

# CMS Manual System

## Pub 100-04 Medicare Claims Processing

Transmittal 914

Department of Health & Human Services (DHHS)

Centers for Medicare & Medicaid Services (CMS)

Date: APRIL 21, 2006

Change Request 4361

**SUBJECT: Additional \$50 Payment for New Technology Intraocular Lenses (NTIOLs) Furnished in Ambulatory Surgical Centers (ASCs)**

**I. SUMMARY OF CHANGES:** Effective for a 5-year period for dates of service on or after February 27, 2006, through February 26, 2011, an additional \$50 Medicare payment adjustment for NTIOLs (HCPCS code Q1003) inserted in approved ASC settings will be paid. The Medicare Claims Processing Manual, Chapter 14, Sections 10.2 & 40.3, have been updated to reflect this change.

### NEW/REVISED MATERIAL

**EFFECTIVE DATE: February 27, 2006**

**IMPLEMENTATION DATE: May 22, 2006**

*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 – *Only One Per Row.*

R/N/D	Chapter / Section / SubSection / Title
R	14/10.2/Ambulatory Surgical Center Services on ASC List
R	14/40.3/Payment for Intraocular Lenses (IOLs)

### III. FUNDING:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.

### IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

# Attachment - Business Requirements

Pub. 100-04	Transmittal: 914	Date: April 21, 2006	Change Request 4361
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**SUBJECT: Additional \$50 Payment for New Technology Intraocular Lenses (NTIOLs) Furnished in Ambulatory Surgical Centers (ASCs)**

## I. GENERAL INFORMATION

**A. Background:** Section 141(b) of the Social Security Act Amendments of 1994 (Pub. L. 103-432) (SSAA 1994) requires the Centers for Medicare & Medicaid Services (CMS) to establish a process for designating particular intraocular lenses (IOLs) as “new technology” and therefore eligible for additional payment. A final rule was published in the Federal Register on June 16, 1999 ([64 FR 32198](#)), which established: (1) the process for adjusting payment amounts for NTIOLs furnished by ASCs; (2) an initial flat rate payment adjustment of \$50; and, (3) a 5-year payment adjustment period beginning when CMS recognizes the first IOL of a new subset or class. Any subsequent IOLs recognized by CMS as having the same characteristics as the first IOL recognized for a payment adjustment will receive the same adjustment for the remainder of the 5-year period established by the first recognized IOL.

**B. Policy:** Pursuant to section 141(b) of SSAA 1994, and effective for dates of service on or after February 27, 2006, the additional \$50, 5-year Medicare payment adjustment for NTIOLs (HCPCS code Q1003, New Technology Intraocular Lens Category 3 (Reduced Spherical Aberration) when furnished in ASCs, is approved for Advanced Medical Optics (AMO); Tecnis® IOL model numbers Z9000, Z9001, and ZA9003. Any subsequent IOLs recognized by CMS as being a member of the reduced spherical aberration subset will receive the same payment adjustment effective upon CMS recognition. Contractors and providers will be aware that HCPCS Q1003, along with one of the approved procedure codes (66982, 66983, 66984, 66985, 66986) are to be used on all NTIOL Category 3 claims associated with reduced spherical aberration from February 27, 2006, through February 26, 2011.

CMS announced a new process for interested parties to apply for entry into an existing NTIOL subset. This process is described at:

<http://www.cms.hhs.gov/CoverageGenInfo/downloads/AppforcurrentNTIOLsubset.pdf>. Accordingly, a list of NTIOLs approved under 42 CFR Subpart F, section 416.180 is listed at: <http://www.cms.hhs.gov/center/coverage.asp>.

## II. BUSINESS REQUIREMENTS

*“Shall” denotes a mandatory requirement*

*“Should” denotes an optional requirement*

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)					
		F	R	C	D	Shared System	Other
		I	H	a	M	Maintainers	
		U	H	a	F		

					F I S S	M C S	V M S	C W F	
4361.1	Effective for claims with dates of service on and after February 27, 2006, carriers shall pay an additional \$50 for an NTIOL when a claim is submitted containing Q1003 with one of the following procedure codes (66982, 66983, 66984, 66985, 66986) in place of service 24 (ASC). <b>NOTE:</b> Q1003 is already established and listed in the HCPCS file.			X					
4361.2	Carriers shall pay the additional \$50 for Q1003 for 5 years. The beginning date is February 27, 2006, and the termination date is February 26, 2011.			X					
4361.3	Carriers shall return as unprocessable any claims for NTIOLs billed with Q1003 alone or with a code other than one of the procedure codes mentioned in 4361.1.			X					
4361.3.1	Carriers shall use the following Remittance Advice (RA) messages when returning these claims:  Claim Adjustment Reason Code 16 - Claim/service lacks information which is needed for adjudication. Additional information is supplied using remittance advice remark codes whenever appropriate.  RA Remark Code M67 - Missing/Incomplete/Invalid other procedure codes.  RA Remark Code MA130 - Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.			X					
4361.4	Carriers shall only pay for Q1003 when furnished in a Medicare-approved ASC.			X					

