to the collection of co-payments and deductibles. At the very least, the provider who balance bills patients may breach his/her pre-existing agreement with the payer, which could result in termination of his/her provider agreement and/or other contractual remedies such as monetary penalties. Some state insurance laws or consumer protection laws also might be implicated.

Despite the prohibitions against balance billing, third party payers generally agree that enrollees may be billed for non-covered services. In this context, it is useful to clearly define and separate covered from non-covered services and to obtain the patient's voluntary acceptance of financial responsibility for the latter.

### CMS Ruling

On May 3, Dr. Mark McClellan, Administrator of CMS, published a ground-breaking new ruling concerning access to presbyopia-correcting IOLs for Medicare beneficiaries (see Appendix). Simply put, the Medicare program allows beneficiaries to purchase an upgrade from a conventional IOL to a presbyopia-correcting IOL and pay additional charges beyond those associated with standard cataract surgery.

The new ruling makes a clear distinction between covered and non-covered items and services. There is no change in Medicare coverage of medically necessary cataract surgery and the corresponding payments. The charges for additional services to correct presbyopia are not covered and are the patient's responsibility.

A Medicare beneficiary who does not meet Medicare's medical necessity criteria for cataract surgery can pay for the entire procedure. For example, if the beneficiary requests surgery for presbyopia and an incipient cataract that is

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<sup>4</sup> For physicians who are non-participating with Medicare, a limiting charge is imposed by CMS which is generally less than the physician's nominal charge.

visually insignificant, the cataract surgery would not be covered by Medicare.

### Other Third Party Payers

Third party payers are not obliged to agree with the concepts described in the CMS Ruling, although many have. Some have modified CMS's approach; others have dismissed the concept altogether. So, some beneficiaries with visually significant cataracts may find that they cannot obtain a presbyopia-correcting IOL unless they pay for the entire procedure. This was the same position taken by Medicare prior to the recent CMS ruling. Almost certainly, these beneficiaries will be unhappy with such a restrictive policy just as Medicare beneficiaries objected to being excluded from access to new technology. These patients may want to contact their health plan directly to gain some leeway. See the Appendix for a sample patient letter to the health plan.

### Deluxe Items

One very helpful concept that has been well established in other aspects of reimbursement is the notion of a "deluxe" item which incorporates both covered and non-covered elements (*e.g.*, wheelchairs, hearing aids). Within ophthalmology, the classic example is eyeglass frames. The payer establishes a preset covered amount for eyeglass frames and permits the optician to accept payment from the beneficiary for any additional amount to upgrade the frame. It is important to note that this billing method is not balance billing, and that the mechanism for claim submission includes two distinct lines on the claim form to discriminate between the covered and non-covered elements.

### *Example*

Your pseudophakic patient orders a \$300 frame. Medicare allows \$60 for a standard frame. The beneficiary agrees to pay \$240 for a deluxe frame. The claim will read as follows:

21 1. V43.1					
24a	24b	24d	24e	24f	24g
mm/dd/yyyy	12	V2020	1	60.00	1
mm/dd/yyyy	12	V2025 EYGA	1	240.00	1

As with eyeglasses, Medicare and some third party payers have applied the “deluxe” concept to presbyopia-correcting IOLs, permitting providers (*i.e.*, hospitals and ASCs) to collect an extra fee from beneficiaries for the non-covered aspect of an otherwise covered IOL. At the same time, they have also agreed to allow the surgeon to charge the beneficiary for an assortment of ancillary services that constitute extended care for refractive error that are non-covered whether the patient receives a conventional IOL or a presbyopia-correcting IOL. These might include one or more of the following services.

- Refraction to determine refractive error
- Contact lens trial fitting to assess refractive error
- Wavefront aberration testing to assess refractive error
- Corneal topography associated with refractive surgery
- Corneal pachymetry associated with refractive surgery
- Routine eye care, wellness care, or preventive care (*e.g.*, to cope with refractive error)
- Refractive keratoplasty for the purpose of reducing dependence on eyeglasses or contact lenses (*e.g.*, limbal relaxing incisions, corneal relaxing incisions, LASIK, enhancements, etc.)
- IOL exchange in extraordinary cases

Each surgeon will need to construct an individual protocol for refractive services and determine which are appropriate on a case-by-case basis.

Once constructed, the surgeon should establish a reasonable fee for the refractive package considering the services included, and also taking into account what the local market will accept.

To derive a fee, consider the following approach.

1. Develop a comprehensive list of all services included in the extended care package with your usual and customary charge
2. Determine the frequency that each service is likely to occur within the population of patients who elect the ReZoom™ IOL
3. Multiply the frequency times the usual and customary fee to arrive at a weighted average fee
4. Total the weighted average fees to establish the extended care package charge for refractive error

This approach is analogous to CMS’ methodology for establishing relative value units for a procedure using estimates of the time and effort involved.

Prior to surgery, and in addition to informed consent, these beneficiaries should be educated that cataract surgery with a presbyopia-correcting IOL encompasses both covered and non-covered items and services (Figure 1). This concept is sometimes called “patient shared billing” to describe that dichotomy.

Figure 1 **Reimbursement Grid**

	Facility	Physician
Covered	Cataract surgery	Cataract surgery
Not Covered	Deluxe IOL, Keratoplasty	Refractive services

## BILLING ISSUES

### CPT and HCPCS Codes

There are two CPT codes that describe cataract surgery with the ReZoom™ IOL.

- 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)

These codes apply to the surgeon and the facility where the surgery is performed, to report a covered service.

CMS Transmittal 636 dated August 5, 2005 provides instructions for implementation of CMS Ruling No. 05-01, Presbyopia-Correcting Intraocular Lens (P-C IOLs). It states “*No new codes are being established at this time to identify a presbyopia-correcting IOL or procedures and services related to a presbyopia-correcting IOL.*” There is no benefit category for coverage of these services and supplies; therefore, Medicare does not require reporting of these items or services (see Appendix).

For the sake of clarity and line item bookkeeping, it is useful to assign codes to these non-covered items to track them internally. In some situations, it may be necessary to include these items or services on the claim for

reimbursement. For example, a commercial payer may require it; or, the patient may desire a denial from Medicare or another payer for submission to a secondary payer. Some patients just want something official on an Explanation of Medicare Benefits to corroborate what they been told by a staff member. HCPCS codes provide a practical means to identify these non-covered items or services both internally and externally as needed.

HCPCS code V2788, *presbyopia correcting function of IOL*, first published in January 2006, distinguishes the non-covered portion of the IOL from the covered portion. This code may be used by the facility (ASC or HOPD) to report the non-covered or deluxe portion of a presbyopia-correcting IOL.

For Medicare claims filed by the physician, use HCPCS A9270 (*Non-covered item or service*) for the non-covered extended care package for refractive error. (see Figures 2A and 2B for claim examples). It is noteworthy that A9270 is recognizable during electronic claims processing where some other HCPCS codes may not be.

