

Application Process and Information Requirements for Requests to Adjust Payment to Ambulatory Surgical Centers for Insertion of a New Class of New Technology Intraocular Lens (NTIOL)

Please note:

For process and information required to apply for transitional pass-through payment status for additional device categories under the hospital outpatient prospective payment system (OPPS), go to the main OPPS web page, currently at <http://www.cms.hhs.gov/HospitalOutpatientPPS/> to see the latest instructions. (NOTE: Due to the continuing development of the cms.hhs.gov web site, references to links herein may change.)

CMS accepts requests for recognition of IOLs as belonging to an **existing, active NTIOL category or subset** on an ongoing basis, throughout a given calendar year. Details pertaining to such requests are addressed in a guidance document, which can be found at http://www.cms.hhs.gov/ASCPayment/05_NTIOls.asp#TopOfPage. The guidance document provides details regarding requests for recognition of IOLs as belonging to an active NTIOL category, the review process, and information required for a request to review. **Review of candidate lenses for an existing, active NTIOL subset is not limited to the annual review process described below, which applies solely to new NTIOL classes.** CMS ordinarily completes the review of a request for eligibility of an IOL to receive a payment adjustment as a member of an active NTIOL class within 90 days of receipt. CMS notifies the requestor about its determination, and notification of a lens newly approved for a payment adjustment as an NTIOL belonging to an active NTIOL class when furnished at an ASC is posted on the CMS website.

PART 1--PROCESS RELATED TO SUBMISSION OF REQUESTS TO ADJUST PAYMENT FOR A NEW CLASS OF NEW TECHNOLOGY INTRAOCULAR LENS (NTIOL) FURNISHED BY AN AMBULATORY SURGICAL CENTER (ASC)

This announcement describes in detail the process and information required for applications requesting a review of the appropriateness of the payment amount for insertion of an intraocular lens (IOL), to ensure that the ASC facility fee for the procedure includes payment that is reasonable and related to the cost of acquiring a lens that is approved as belonging to a new class of new technology intraocular lenses (NTIOLs).

Refer to the final rule with comment period in the November 24, 2006 *Federal Register* for a full discussion of the factors CMS considers in determining whether an adjustment of payment for insertion of a new class of NTIOL is appropriate (71 FR 68175). This rule can currently be found at <http://www.gpoaccess.gov/fr/index.html>

Applicants are advised that any information submitted, including commercial or financial data, is subject to public disclosure unless the applicant clearly identifies all information that is to be characterized as confidential, and therefore, subject to the protection allowed under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and, with respect to trade secrets, the Trade Secrets Act (18 U.S.C. 1905).

Timing of Submission of Requests and Determination of NTIOL Status:

By law, CMS is required both to implement the payment adjustment for **new classes** of NTIOLs through notice and comment rulemaking in the Federal Register and to provide for a 30-day comment period on the lenses that are the subjects of the requests contained in the notice. Beginning in CY

2007, NTIOL-related notifications will be integrated into the annual notice and comment rulemaking cycle for updating ASC and OPPS payment rates, as follows:

- Announcement of deadline for requests for review: The deadline for each year's requests for review of a new class of NTIOLs is announced in the final rule updating the ASC and OPPS payment rates for that calendar year.
- Announcement of new classes of NTIOLs for which review requests have been made and solicitation of public comments: The requests for review received in a calendar year and the deadline for public comments regarding the requests are announced in the proposed rule updating the ASC and OPPS payment rates for the following calendar year.
- Deadline for receipt of public comments: Public comments regarding the requests must be submitted 30 days following the date of publication of the proposed rule.
- Announcement of determinations regarding requests for review: CMS reviews the information submitted with a completed request for review, public comments submitted timely, and other pertinent information and announces its determinations in the final rule updating ASC and OPPS payment rates for the following calendar year. The codes and effective dates allowed for those lenses recognized by CMS as belonging to a class of NTIOLs are effective 30 days following the date of publication of the final rule.

The table below illustrates the timetable for approval of candidate new classes of NTIOLs for CY 2009:

<u>ACTION</u>	<u>DEADLINE</u>
<u>Deadline for request for review</u> : In order to be considered for payment effective January 1, 2009, requests for review of applications for a new class of NTIOL must be submitted to CMS.	Must be received by close of business, March 14, 2008
Announcement of new classes of NTIOLs for which review requests were received timely and solicitation of public comments.	Announced in the proposed rule updating the ASC payment rates for CY 2009, which will be included in the proposed rule to update CY 2009 payment rates under the OPPS. Publication of the proposed rule in the Federal Register will be announced in the Quarterly Publication Update, which can be found at: http://www.cms.hhs.gov/QuarterlyProviderUpdates/
<u>Deadline for receipt of public comments</u>	30 days following the date of publication of the proposed rule, as set forth in the proposed rule.
Announcement of determinations regarding requests for review.	Announced in the final rule updating CY 2009 ASC and OPPS payment rates. Publication of the final rule in the Federal Register will be announced in the Quarterly Publication Update, which can be found at: http://www.cms.hhs.gov/QuarterlyProviderUpdates/
<u>Effective date of payment adjustment for insertion of newly approved classes of NTIOLs.</u>	30 days following the date of publication of the final rule updating ASC and OPPS payment rates for CY 2009. The effective date will be announced in the final rule.