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R 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	
4361.4.1	Carriers shall deny payment for Q1003 if services are performed in a facility other than a Medicare-approved ASC.			X						
4361.4.2	Carriers shall use appropriate messages: MSN #16.2 (This service cannot be paid when provided in this location/facility) and Claims Adjustment Reason Code #58 (Payment adjusted because treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service).			X						
4361.4.3	Carriers shall deny claims for Q1003 when billed by an entity other than an approved ASC.			X						
4361.4.4	Carriers shall use appropriate messages: MSN 33.1 (the ambulatory surgical center must bill for this service) and Claim Adjustment Reason 170 (Payment is denied when performed/billed by this type of provider).			X						
4361.5	Carriers shall deny Q1003 when submitted for payment past the discontinued date (after the 5-year period, or after February 26, 2011).			X						
4361.5.1	Carriers shall use appropriate messages: MSN #21.11 (This service was not covered by Medicare at the time you received it) and Claims Adjustment Reason Code #27 (Expenses incurred after coverage terminated).			X						
4361.6	Carriers shall be in compliance with the manual instruction in Publication 100-04, Chapter 14, Sections 10 and 40, regarding NTIOL payment in an ASC.			X						
4361.7	Carriers shall be advised that further information regarding current and future updates for Medicare-approved NTIOLs can be found at: <a href="http://www.cms.hhs.gov/center/coverage.asp">http://www.cms.hhs.gov/center/coverage.asp</a> .			X						

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)							
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers			
F I S S	M C S					V M S	C W F		
4361.8	Contractors need not search their files to either retract payment for claims already paid or to retroactively pay claims. However, contractors shall adjust claims brought to their attention.			X					

### III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)							
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers			
F I S S	M C S					V M S	C W F		
4361.9	A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles">www.cms.hhs.gov/MLNMattersArticles</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN 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 MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.			X					

### 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><b>Effective Date*:</b> February 27, 2006</p> <p><b>Implementation Date:</b> May 22, 2006</p> <p><b>Pre-Implementation Contact(s):</b>  Michael Lyman (Coverage),  410-786-6938, <a href="mailto:michael.lyman@cms.hhs.gov">michael.lyman@cms.hhs.gov</a>  Yvette Cousar (Part B claims processing),  410-786-2160, <a href="mailto:Yvette.cousar@cms.hhs.gov">Yvette.cousar@cms.hhs.gov</a>  Chuck Braver (ASC policy/payment), 410-786-6719, <a href="mailto:Robert.braver@cms.hhs.gov">Robert.braver@cms.hhs.gov</a></p> <p><b>Post-Implementation Contact(s):</b>  Appropriate CMS RO</p>	<p><b>No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.</b></p>
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## **10.2 - Ambulatory Surgical Center Services on ASC List**

*(Rev. 914, Issued: 04-21-06; Effective: 02-27-06; Implementation: 05-22-06)*

ASC services are those surgical procedures that are identified by CMS on an annually updated ASC listing. Some medical services covered by Medicare are not on the list. These may be billed by the rendering provider as Part B services but not as ASC services.

The ASC payment rate includes only the specific ASC services. All other non-ASC services such as physician services, prosthetic devices, may be covered and separately billable under Medicare Part B. The Medicare definition of covered facility services includes services that would be covered if furnished on an inpatient or outpatient basis in connection with a covered surgical procedure. This includes operating and recovery rooms, patient preparation areas, waiting rooms, and other areas used by the patient or offered for use to patients needing surgical procedures. It includes all services and procedures in connection with covered procedures furnished by nurses, technical personnel and others involved in patient care. These do not include physician services, or medical and other health services for which payment may be made under other Medicare provisions (e.g., services of an independent laboratory located on the same site as the ASC, prosthetic devices other than intraocular lenses (IOLs), anesthetist services, DME).

Carriers are not concerned with whether a given item or service is a covered ASC facility service, unless the ASC makes a separate charge for it. Where a separate charge is made the carrier must determine whether the item or service falls into the categories described in the following section. If the item or service falls into one of those categories, payment is made following the applicable rules for such items and services found elsewhere in this chapter. If the item or service does not fall into one of the categories described, the claim is denied.

Examples of covered ASC facility services include:

- Nursing services, services of technical personnel, and other related services;
- The use by the patient of the ASC facilities;
- Drugs, biologicals, surgical dressings, supplies, splints, casts, appliances, and equipment;
- Diagnostic or therapeutic items and services;
- Administrative, recordkeeping, and housekeeping items and services;
- Blood, blood plasma, platelets, etc., except for those to which the blood deductible applies;
- Materials for anesthesia; and
- Intraocular lenses (IOLs) except for new technology IOLs (NTIOLs) (refer to [42 CFR 416.180-200](#) ).