Other third party payers may want more specific codes for the non-covered items and services, although A9270 is a workable fallback alternative. Depending on the terms of the provider’s contract with the third party payer, the intraocular lens may be itemized on the CMS-1500 or UB-92 claim form, or bundled as part of the CPT code (*i.e.*, 66984 or 66982) used to identify the facility fee. The significance of V2788 is the ease with which payments from the insurer and patient can be allocated appropriately and minimize confusion for the patient and office staff. This is particularly important for assigned claims because any contractual adjustments (write-off) apply only to the covered items and services.

Another HCPCS code, S9986 (*Not medically necessary service, patient is aware that service is not medically necessary*) is useful for identifying a package of physician services that

constitute extended care for refractive error that are likewise non-covered. Just like V2788, the significance of S9986 is the added clarity and understanding afforded to all concerned. Misunderstandings with payers and patients may be avoided by straightforward bookkeeping, especially when the potential for balance billing allegations is ever-present.

**Figure 2A Cataract Surgery with Deluxe IOL (Medicare)**

	Facility	Physician
Covered	66984 or 66982	66984 or 66982
Not Covered*	V2788*	A9270*

\* Used for internal tracking and when patient seeks a denial

**Figure 2B Cataract Surgery with Deluxe IOL (Non-Medicare Payer)**

	Facility	Physician
Covered	66984 or 66982	66984 or 66982
Not Covered*	V2788	S9986*

\* Used for internal tracking, if required by payer or when patient seeks denial. A9270 is an alternative HCPCS code for the physician.

Diagnosis Codes

A series of ICD-9 codes apply. For cataract surgery, one of the codes in the 366.xx series is usually used. For refractive services, one of the codes in the 367.xx series is used. The claim is submitted with your usual and customary charge to the insurance company.

Modifiers

The following modifiers may be applicable on claims for cataract surgery with ReZoom™ IOL.

51 ..... Indicates multiple procedures were performed on the same day

79 ..... Indicates unrelated procedure during

the postoperative period (e.g., other eye)

GY ..... Service is statutorily non-covered  
*“Item or service statutorily excluded or does not meet the definition of any Medicare benefit.” (Medicare modifier only)*

RT or LT To identify the eye involved

Sample Claims

Each entity (clinic and facility) should file its own claim, even if owned by the same person or corporation, because contracts with payers are discrete and funds should not be commingled.

**Figure 3A Claim Form for Physician (Medicare)**

19 Patient seeks denial for secondary payer*					
21 1. 366.16 Cataract 2. 367.4 Presbyopia					
24a	24b	24d	24e	24f	24g
mm/dd/yyyy	24	66984 RT	1	\$\$\$\$	1
mm/dd/yyyy	24	A9270-GY *	2	\$\$\$\$	1

\*Included only at the patient's request

**Figure 3B Claim Form for Physician (Non-Medicare Payer)**

19					
21 1. 366.16 Cataract 2. 367.4 Presbyopia					
24a	24b	24d	24e	24f	24g
mm/dd/yyyy	24	66984 RT	1	\$\$\$\$	1
mm/dd/yyyy	24	S9986 *	2	\$\$\$\$	1

\* Included if required by payer or at the patient's request; A9270 is an alternative HCPCS code

**Figure 4A Claim Form for Facility (Medicare)**

19 Patient seeks denial for secondary payer*					
21 1. 366.16 Cataract 2. 367.4 Presbyopia					
24a	24b	24d	24e	24f	24g
mm/dd/yyyy	24	66984 RT	1	\$\$\$\$	1
mm/dd/yyyy	24	V2788-GY *	2	\$\$\$\$	1

\*Included only at the patient's request

**Figure 4B Claim Form for Facility  
(Non-Medicare Payer)**

19					
21					
1. 366.16 Cataract					
2. 367.4 Presbyopia					
24a	24b	24d	24e	24f	24g
mm/dd/yyyy	24	66984 RT	1	\$\$\$\$	1
mm/dd/yyyy	24	V2788 *	2	\$\$\$\$	1

\* Included if required by payer or at the patient's request; A9270 is an alternative HCPCS code

See the Appendix for a sample claim attachment for the ASC or HOPD.

### Anesthesia

Charges and payment for anesthesia services are not affected in any way by the use of a ReZoom™ IOL, or by the concepts inherent in patient shared billing. Claims for anesthesia services remain unchanged.

### **PAYMENT LEVELS**

A small minority of providers do not accept assignment, or elect to opt out of health plans altogether. Their patients simply pay cash for their services without any of the hindrances imposed by insurance regulations. Since more than 90% of claims for reimbursement are assigned, most providers are obligated to accept a previously agreed upon amount as full payment and write off the difference between the stated fee and the allowable fee. Using the ReZoom™ IOL doesn't change that state of affairs. Consequently, most ophthalmic surgeons don't expect to receive full payment for cataract surgery, and neither does the ASC or HOPD. For better or worse, the actual payments are usually indexed to Medicare's fee schedule (see Table 1).

In the schema outlined in Figure 5, the covered services would probably be treated as assigned claims and subject to the discount described above. The contractual adjustment would be written off. The non-covered items and services would not be discounted.

**Table 1 Medicare Reimbursement for  
Cataract Surgery**

	<b>Code</b>	<b>Payment</b>
Physician (1)	66984	\$684
	66982	\$910
ASC (2)	Group 8	\$973
HOPD (3)	APC 246	\$1,388

(1) National Medicare Physician Fee Schedule, 2006 (proposed)

(2) Medicare ASC fees, 2006 national amounts

(3) Hospital Outpatient Prospective Payment, 2006 national amounts

**Figure 5 Cataract Surgery  
with Deluxe IOL**

	<b>Facility</b>	<b>Physician</b>
Covered	Assigned claim; discounted pmt	Assigned claim; discounted pmt
Not Covered	Patient pay	Patient pay

### Patient's Out-of-Pocket Expense

The amount that a patient can expect to pay out-of-pocket varies. The two principal determinants are: 1) the extent of the cataract formation, and 2) the amount of payment expected from Medicare or another third party payer. For patients with visually insignificant cataract, the surgery would not qualify for insurance coverage and the patient could expect to pay for the entire procedure. Alternately, for patients with visually significant cataract, the insurance plan would only cover the standard operation, and the patient would pay for any non-covered items and services, as well as the applicable co-payments and deductible.

Consider the following four patients:

Patient #1 – Employer's health plan

- BCVA 20/50 OU
- 3+ NSC OU
- Patient's out-of-pocket expense -  
*upgrade only*

#### Patient #2 – Employer’s health plan

- BCVA 20/25 OU
- Presbyopic, incipient cataract
- Non-covered
- Patient’s out-of-pocket expense - *entire procedure*

#### Patient #3 – Medicare

- BCVA 20/30 OU
- Presbyopic, incipient cataract
- Non-covered
- Patient’s out-of-pocket expense - *entire procedure*

#### Patient #4 – Medicare

- BCVA 20/50 OU
- 3+ NSC
- Patient’s out-of-pocket expense - *upgrade only*

Because patients are concerned about their financial obligations, but oftentimes too proud or too intimidated to ask for a detailed explanation, it is helpful to anticipate this desire for information and break down the fees in a readily understandable fashion. A solitary all-inclusive number does not segregate the charges that will be reimbursed by insurance from the non-covered fees, and raises the specter of balance billing violations. Most importantly, the patient wants to know what he/she owes, and the provider should take the opportunity to collect payment for the non-covered items and services in advance of the procedure.

