CMS Manual System

Pub 100-04 Medicare Claims Processing

Transmittal 639

Department of Health & Human Services (DHHS)

Centers for Medicare & Medicaid Services (CMS)

Date: AUGUST 5, 2005

Change Request 3901

SUBJECT: Cessation of Additional $50 Payment for New Technology Intraocular Lenses (NTIOLs)

I. SUMMARY OF CHANGES: Effective for dates of service on or after May 19, 2005, the additional $50, 5-year Medicare payment adjustment for NTIOLs (procedure codes Q1001 and Q1002) inserted in ASC settings will no longer be paid or valid for Medicare reimbursement. The Medicare Claims Processing Manual, chapter 14, section 40.3, has been updated to reflect this change.

NEW/REVISED MATERIAL :

EFFECTIVE DATE : *May 19, 2005

IMPLEMENTATION DATE : October 3, 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 – *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 Lens (IOL)

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:

Business Requirements

Manual Instruction

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 639	Date: August 5, 2005	Change Request 3901

SUBJECT: Cessation of Additional $50 Payment for New Technology Intraocular Lenses (NTIOLs)

I. GENERAL INFORMATION

A. Background: Section 1833(i)(2)(A)(iii) of the Social Security Act (the Act) requires the Centers for Medicare & Medicaid Services (CMS) to establish a process of designating particular intraocular lenses (IOLs) as "new technology" and therefore eligible for additional payment. A final rule was published June 16, 1999, which established: (1) the process for adjusting payment amounts for NTIOLS furnished by ambulatory surgical centers (ASCs); (2) a 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.

Listed below are the two IOLs that have been considered NTIOLs for the past five years:

Allergan: AMO Array Multifocal lens: model # SA40N
Characteristic – Multi-focal
Procedure Code: Q1001- NTIOL Category 1
Additional 5-year $50 payment adjustment began May 18, 2000, and expires May 18, 2005

STAAR Surgical: Elastic Ultraviolet-Absorbing Silicone Posterior Chamber lens
IOL with Toric Optic model #s AA4203T, AA4203TF & AA4203TL
Characteristic - Reduction in Preexisting Astigmatism
Procedure Code: Q1002-NTIOL Category 2
Additional 5-year $50 payment adjustment began May 18, 2000, and expires May 18, 2005

B. Policy: Pursuant to section 1833(i)(2)(A)(iii) of the Act, and effective for dates of service on or after May 19, 2005, the additional $50, 5-year Medicare payment adjustment for NTIOLs (procedure codes Q1001 and Q1002) inserted in ASC settings expires.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3901.1	Effective for dates of service on or after 05/19/05, carriers shall stop the additional $50 Medicare payment adjustment for NTIOLs (procedure codes Q1001 and Q1002) inserted in ASC settings.			X					X	
3901.2	Effective for dates of service on and after 05/19/05, carriers that have not already done so shall manually change the indicator for Q1001 and Q1002 in their files/payment systems to indicate that these codes are "Not Valid for Medicare Purposes."			X						
3901.3	Carriers shall not search for and adjust claims already processed unless brought to their attention.			X						

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3901.4	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			X						

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	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.									

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

Effective Date*: May 19, 2005 **Implementation Date:** October 3, 2005 **Pre-Implementation Contact(s):** Michael Lyman (coverage), 410-786-6938, michael.lyman@cms.hhs.gov Yvette Cousar (Part B claims processing), 410-786-	**No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2005 operating budgets.**

2160, Yvette.cousar@cms.hhs.gov Chuck Braver (ASC policy/payment), 410-786-6719 **Post-Implementation Contact(s):** Appropriate CMS RO	

*__Unless otherwise specified, the effective date is the date of service.__

10.2 - Ambulatory Surgical Center Services on ASC List

(Rev. 639, Issued: 08-05-05; Effective: 05-19-05; Implementation: 10-03-05)

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, etc.).

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) - 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*

While FDA has approved many IOLs and NTIOLs, it may consider some IOLs and NTIOLs to be experimental. Medicare does not cover or pay for experimental items or services.

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. 639, Issued: 08-05-05; Effective: 05-19-05; Implementation: 10-03-05)

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 Silcone Posterior Chamber Lens) when billed for dates of service from May 18, 2000 through May 18, 2005. 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.*