

CMS Manual System

Pub 100-04 Medicare Claims Processing

Transmittal 636

Department of Health & Human Services

Centers for Medicare & Medicaid Services

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

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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

Benefits for Which Medicare Makes Payment	Services for Which Medicare Does NOT Pay – No Benefit Category
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 OPPS 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
Spanish language at: http://cms.hhs.gov/medicare/bni/20007_Spanish.pdf

II. BUSINESS REQUIREMENTS

“Shall” denotes a mandatory requirement

“Should” denotes an optional requirement

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	RHHI	Carrier	DME RC	Shared System Maintainers				Other
						F I S S	MC S	VM S	CW F	
3927.1	<p>Carriers shall continue to accept and pay the ASC facility rate for claims from ASC facilities for the following procedures: 66982, 66983, or 66984.</p> <p>NOTE: These procedure codes shall continue to be used by ASCs when either a conventional IOL or a presbyopia- correcting IOL (P-C IOL) is furnished to replace the organic lens following removal of a cataract performed in an ASC.</p>			X						
3927.1.2	<p>Carriers shall continue to accept and pay claims from physicians who perform the following procedures in an ASC (POS = 24) whether a conventional or a presbyopia-correcting IOL is inserted following cataract extraction surgery: CPT codes 66982, 66983, or 66984.</p> <p>NOTE: These physician services continue to be paid under the Medicare Physician Fee Schedule.</p>			X						
3927.2	<p>Carriers shall continue to accept and pay claims for removal of a cataract performed in a physician’s office (POS = 11) for CPT codes 66982, 66983 or 66984.</p>			X						

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	RHHI	Carrier	DME RC	Shared System Maintainers				Other
						F I S S	MC S	VM S	CW F	
3927.2.1	<p>In addition to the above procedure codes when performed in a physician’s office, carriers shall continue to accept claims that also contain the following HCPCS code when either a P-C IOL or conventional IOL is implanted: V2632 - Posterior chamber intraocular lens</p> <p>NOTE: The code for the lens shall continue to be paid at reasonable charge. Only physicians can bill V2632 when cataract extraction with IOL insertion is performed in a physician’s office, which is indicated by POS = 11 on the claim.</p>			X						
3927.3	FIs shall continue to accept and pay hospital outpatient claims (12X, 13X, 83X, 85X TOB) for insertion of conventional or presbyopia-correcting IOLs following cataract extraction.	X								
3927.4	FIs shall continue to pay claims that contain CPT procedure codes 66982, 66983, 66984 under current payment methodologies.	X								
3927.4.1	FIs shall continue to pay CAH method 2 claims that contain HCPCS code V2632 under current payment methodologies.	X								
3927.5	Contractors shall educate the provider community via the Medlearn Matters article that effective for dates of service on	X		X						

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	RHHI	Carrier	DME RC	Shared System Maintainers				Other
						F I S S	MC S	VM S	CW F	
	or after May 3, 2005, Medicare will pay the same amount for cataract extraction with P-C IOL insertion that it pays for cataract extraction with conventional IOL insertion. The beneficiary is responsible for payment of that portion of the hospital, or ASC charge for the procedure that exceeds the facility's usual charge for cataract extraction and insertion of a conventional IOL following cataract surgery as well as any fees that exceed the physician's usual charge to perform a cataract extraction with insertion of a conventional IOL.									
3927.6	Carriers shall remind physicians via the Medlearn Matters article that they can be reimbursed for the conventional or P-C IOL (V2632) only when the service is performed in a physicians office (POS = 11). When performing cataract surgery in an ASC or outpatient setting, the physician shall only bill for the professional service because payment for the lens is bundled into the facility payment for the cataract extraction.			X						

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3927.7	<p>A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.</p>									

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

<p>Effective Date*: May 3, 2005</p> <p>Implementation Date: September 6, 2005</p> <p>Pre-Implementation Contact(s): Dana Burley at Dana.Burley@cms.hhs.gov, 410-786-4547;</p> <p>Chuck Braver (payment policy) at Robert.Braver@cms.hhs.gov, 410-786-6719;</p> <p>Yvette Cousar (Part B Claims Processing) at Yvette.Cousar@cms.hhs.gov, (410) 786-2160; or</p> <p>Antoinette Johnson (Part A Claims Processing) at Antoinette.Johnson@cms.hhs.gov, (410) 786-9326</p> <p>Post-Implementation Contact(s): Appropriate Regional Office</p>	<p>No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2005 operating budgets.</p>
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