## DOCUMENTATION

Other than the usual medical records, there are important documents required to address the economic considerations of cataract surgery with the ReZoom™ IOL. Patients must be notified in advance of financial responsibility, and agree to pay for the non-covered services. The financial agreement with the patient delineates covered and non-covered services and the amount of the patient’s financial responsibility.

For Medicare beneficiaries with visually significant cataract, a Notice of Exclusion from Medicare Benefits (NEMB) serves this objective (see Appendix). The CMS Transmittal 636 advocates the use of this form by the surgeon and the facility to clearly identify the non-covered items and services and the associated fees. The facility and surgeon should each execute an NEMB.

For non-Medicare beneficiaries, an additional requirement exists. Prior to surgery, the third party payer must give permission to the surgeon and the hospital or ASC to bill beneficiaries for presbyopia correction and a deluxe IOL as non-covered services (see sample letters in the Appendix). Also, prior to surgery, the beneficiary must agree to pay for the additional services and the upgrade to a deluxe IOL under the principle of patient shared billing. A Notice of Exclusion from Health Plan Benefits (NEHB) serves to memorialize the acceptance of financial responsibility by the beneficiary (see Appendix). The facility and surgeon should each execute an NEHB.

## CONCLUSION

As cataract surgery has evolved since the introduction of the IOL, surgeons have eliminated or minimized sources of dissatisfaction, including overnight hospitalization, lengthy recovery period, retrobulbar anesthesia injections, and irritating sutures, to name just a few. The ReZoom™ IOL represents another step forward in the evolution of this procedure. Patients who elect this procedure not only want to improve the clarity of their vision, but also enjoy a full range of quality vision. The market for this procedure contains savvy and demanding consumers. Careful patient selection is a crucial part of meeting their expectations.

This new and exciting opportunity for both surgeon and patient poses some unique challenges for practice administration. For example, patients cannot be expected to pay for

the extra cost and additional services inherent in this procedure without a clear understanding of the distinction between covered and non-covered services. To cover all bases, and to avoid allegations of balance billing, providers should educate third party payers prior to the surgery and get written authorization to bill patients for non-covered services. The new CMS ruling makes this unnecessary for Medicare patients.

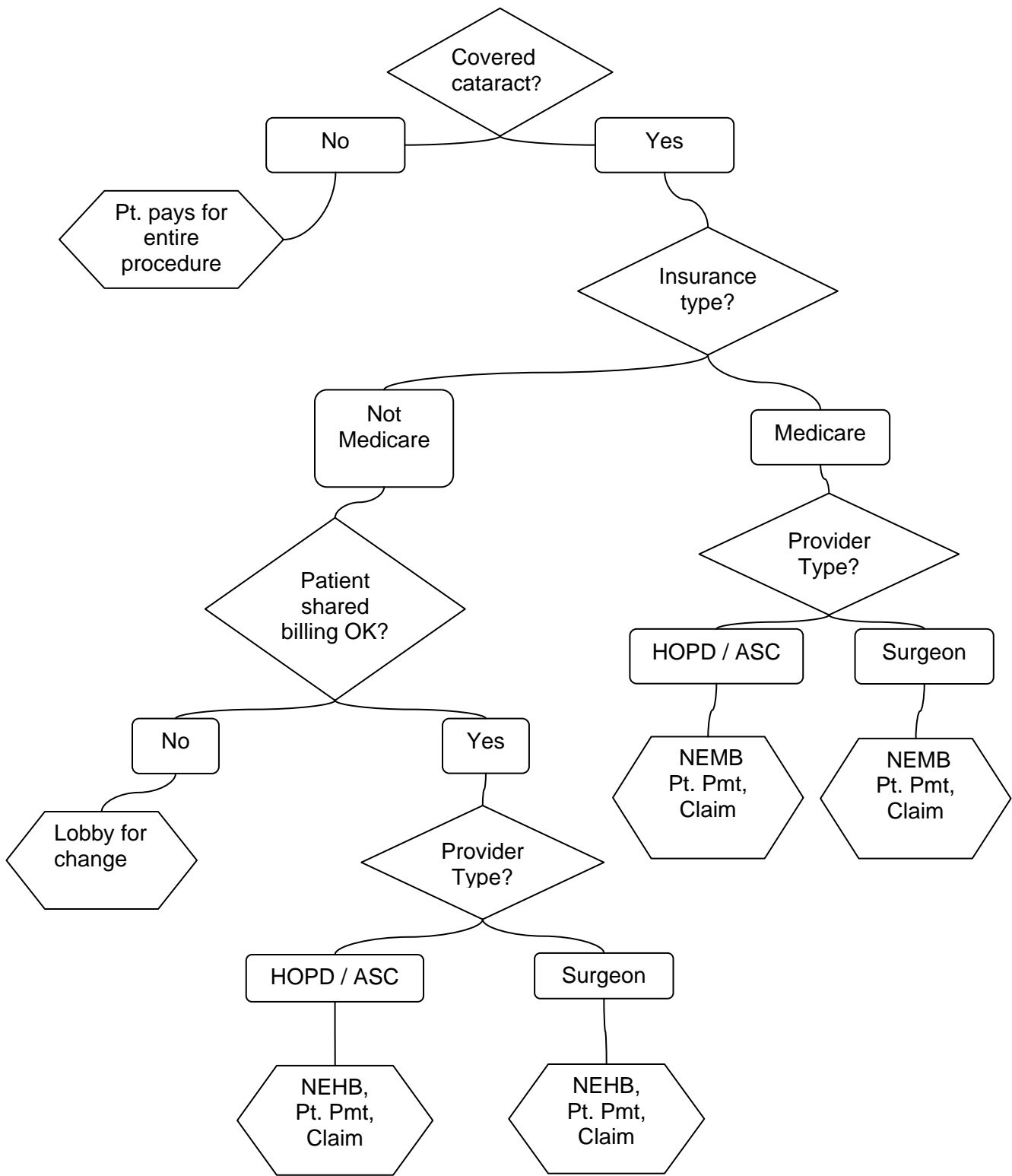
From a bookkeeping perspective, the office staff should make the same distinction when posting charges and payments, and use appropriate CPT and HCPCS codes to identify the pertinent items and services. Good record keeping also entails a paper trail of patient consents, financial waivers, and contract amendments.

Lastly, patients with insignificant cataracts that do not meet the health plan's coverage criteria may still desire the ReZoom™ IOL for refractive purposes. With few exceptions, third party payers do not cover cosmetic refractive procedures.

Figure 6 is a reimbursement schematic that diagrammatically represents all of the concepts discussed in this monograph. The reader is encouraged to use it as a mechanism for sorting out the many varied intersecting issues.

This discussion is intended to assist the reader to better understand the rules and regulations regarding reimbursement for cataract surgery with implantation of a ReZoom™ IOL. However, the responsibility for appropriate usage, adequate documentation, and proper coding are always the physician's.