### **Nursing Services, Services of Technical Personnel, and Other Related Services**

These include all services in connection with covered procedures furnished by nurses and technical personnel who are employees of the ASC. In addition to the nursing staff, this category includes orderlies, technical personnel, and others involved in patient care.

### **Use by the Patient of the ASC Facilities**

This category includes operating and recovery rooms, patient preparation areas, waiting rooms, and other areas used by the patient or offered for use by the patient's relatives in connection with surgical services.

### **Drugs, Biologicals, Surgical Dressings, Supplies, Splints, Casts, Appliances, and Equipment**

This category includes all supplies and equipment commonly furnished by the ASC in connection with surgical procedures. See the following paragraphs for certain exceptions. Drugs and biologicals are limited to those which cannot be self-administered. See the Medicare Benefit Policy Manual, Chapter 15, §50.2, for a description of how to determine whether drugs can be self-administered.

Under Part B, coverage for surgical dressings is limited to primary dressings, i.e., therapeutic and protective coverings applied directly to lesions on the skin or on openings to the skin required as the result of surgical procedures. (Items such as Ace bandages, elastic stockings and support hose, Spence boots and other foot coverings, leotards, knee supports, surgical leggings, gauntlets and pressure garments for the arms and hands are used as secondary coverings and therefore are not covered as surgical dressings.) Although surgical dressings usually are covered as "incident to" a physician's service in a physician's office setting, in the ASC setting, such dressings are included in the facility's services.

However, surgical dressings may be reapplied later by others, including the patient or a member of his family. When surgical dressings are obtained by the patient on a physician's order from a supplier, e.g., a drugstore, the surgical dressing is covered under Part B. The same policy applies in the case of dressings obtained by the patient on a physician's order following surgery in an ASC; the dressings are covered and paid as a Part B service by the DMERC.

Similarly, "other supplies, splints, and casts" include only those furnished by the ASC at the time of the surgery. Additional covered supplies and materials furnished later are generally furnished as "incident to" a physician's service, not as an ASC facility service. The term "supplies" includes those required for both the patient and ASC personnel, e.g., gowns, masks, drapes, hoses, and scalpels, whether disposable or reusable. These are included in the rate for the service (HCPCS code).

### **Diagnostic or Therapeutic Items and Services**

These are items and services furnished by ASC staff in connection with covered surgical procedures. Many ASCs perform diagnostic tests prior to surgery that are generally included in the facility charges, such as urinalysis, blood hemoglobin, hematocrit levels, etc. To the extent that such simple tests are included in the ASC facility charges, they are considered facility services. However, under the Medicare program, diagnostic tests are not covered in laboratories independent of a physician's office, rural health clinic, or hospital unless the laboratories meet the regulatory requirements for the conditions for coverage of services of independent laboratories. (See [42 CFR 405.1310](#) ) Therefore, diagnostic tests performed by the ASC other than those generally included in the facility's charge are not covered under Part B and are not to be billed as diagnostic tests. If the ASC has its laboratory certified, the laboratory itself may bill for the tests performed.

The ASC may make arrangements with an independent laboratory or other laboratory, such as a hospital laboratory, to perform diagnostic tests it requires prior to surgery. In general, however, the necessary laboratory tests are done outside the ASC prior to scheduling of surgery, since the test results often determine whether the beneficiary should have the surgery done on an outpatient basis in the first place.

### **Administrative, Recordkeeping and Housekeeping Items and Services**

These include the general administrative functions necessary to run the facility e.g., scheduling, cleaning, utilities, and rent.

### **Blood, Blood Plasma, Platelets, etc., Except Those to Which Blood Deductible Applies**

While covered procedures are limited to those not expected to result in extensive loss of blood, in some cases, blood or blood products are required. Usually the blood deductible results in no expenses for blood or blood products being included under this provision. However, where there is a need for blood or blood products beyond the deductible, they are considered ASC facility services and no separate charge is permitted to the beneficiary or the program.

### **Materials for Anesthesia**

These include the anesthetic itself, and any materials, whether disposable or re-usable, necessary for its administration.

### **Intraocular Lenses (IOLs) and New Technology IOLs (NTIOLs)**

The ASC facility services include IOLs (effective for services furnished on or after March 12, 1990), and NTIOLs (effective for services furnished on or after May 18, 2000), approved by the Food and Drug Administration (FDA) for insertion during or subsequent to cataract surgery.