**Figure 6 Reimbursement Schematic**



## **APPENDIX**

## Sample NEMB for Hospital or ASC

Patient's Name: \_\_\_\_\_

Medicare # (HICN): \_\_\_\_\_

### Notice of Exclusion from Medicare Benefits

- Medicare does **not** pay for all of your health care costs. Medicare only pays for covered benefits. Some items and services are not Medicare benefits and Medicare will not pay for them.
- When you receive an item or service that is not a Medicare benefit, **you are responsible to pay for it, personally or through any other insurance that you may have.**

The purpose of this notice is to help you make an informed choice about whether or not you want to receive these items or services, knowing that you will have to pay for them yourself. **Before you make a decision about your options, you should read this entire notice carefully.**

- Ask us to explain, if you don't understand why Medicare won't pay.
- Ask us how much these items or services will cost you (Estimated Cost: \$\_\_\_\_\_)

#### Medicare will not pay for:

- 1) The deluxe component, or the upgrade feature, of a presbyopia-correcting intraocular lens.
- 2) Refractive keratoplasty for the purpose of reducing dependence on eyeglasses or contact lenses (e.g., limbal relaxing incisions, corneal relaxing incisions, LASIK, etc.).

#### Because it does not meet the definition of any Medicare benefit.

Medicare has established a specific policy\* concerning presbyopia-correction that declares these items and services to be not covered and the financial responsibility of the beneficiary.

\* CMS Ruling No 05-01 (May 3, 2005), and Transmittal 636 (August 5, 2005)

#### Medicare will only pay for:

Standard cataract surgery including the required examinations, testing, follow-up care, and a conventional IOL.

You do not need a presbyopia-correcting IOL and the related services; implantation of this type of IOL is not medically necessary and completely optional. The major difference between cataract surgery with a traditional IOL versus cataract surgery with a presbyopia-correcting IOL is the degree of dependence on eyeglasses thereafter; it's probably less with the presbyopia-correcting IOL.

In addition to the cost of non-covered items and services, you are responsible for the usual co-payments and deductibles associated with covered services (*i.e.*, cataract surgery).

I understand and agree.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of patient or person acting on patient's behalf

## Sample NEMB for Surgeon

Patient's Name:

Medicare # (HICN):

### Notice of Exclusion from Medicare Benefits

- Medicare does **not** pay for all of your health care costs. Medicare only pays for covered benefits. Some items and services are not Medicare benefits and Medicare will not pay for them.
- When you receive an item or service that is not a Medicare benefit, **you are responsible to pay for it**, personally or through any other insurance that you may have.

The purpose of this notice is to help you make an informed choice about whether or not you want to receive these items or services, knowing that you will have to pay for them yourself. **Before you make a decision about your options, you should read this entire notice carefully.**

- Ask us to explain, if you don't understand why Medicare won't pay.
- Ask us how much these items or services will cost you (Estimated Cost: \$\_\_\_\_\_)

#### Medicare will not pay for:

- 1) Added diagnostic tests beyond those required for standard cataract surgery that are necessary for presbyopia correction.
- 2) Refractive keratoplasty for the purpose of reducing dependence on eyeglasses or contact lenses (e.g., limbal relaxing incisions, corneal relaxing incisions, LASIK, etc.).

#### Because it does not meet the definition of any Medicare benefit.

Medicare has established a specific policy\* concerning presbyopia-correction that declares these items and services to be not covered and the financial responsibility of the beneficiary.

\* CMS Ruling No 05-01 (May 3, 2005), and Transmittal 636 (August 5, 2005)

#### Medicare will only pay for:

Standard cataract surgery including the required examinations, testing, follow-up care, and a conventional IOL.

You do not need a presbyopia-correcting IOL and the related services; implantation of this type of IOL is not medically necessary and completely optional. The major difference between cataract surgery with a traditional IOL versus cataract surgery with a presbyopia-correcting IOL is the degree of dependence on eyeglasses thereafter; it's probably less with the presbyopia-correcting IOL.

In addition to the cost of non-covered items and services, you are responsible for the usual co-payments and deductibles associated with covered services (*i.e.*, cataract surgery).

I understand and agree.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of patient or person acting on patient's behalf

Patient's Name: \_\_\_\_\_

## Notice of Exclusion from Health Plan Benefits

You need to make a choice about having cataract surgery with a presbyopia-correcting IOL (e.g., ReZoom™ IOL). Some aspects of this surgery are covered by your health care service plan, however some other aspects are not covered benefits and your health plan will not pay for them. When you receive an item or service that is not a covered benefit, you are responsible to pay for it.

The purpose of this notice is to help you make an informed choice about whether or not you want to receive these items or services, knowing that you will have to pay for them yourself. Before you make a decision about your options, you should read this entire notice carefully. **Ask us to explain, if you don't understand why your health care service plan won't pay.**

Your doctor has recommended cataract surgery with a presbyopia-correcting IOL after determining that you are a good candidate for the procedure, and we expect that your health care service plan will pay for cataract surgery but not for the additional cost of a presbyopia-correcting IOL and the extended care for refractive surgery. You do not need a presbyopia-correcting IOL and the related services; it is optional. The major difference between cataract surgery with a traditional IOL versus cataract surgery with a presbyopia-correcting IOL is the degree of dependence on eyeglasses thereafter; it's probably less with the presbyopia-correcting IOL.

### Cataract Surgery with Presbyopia-Correcting IOL

	FACILITY	PHYSICIAN
<b>COVERED</b>	Cataract Surgery	Cataract Surgery
<b>NOT COVERED</b>	Deluxe component of the presbyopia-correcting IOL, refractive keratoplasty	Extended care for refractive error

Extended care for refractive error includes one or more of the following services.

- Refraction to determine refractive error
- Contact lens trial fitting to assess refractive error
- Wavefront aberration testing to assess refractive error
- Corneal topography associated with refractive surgery
- Corneal pachymetry associated with refractive surgery
- Routine eye care, wellness care, or preventive care (e.g., to cope with refractive error)
- Refractive keratoplasty for the purpose of reducing dependence on eyeglasses or contact lenses (e.g., limbal relaxing incisions, corneal relaxing incisions, LASIK, enhancements, etc.)
- IOL exchange in extraordinary cases

You are responsible for the usual co-payments and deductibles associated with covered services (i.e., cataract surgery). You are also responsible for all of the fees associated with non-covered items and services. The charge for the deluxe component of the IOL is \$\_\_\_\_\_ and the charge for the extended care for refractive error is \$\_\_\_\_\_.

### Beneficiary Agreement

Accordingly, the undersigned accepts full financial responsibility for the non-covered services described above.

\_\_\_\_\_  
Signature of patient or person acting on patient's behalf

\_\_\_\_\_  
Date

## Sample Letter to Health Plan on Behalf of Surgeon

Date

Payer

Address

RE: Contract clarification on correction of refractive error

To Whom It May Concern:

We are seeking clarification of a coverage and payment issue related to cataract surgery with intraocular lens. Following surgery, some patients also would like to reduce their dependence on glasses or contact lenses. For these patients, we offer additional services to reduce or eliminate refractive error, particularly presbyopia. This extended care for refractive error includes one or more of the following services:

- Refraction to determine refractive error
- Contact lens trial fitting to assess refractive error
- Wavefront aberration testing to assess refractive error
- Corneal topography associated with refractive surgery
- Corneal pachymetry associated with refractive surgery
- Routine eye care, wellness care, or preventive care (*e.g.*, to cope with refractive error)
- Refractive keratoplasty for the purpose of reducing dependence on eyeglasses or contact lenses (*e.g.*, limbal relaxing incisions, corneal relaxing incisions, LASIK, enhancements, etc.)
- IOL exchange in extraordinary cases

Removal of a cataract and replacement of the crystalline lens with a prosthetic intraocular lens comports with your coverage guidelines for traditional cataract surgery. Diagnostic and therapeutic services to correct refractive error are usually considered to be non-covered services by Medicare and most third party payers.

Please confirm that any and all of these professional services are not covered benefits of the health plan when performed alone or in concert with cataract surgery. Please contact me if you have any additional questions or concerns. I can be reached at \_\_ (phone) \_\_ or \_\_ (e-mail) \_\_. Thank you for your prompt consideration of this inquiry.

Sincerely,

Surgeon

### Addendum to Contract

The following items and services are not covered benefits of the health plan.

- Services to diagnose and correct refractive error

Plan beneficiaries may choose to pay out-of-pocket for these services, provided they are notified in advance of the additional charges and agree in writing to be responsible for the charges.

All other provisions of the plan remain unchanged.

\_\_\_\_\_  
Name

\_\_\_\_\_  
Title

\_\_\_\_\_  
Date

## Sample Letter to Health Plan on Behalf of ASC or HOPD

Date \_\_\_\_\_

Payer \_\_\_\_\_

RE: Contract clarification on presbyopia-correcting intraocular lens (IOL)

To Whom It May Concern:

We are seeking clarification of a coverage and payment issue that arose from the recent introduction of a unique, deluxe, dual-purpose IOL (ReZoom™ IOL) that is indicated for:

- 1) cataract (366.xx)                      2) presbyopia (367.4)

Removal of a cataract and replacement of the crystalline lens with a prosthetic intraocular lens comports with your coverage guidelines for traditional cataract surgery. Surgery to correct presbyopia is usually considered to be cosmetic refractive surgery and a non-covered service.

Following surgery, most patients still require postcataract glasses for near vision. The ReZoom™ IOL is a multifocal IOL for persons 60 years of age or older with cataract who would benefit from near, intermediate, and far vision without the use of spectacles.

This presbyopia-correcting IOL is more costly than standard monofocal IOLs. We intend to offer your beneficiary the opportunity to receive a standard IOL under the usual terms of the health plan or pay out-of-pocket for the additional cost of the ReZoom™ IOL. This is analogous to the policy for hearing aids where the beneficiary may pay for an upgrade to a more expensive model. Prior to surgery, we will document the beneficiary's election on an insurance waiver. The claim will read as follows:

CPT/HCPCS	Procedure	Benefit
66984	Cataract surgery with IOL	Covered
V2788	Presbyopia correcting function of IOL	Non-covered
Sxxxx	Refractive keratoplasty (if necessary)	Non-covered

Other third party payers, including Medicare, have agreed to this method of billing when cataract surgery is involved (see attached CMS Ruling #05-01). Please confirm that this billing methodology is acceptable to you. Please contact me if you have any additional questions or concerns. I can be reached at \_\_ (phone) \_\_ or \_\_ (e-mail) \_\_. Thank you for your prompt consideration of this inquiry.

Sincerely,

Director of Facility

### Addendum to Contract

The following items and services are not covered benefits of the health plan.

- Upgrade to a presbyopia-correcting intraocular lens
- Refractive keratoplasty for ametropias

Plan beneficiaries may choose to pay out-of-pocket for this upgrade, provided they are notified in advance of the additional charges and agree in writing to be responsible for the charges. All other provisions of the plan remain unchanged.

\_\_\_\_\_  
Name

\_\_\_\_\_  
Title

\_\_\_\_\_  
Date

## Sample Claim Attachment for ASC or HOPD

**Date of service:**

**Patient's name:**

**Procedure:** Cataract extraction with implantation of a presbyopia-correcting intraocular lens (ReZoom™ IOL)

**Indications:** 1) Cataract  
2) Presbyopia

**Description:** Cataract surgery was performed in the customary fashion and the ReZoom™ IOL was implanted.

**Claim Explanation:** The ReZoom™ IOL is a unique and proprietary IOL with dual purposes: 1) to take the place of the cataractous lens, and 2) to reduce the need for postcataract glasses, particularly reading glasses. The first purpose comports with coverage guidelines for traditional cataract surgery. The second purpose is considered to be cosmetic refractive surgery and therefore non-covered.

Prior to surgery, the patient was given the opportunity to receive a standard IOL at no additional charge or the ReZoom™ IOL at an additional charge. The patient elected to receive the ReZoom™ IOL and has agreed to pay for this upgrade.

We expect to be reimbursed for standard cataract surgery and a standard IOL. We do not expect to be reimbursed for the non-covered upgrade to the ReZoom™ IOL.

## Patient's Letter to Health Plan

Date

Health Plan

Dear Sir or Madam:

Recently, my vision diminished to the point that I could not perform normal activities such as reading, driving, and playing sports. I have been diagnosed with cataracts and will undergo cataract surgery with I. Surgeon, M.D.

In addition to having standard cataract surgery, I would also like to reduce my dependency on glasses or contact lenses, as much as possible. Dr. Surgeon has offered to implant a presbyopia-correcting IOL (ReZoom™ IOL) that is intended for persons 60 years of age or older with cataract who would benefit from a full range of vision - near, intermediate and far - and who desire reduced dependence on glasses or contact lenses following cataract surgery.

I understand that there is an extra charge for this IOL that is not covered by my health plan.

Additionally, Dr. Surgeon has offered to provide one or more of the following services besides cataract surgery.

- Refraction to determine refractive error
- Contact lens trial fitting to assess refractive error
- Wavefront aberration testing to assess refractive error
- Corneal topography associated with refractive surgery
- Corneal pachymetry associated with refractive surgery
- Routine eye care, wellness care, or preventive care (*e.g.*, to cope with refractive error)
- Refractive keratoplasty for the purpose of reducing dependence on eyeglasses or contact lenses (*e.g.*, limbal relaxing incisions, corneal relaxing incisions, LASIK, enhancements, etc.)
- IOL exchange in extraordinary cases

I understand that these services are not covered by my health plan.

The staff at Dr. Surgeon's office have explained all of the covered and non-covered charges to my satisfaction, and I have signed a form that details all of the pertinent points prior to surgery. I have assigned my health plan benefits to Dr. Surgeon and the Anywhere Ambulatory Surgery Center. Besides my deductible and co-payment for cataract surgery, I agreed to pay for the non-covered services.

Dr. Surgeon and Anywhere Ambulatory Surgery Center would like corroboration from you that this arrangement is acceptable. Would you please fax your acknowledgement and authorization (see below) to Dr. Surgeon at     (phone)    . Thank you in advance to your prompt attention to this matter.