FDA has classified IOLs into the following categories, any of which are included:

1. Anterior chamber angle fixation lenses;
2. Iris fixation lenses;
3. Irido-capsular fixation lenses; and
4. Posterior chamber lenses.
5. NTIOL Category 1 (as defined in “Federal Register” Notice, VOL 65, dated May 3, 2000). *Note: This category expired May 18, 2005*
6. NTIOL Category 2 (as defined in “Federal Register” Notice, VOL 65, dated May 3, 2000). *Note: This category expired May 18, 2005*
7. *NTIOL Category 3 (as defined in Federal Register Notice, 71 FR 4586, dated January 27, 2006): This category will expire on February 26, 2011.*

Note that while generally no separate charges for intraocular lenses (IOLs) are allowed, *approved* NTIOLs may be billed separately in addition to the facility rate. (See §40.3)

## **40.3 - Payment for Intraocular Lens (IOL)**

*(Rev. 914, Issued: 04-21-06; Effective: 02-27-06; Implementation: 05-22-06)*

Payment for facility services furnished by an ASC for IOL insertion during or subsequent to cataract surgery includes an allowance for the lens. The procedures that include insertion of an IOL are:

Payment Group 6: CPT-4 Codes 66985 and 66986

Payment Group 8: CPT-4 Codes 66982, 66983 and 66984

Do not pay physicians or suppliers for an IOL furnished to a beneficiary in an ASC after July 1, 1988. Deny separate claims for IOLs furnished to ASC patients beginning March 12, 1990. Also, effective March 12, 1990, procedures 66983 and 66984 are treated as single procedures for payment purposes.

Refer to [42 CFR 416.185](#) for discussion of New Technology Intraocular Lenses (NTIOLs). While the carrier claims processing systems allow no separate charges for conventional intraocular lenses (IOLs), the cost of the IOL is bundled into the ASC facility fee, NTIOLs may be billed separately in addition to the facility fee. Medicare pays an additional \$50 on the following NTIOLs Q1001 (Category 1, Model AMO Array Multifocal lens) and Q1002 (Category 2, Model Elastic Ultraviolet-Absorbing Silicone Posterior Chamber Lens) when billed for dates of service from May 18, 2000 through May 18, 2005. *However*, effective for dates of service on and after May 19, 2005, Medicare will no longer reimburse the additional \$50 and these two codes will be invalid for Medicare.

*Effective for dates of service on and after February 27, 2006, through February 26, 2011, Medicare will pay an additional \$50 for NTIOL [Category 3(Reduced Spherical Aberration), Model Advanced Medical Optics (AMO) Tecnis® IOL model numbers Z9000, Z9001, and ZA9003]. HCPCS code Q1003 has been created to bill for the additional \$50. Q1003 shall be billed on the same claim as the surgical insertion procedure.*

*Any subsequent IOLs recognized by CMS as having the same characteristics as the first IOL recognized by CMS for a payment adjustment (those of reduced spherical aberration) will receive the same adjustment for the remainder of the 5-year period established by the first recognized IOL. Contractors and providers will be aware that HCPCS Q1003, along with one of the approved procedure codes (66982, 66983, 66984, 66985, 66986) are to be used on all NTIOL Category 3 claims associated with reduced spherical aberration from February 27, 2006, through February 26, 2011. See:*

*<http://www.cms.hhs.gov/CoverageGenInfo/downloads/AppforcurrentNTIOL.subset.pdf>.*

*Additionally, contractors may obtain information on Medicare-approved NTIOLs at:*

*<http://www.cms.hhs.gov/center/coverage.asp>.*

### ***Medicare Summary Notice (MSN) and Claims Adjustment Reason Codes***

*Carriers shall return as unprocessable any claims for NTIOLs containing Q1003 alone or with a code other than one of the above listed procedure codes. Use the following messages for these returned claims:*

- Claim Adjustment Reason Code 16 - Claim/service lacks information which is needed for adjudication. Additional information is supplied using remittance advice remark codes whenever appropriate.*
- RA Remark Code M67 - Missing/Incomplete/Invalid other procedure codes.*

- *RA Remark Code MA130 - Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.*

*Carriers shall deny payment for Q1003 if services are furnished in a facility other than a Medicare-approved ASC. Use the following messages when denying these claims:*

- *MSN 16.2 - This service cannot be paid when provided in this location/facility.*
- *Claims Adjustment Reason Code 58 - Payment adjusted because treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service.*

*Carriers shall deny payment for Q1003 if **billed** by an entity other than a Medicare-approved ASC. Use the following messages when denying these claims:*

- *MSN 33.1 - The ambulatory surgical center must bill for this service.*
- *Claim Adjustment Reason Code 170 - Payment is denied when performed/billed by this type of provider.*

*Carriers shall deny payment for Q1003 if submitted for payment past the discontinued date (after the 5-year period, or after February 26, 2011). Use the following messages when denying these claims:*

- *MSN 21.11 - This service was not covered by Medicare at the time you received it.*
- *Claim Adjustment Reason Code 27 - Expenses incurred after coverage terminated.*