Sincerely,

Patient

### Health Plan Attestation

The following items and services are not covered benefits of the health plan:

- Upgrade to a presbyopia-correcting IOL
- Services to diagnose and correct refractive error

\_\_\_\_\_  
Name

\_\_\_\_\_  
Title

\_\_\_\_\_  
Date

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# CMS Rulings

Department of Health  
and Human Services

Centers for Medicare &  
Medicaid Services

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Ruling No. 05-01

Date: May 3, 2005

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**CMS Rulings** are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, utilization and peer review by Quality Improvement Organizations, private health insurance, and related matters.

CMS Rulings are binding on all CMS components, Medicare contractors, the Provider Reimbursement Review Board, the Medicare Geographic Classification Review Board, and Administrative Law Judges who hear Medicare appeals. These Rulings promote consistency in interpretation of policy and adjudication of disputes.

This Ruling sets forth CMS policy concerning the requirements for determining payment for insertion of presbyopia-correcting intraocular lenses following cataract surgery under the following sections of the Social Security Act (the Act):

- Section 1832(a)(2)(F) for services furnished in connection with surgical procedures performed in an Ambulatory Surgical Center (ASC).
- Section 1833(t)(1)(B)(iii) for implantable items described in paragraphs (3), (6), or (8) of section 1861(s) that are covered hospital outpatient department services.
- Section 1861(s)(1) for physicians' services.
- Section 1861(s)(2)(A) for services and supplies furnished incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either furnished without charge or included in the physicians' bills. Section 1861(s)(2)(B) for hospital services incident to physicians' services furnished to outpatients.
- Section 1861(s)(8) for one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.
- Section 1862(a)(7) where notwithstanding any other provision of this title, no payment may be made under Medicare Part A or Part B for any expenses incurred for items or services where such expenses are for ...eyeglasses (other than eyewear described in section 1861(s)(8)) or eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes.

## **MEDICARE PROGRAM**

### Supplemental Medical Insurance (Part B)

**TITLE:** Requirements for Determining Coverage of Presbyopia-Correcting Intraocular Lenses that Provide Two Distinct Services for the Patient: (1) Restoration of Distance Vision Following Cataract Surgery, and (2) Refractive Correction of Near and Intermediate Vision with Less Dependency on Eyeglasses or Contact Lenses

**PURPOSE:** This Ruling sets forth the policy of the CMS concerning the requirements for determining payment made for insertion of presbyopia-correcting intraocular lenses following cataract surgery under the following sections of the Act:

- Section 1832(a)(2)(F) for services furnished in connection with surgical procedures performed in an Ambulatory Surgical Center (ASC).
- Section 1833(t)(1)(B)(iii) for implantable items described in paragraphs (3), (6), or (8) of section 1861(s) that are covered hospital outpatient department services.
- Section 1861(s)(1) for physicians' services.
- Section 1861(s)(2)(A) for services and supplies furnished incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either furnished without charge or included in the physicians' bills.
- Section 1861(s)(2)(B) for hospital services incident to physicians' services furnished to outpatients.
- Section 1861(s)(8) for one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.
- Section 1862(a)(7) where notwithstanding any other provision of this title, no payment may be made under Medicare Part A or Part B for any expenses incurred for items or services where such expenses are for ...eyeglasses (other than eyewear described in section 1861(s)(8)) or eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes.

**CITATIONS:** Sections 1832, 1833, 1861, 1862 of the Act; (42 U.S.C. 1395k, 1395l, 1395x, 1395y); (42 CFR 411.15, 489.32).

## **BACKGROUND**

In general, items or services covered by Medicare must satisfy three basic requirements: (1) they must fall within a statutorily-defined benefit category; (2) they must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body part; and (3) the item or service must not be excluded from coverage.

A conventional intraocular lens (IOL) is covered when implanted following cataract surgery. A cataract is an opacity or cloudiness in the crystalline lens of the eye, blocking the passage of light through the lens, sometimes resulting in blurred or impaired vision. A conventional IOL is a small, lightweight, clear disk that replaces the distance focusing power of the eye's natural crystalline lens.

Medicare specifically excludes certain items and services from coverage, including eyeglasses and contact lenses. The Congress, however, has provided an exception for one pair of eyeglasses or contact lenses covered as a prosthetic device furnished after each cataract surgery with insertion of an IOL.

## **PRESBYOPIA-CORRECTING IOLS**

Presbyopia, a type of refractive error, is an age-associated progressive loss of the focusing power of the lens of the eye resulting in difficulty seeing objects at near distance, or close-up. Presbyopia occurs as the natural lens of the eye becomes thicker and less flexible with age. As noted above, except following cataract surgery with insertion of an IOL, Medicare does not cover eyeglasses or contact lenses. Additionally, Medicare also does not cover the accommodative change in eyeglass or contact lens power that is required to compensate for the gradual loss of near vision as presbyopia progresses.

A presbyopia-correcting IOL is indicated for primary implantation in the capsular bag of the eye for the visual correction of aphakia (absence of the lens of the eye) in patients, and is also intended to provide near, intermediate, and distance vision without, in many patients, the need for eyeglasses or contact lenses. A single presbyopia-correcting IOL essentially provides what is otherwise achieved by two separate items: an implantable conventional IOL (one that is not presbyopia-correcting), and eyeglasses or contact lenses.

## **CONCLUSION**

The statute specifically states that one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an IOL is covered. A single presbyopia-correcting IOL essentially provides what is otherwise achieved by two separate items: an implantable conventional IOL (one that is not presbyopia-correcting), and eyeglasses or contact lenses. Although presbyopia-correcting IOLs may serve the same function as eyeglasses or contact lenses furnished following cataract surgery, IOLs are neither eyeglasses nor contact lenses. Therefore, the presbyopia-correcting functionality of an IOL does not fall into the benefit category and is not covered. Any additional provider or physician services required to insert or monitor a patient receiving a presbyopia correcting IOL are also not covered. For example, eye examinations performed to determine the refractive state of the eyes following insertion of a presbyopia-correcting IOL are non-covered.

### Facility Charge

The payment for insertion of a conventional IOL furnished in a hospital outpatient department or in a Medicare-approved ambulatory surgical center is packaged or bundled into the payment for the surgical procedure performed to remove a cataractous lens. A beneficiary may request insertion of a presbyopia-correcting IOL in place of a conventional IOL following cataract surgery. In this case, the facility charge for insertion of the presbyopia-correcting IOL is considered partially covered. The beneficiary is responsible for payment of that portion of the facility charge that exceeds the facility charge for insertion of a conventional IOL following cataract surgery. In addition, the beneficiary is responsible for the payment of facility charges for resources required for fitting and vision acuity testing of a presbyopia-correcting IOL that

exceeds the facility charges for resources furnished for a conventional IOL following cataract surgery.

### Physician Services Charge

The payment for a conventional IOL furnished in a physician's office is not bundled with the procedure to insert the IOL following cataract surgery. The payment amounts for the IOL device and insertion procedure are two separate charges. A beneficiary may request insertion of a presbyopia-correcting IOL in place of a conventional IOL following cataract surgery. In this case, the presbyopia-correcting IOL device is considered partially covered. The beneficiary is responsible for payment of that portion of the physician's charge for the presbyopia-correcting IOL that exceeds the physician's charge for a conventional IOL following cataract surgery.

Regardless of site-of-service for insertion of a presbyopia-correcting IOL, the beneficiary is responsible for payment of physician services attributable to the non-covered functionality of a presbyopia-correcting IOL inserted following cataract surgery. In determining the physician service charge, the physician may take into account the additional physician work and resources required for insertion, fitting, and vision acuity testing of the presbyopia-correcting IOL compared to insertion of a conventional IOL. The beneficiary is responsible for payment of the charges for physician services that exceeds the physician charge for insertion of a conventional IOL following cataract surgery.

### **EFFECTIVE DATE**

This Ruling is effective May 3, 2005.

**Dated:** \_\_\_\_\_

\_\_\_\_\_  
**Mark B. McClellan,**  
Administrator,  
Centers for Medicare & Medicaid Services.

# CMS Manual System

Department of Health & Human  
Services

## Pub 100-04 Medicare Claims Processing

Centers for Medicare & Medicaid  
Services

Transmittal 636

Date: AUGUST 5, 2005

### Change Request 3927

**SUBJECT: Instructions for Implementation of CMS Ruling 05-01; Presbyopia-Correcting Intraocular Lens (P-C IOLs)**

**I. SUMMARY OF CHANGES:** This instruction announces a new CMS Administrator Ruling regarding presbyopia-correcting intraocular lenses (P-C IOLs) following cataract surgery. The new policy is effective for dates of service on and after May 3, 2005.

**NEW/REVISED MATERIAL :**

**EFFECTIVE DATE : May 3, 2005**

**IMPLEMENTATION DATE : September 6, 2005**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)

R = REVISED, N = NEW, D = DELETED

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N/A	

**III. FUNDING:**

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2005 operating budgets.

**IV. ATTACHMENTS:**

One-Time Notification

*\*Unless otherwise specified, the effective date is the date of service.*

## Attachment -- One-Time Notification

Pub. 100-04

Transmittal: 636

Date: August 5, 2005

Change Request  
3927

**SUBJECT: Instructions for Implementation of CMS Ruling 05-01; Presbyopia-Correcting Intraocular Lenses (P-C IOLs)**

### I. GENERAL INFORMATION

**A. Background:** The CMS rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, utilization and peer review by Quality Improvement Organizations, private health insurance, and related matters.

The CMS rulings are binding on all CMS components, Medicare contractors, the Provider Reimbursement Review Board, the Medicare Geographic Classification Review Board, and Administrative Law Judges who hear Medicare appeals. These rulings promote consistency in interpretation of policy and adjudication of disputes.

On May 3, 2005, CMS issued CMS Ruling 05-01, which sets forth CMS policy concerning the requirements for determining payment for insertion of a presbyopia-correcting intraocular lens following removal of a cataract under the Social Security Act (the Act).

- A cataract is an opacity or cloudiness in the crystalline lens of the eye, blocking the passage of light through the lens, sometimes resulting in blurred or impaired vision. Surgical extraction of the clouded lens and insertion of an artificial intraocular lens is the conventional treatment for cataracts.
- Presbyopia is a type of age-associated refractive error that results in progressive loss of the focusing power of the lens of the eye, causing difficulty seeing objects at near distance, or close-up. Presbyopia occurs as the natural lens of the eye becomes thicker and less flexible with age.
- A presbyopia-correcting IOL is indicated for primary implantation in the capsular bag of the eye for the visual correction of aphakia (absence of the lens of the eye) following cataract extraction that is intended to provide near, intermediate, and distance vision without the need for eyeglasses or contact lenses.

### B. Policy:

#### Coverage Policy

1. In general, an item or service covered by Medicare must satisfy three basic requirements:

- a. Fall within a statutorily-defined benefit category;
  - b. Be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body part;
  - c. Not be excluded from coverage.
2. The Act specifically excludes eyeglasses and contact lenses from coverage, with an exception for one pair of eyeglasses or contact lenses covered as a prosthetic device furnished after each cataract surgery with insertion of an IOL.
3. There is no Medicare benefit category to allow payment for the accommodative change in eyeglass or contact lens power that is required to compensate for the gradual loss of near vision as presbyopia progresses.
4. The presbyopia-correcting IOL is intended to provide what is otherwise achieved by two separate items: an implantable conventional IOL (one that is not presbyopia-correcting), and eyeglasses or contact lenses.
5. Although presbyopia-correcting IOLs may serve the same function as eyeglasses or contact lenses furnished following removal of a cataract, presbyopia-correcting IOLs are neither eyeglasses nor contact lenses.

**BENEFIT SUMMARY**

<b>Benefits for Which Medicare Makes Payment</b>	<b>Services for Which Medicare Does NOT Pay – No Benefit Category</b>
A conventional intraocular lens (IOL) implanted following cataract surgery.	The presbyopia-correcting functionality of an IOL implanted following cataract surgery.
Facility or physician services and supplies required to insert a conventional IOL following cataract surgery.	Facility or physician services and resources required to insert and adjust a presbyopia-correcting IOL following cataract surgery that exceed the services and resources furnished for insertion of a conventional IOL.
One pair of eyeglasses or contact lenses as a prosthetic device furnished after each cataract surgery with insertion of an IOL.	The accommodative change in eyeglass or contact lens power required to compensate for the gradual loss of near vision as presbyopia progresses.
Eye examinations performed to determine the refractive state of the eyes specifically associated with insertion of a presbyopia-correcting IOL (including subsequent monitoring services) that exceed the one-time eye examination following cataract surgery with insertion of a conventional IOL.	

## **Definition of IOLs**

1. A “conventional IOL” means a small, lightweight, clear disk that replaces the distance focusing power of the eye’s natural crystalline lens. When a conventional IOL is inserted subsequent to removal of a cataract, eyeglasses or contact lenses are usually required to provide near or intermediate vision.
2. A “new technology IOL” (NTIOL) means an IOL that is furnished by an ambulatory surgery center (ASC) and that CMS determines has been approved by the FDA for use in labeling and advertising the IOL’s claims of specific clinical advantages and superiority over existing IOLs with regard to reduced risk of intraoperative or post-operative complication or trauma, accelerated postoperative recovery, reduced induced astigmatism, improved postoperative visual acuity, more stable postoperative vision, or other comparable clinical advantages. Currently there are no NTIOLs that are approved for special payment when furnished by an ASC. As of May 18, 2005, the new technology designation expired for the second of the two IOLs that had previously been designated as NTIOLs.
3. A “presbyopia-correcting IOL” is indicated for primary implantation in the capsular bag of the eye for the visual correction of aphakia (absence of the lens of the eye) following removal of a cataract that is intended to provide near, intermediate, and distance vision without the need for eyeglasses or contact lenses. Effective for services furnished on or after May 3, 2005, CMS now recognizes the following as presbyopia-correcting IOLs:
  - a. Crystalens™, manufactured by Eyeonics, Inc.
  - b. AcrySof RESTOR™, manufactured by Alcon Laboratories, Inc.
  - c. ReZoom™, manufactured by Advanced Medical Optics, Inc.

## **Payment Policy for Facility Services and Supplies**

1. For an IOL inserted following removal of a cataract in a hospital, on either an outpatient or inpatient basis, that is paid under the hospital Outpatient Prospective Payment System (OPPS) or the Inpatient Prospective Payment System (IPPS), respectively; or in a Medicare-approved ambulatory surgical center (ASC) that is paid under the ASC fee schedule:
  - a. Medicare does not make separate payment to the hospital or the ASC for an IOL inserted subsequent to extraction of a cataract. Payment for the IOL is packaged into the payment for the surgical cataract extraction/lens replacement procedure.
  - b. Any person or ASC, who presents or causes to be presented a bill or request for payment for an IOL inserted during or subsequent to cataract surgery for

which payment is made under the ASC fee schedule, is subject to a civil money penalty.

2. For a presbyopia-correcting IOL inserted subsequent to removal of a cataract in a hospital, on either an outpatient or inpatient basis, that is paid under the OPPI or the IPPS, respectively; or in a Medicare-approved ASC that is paid under the ASC fee schedule:

- a. The facility shall bill for removal of a cataract with insertion of a conventional IOL, regardless of whether a conventional or presbyopia-correcting IOL is inserted. When a beneficiary receives a presbyopia-correcting IOL following removal of a cataract, hospitals and ASCs shall report the same CPT code that is used to report removal of a cataract with insertion of a conventional IOL (see “Coding” below).
- b. There is no Medicare benefit category that allows payment of facility charges for services and supplies required to insert and adjust a presbyopia-correcting IOL following removal of a cataract that exceed the facility charges for services and supplies required for the insertion and adjustment of a conventional IOL.
- c. There is no Medicare benefit category that allows payment of facility charges for subsequent treatments, services and supplies required to examine and monitor the beneficiary who receives a presbyopia-correcting IOL following removal of a cataract that exceed the facility charges for subsequent treatments, services and supplies required to examine and monitor a beneficiary after cataract surgery followed by insertion of a conventional IOL.

### **Payment Policy for Physician Services and Supplies**

1. For an IOL inserted following removal of a cataract in a physician’s office:  
Medicare makes separate payment, based on reasonable charges, for an IOL inserted subsequent to extraction of a cataract that is performed at a physician’s office.
2. For a presbyopia-correcting IOL inserted following removal of a cataract in a physician’s office:
  - a. A physician shall bill for a conventional IOL, regardless of whether a conventional or presbyopia-correcting IOL is inserted (see “Coding,” below).
  - b. There is no Medicare benefit category that allows payment of physician charges for services and supplies required to insert and adjust a presbyopia-correcting IOL following removal of a cataract that exceed the physician charges for services and supplies for the insertion and adjustment of a conventional IOL.

c. There is no Medicare benefit category that allows payment of physician charges for subsequent treatments, services and supplies required to examine and monitor a beneficiary following removal of a cataract with insertion of a presbyopia-correcting IOL that exceed the physician charges for services and supplies to examine and monitor a beneficiary following removal of a cataract with insertion of a conventional IOL.

3. For a presbyopia-correcting IOL inserted following removal of a cataract in a hospital or ASC:

a. A physician may not bill Medicare for a presbyopia-correcting IOL inserted during a cataract procedure performed in those settings because payment for the lens is included in the payment made to the facility for the entire procedure.

b. There is no Medicare benefit category that allows payment of physician charges for services and supplies required to insert and adjust a presbyopia-correcting IOL following removal of a cataract that exceed physician charges for services and supplies required for the insertion of a conventional IOL.

c. There is no Medicare benefit category that allows payment of physician charges for subsequent treatments, services and supplies required to examine and monitor a beneficiary following removal of a cataract with insertion of a presbyopia-correcting IOL that exceed the physician charges for services and supplies required to examine and monitor a beneficiary following cataract surgery with insertion of a conventional IOL.

### **Coding**

1. No new codes are being established at this time to identify a presbyopia-correcting IOL or procedures and services related to a presbyopia-correcting IOL.

2. Hospitals, ASCs, and physicians report one of the following CPT codes to bill Medicare for removal of a cataract with IOL insertion:

a. 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

b. 66983 Intracapsular cataract extraction with insertion of intraocular lens prosthesis (one stage procedure)

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

3. Physicians inserting an IOL or a presbyopia-correcting IOL in an office setting may bill code V2632 (posterior chamber intraocular lens) for the IOL or the presbyopia-correcting IOL, which is paid on a reasonable charge basis.

4. Hospitals, ASCs, and physicians use the following CPT codes to bill Medicare for evaluation and management services usually associated with services following cataract extraction surgery:

a. 92002 Ophthalmological services; medical examination and evaluation with initiation of diagnostic and treatment program; intermediate, new patient

b. 92004 Ophthalmological services; medical examination and evaluation with initiation of diagnostic and treatment program; comprehensive, new patient, one or more visits

c. 92012 Ophthalmological services; medical examination and evaluation with initiation or continuation of diagnostic and treatment program; intermediate, established patient

d. 92014 Ophthalmological services; medical examination and evaluation with initiation or continuation of diagnostic and treatment program; comprehensive, established patient, one or more services

### **Beneficiary Liability**

When the beneficiary requests insertion of a presbyopia-correcting IOL instead of a conventional IOL following removal of a cataract and that procedure is performed, the beneficiary is responsible for payment of facility charges for services and supplies attributable to the presbyopia-correcting functionality of the presbyopia-correcting IOL:

1. In determining the beneficiary's liability, the facility and physician may take into account any additional work and resources required for insertion, fitting, vision acuity testing, and monitoring of the presbyopia-correcting IOL that exceeds the work and resources attributable to insertion of a conventional IOL.

2. The physician and the facility may not charge for cataract extraction with insertion of a presbyopia-correcting IOL unless the beneficiary requests this service.

3. The physician and the facility may not require the beneficiary to request a presbyopia-correcting IOL as a condition of performing a cataract extraction with IOL insertion.

## **Provider Notification Requirements**

When a beneficiary requests insertion of a presbyopia-correcting IOL instead of a conventional IOL following removal of a cataract:

1. Prior to the procedure to remove a cataractous lens and insert a presbyopia-correcting lens, the facility and the physician must inform the beneficiary that Medicare will not make payment for services that are specific to the insertion, adjustment or other subsequent treatments related to the presbyopia-correcting functionality of the IOL.
2. The presbyopia-correcting functionality of a presbyopia-correcting IOL does not fall into a Medicare benefit category, and, therefore, is not covered. Therefore, the facility and physician are not required to provide an Advanced Beneficiary Notice to beneficiaries who request a presbyopia-correcting IOL.
3. Although not required, CMS strongly encourages facilities and physicians to issue a **Notice of Exclusion from Medicare Benefits** to beneficiaries in order to clearly identify the non-payable aspects of a presbyopia-correcting IOL insertion. This notice may be found: English language at: [http://cms.hhs.gov/medicare/bni/20007\\_English.pdf](http://cms.hhs.gov/medicare/bni/20007_English.pdf)  
Spanish language at: [http://cms.hhs.gov/medicare/bni/20007\\_Spanish.pdf](http://cms.hhs.gov/medicare/bni/20007_Spanish.pdf)