PART 2--REQUIREMENTS FOR REQUESTS TO ADJUST PAYMENT AMOUNT FOR A NEW CLASS OF NEW TECHNOLOGY INTRAOCULAR LENS (NTIOL) FURNISHED BY AN AMBULATORY SURGICAL CENTER (ASC)

Who may submit a request for CMS to review the appropriateness of the ASC payment for insertion of an IOL that might qualify for a payment adjustment as belonging to a new class of NTIOLs? Any individual, society, scientific or academic establishment or professional or trade organization able to furnish the content of a request required by CMS, as described in Part 3, below, may submit a request. .

Can an NTIOL be included in more than one category? No. One of the factors that CMS considers in making an NTIOL determination is whether the candidate NTIOL is described by an active or expired class of NTIOL. That is, a new NTIOL class cannot share a predominant, class defining characteristic associated with improved clinical outcomes with members of an active or expired class. However, this requirement does not preclude from consideration as a member of a new class of NTIOL, a lens that includes as *one* of its characteristics a class-defining characteristic associated with members of an active or expired class. Only if that shared characteristic is the predominant characteristic of the lens would it be denied approval as a new class of NTIOL. If the candidate lens features other characteristics, one or more of which is predominant, that are clearly tied with improved clinical outcomes, the lens would not be disqualified from consideration as an NTIOL solely because it also shared a characteristic with members of an active or expired class.

Is there a cost threshold that must be met for a lens to qualify as an NTIOL? No. Neither the law nor regulations includes a cost threshold that must be met to be considered an NTIOL. The law simply requires CMS to ensure that the ASC facility fee for insertion of an IOL includes payment that is reasonable and related to the cost of acquiring a lens that belongs to a class of NTIOL.

What are the factors that CMS considers in determining whether an adjustment for payment for insertion of a new class of NTIOL is appropriate?

In determining whether a lens belongs to a new class of NTIOL and whether the ASC payment amount for insertion of that lens in conjunction with cataract surgery is appropriate, CMS expects that the insertion of the candidate IOL would result in significantly improved clinical outcomes compared to currently available IOLs. In addition, to establish a new NTIOL class, the candidate lens must be distinguishable from lenses already approved as members of active or expired classes of NTIOLs that share a predominant characteristic associated with improved clinical outcomes that were identified for each class. CMS uses the following criteria to determine whether an IOL qualifies for payment adjustment as a member of a new class of NTIOLs when inserted at an ASC:

1. The IOL is approved by the FDA.
2. Claims of specific clinical benefits and/or lens characteristics with established clinical relevance in comparison to currently available IOLs are approved by the

- FDA for use in labeling and advertising.
3. The IOL is not described by an active or expired class of new technology IOLs; that is, it does not share a predominant, class-defining characteristic associated with improved clinical outcomes with members of an active or expired class.
 4. Evidence demonstrates that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs. Superior outcomes include:
 - a. Reduced risk of intraoperative or postoperative complication or trauma;
 - b. Accelerated postoperative recovery;
 - c. Reduced induced astigmatism;
 - d. Improved postoperative visual acuity;
 - e. More stable postoperative vision;
 - f. Other comparable clinical advantages.

How does CMS rate a request to review an IOL for NTIOL status?

Upon completion of its review of the information submitted with a completed request, public comments submitted timely, and other pertinent information, CMS makes a determination as follows:

1. The IOL is eligible for a payment adjustment as a member of a new class of new technology IOLs.
2. The IOL is a member of an active class of new technology IOLs and is eligible for a payment adjustment for the remainder of the period established for that class.
3. The IOL does not meet the criteria for designation as a new technology IOL and a payment adjustment is not appropriate.

What payment adjustment results from approval of a lens as belonging to a new class of NTIOL?

CMS establishes the amount of the payment adjustment for classes of NTIOLs through proposed and final rulemaking in connection with ASC facility services. Payment for insertion of an approved NTIOL at an ASC currently equals \$50, which is added to the facility fee for the procedure performed to insert the lens. The \$50 add-on is not subject to wage index adjustment.

For how long is an NTIOL eligible for the NTIOL payment adjustment?

CMS adjusts the payment for insertion of an IOL approved as belonging to a class of new technology IOLs for a period of 5 years, effective as of the implementation date of the new NTIOL class. At the end of 5 years, when the NTIOL payment adjustment expires, payment for insertion of the lens reverts to the standard rate for IOL insertion procedures performed in ASCs.

Is a lens that is recognized as belonging to an existing, active NTIOL category or subset after implementation of the category entitled to receive the full 5-year adjustment?

No. Lenses that are recognized as belonging to an existing, active NTIOL category or subset are eligible to receive the payment adjustment for whatever time remains in the 5-year period allotted to the category. The 5-year adjustment period applies to the NTIOL category, not to the individual lenses subsequently recognized as belonging to the category after its initial effective date.

How are NTIOLs distinguished from other IOLs when an ASC submits a claim for payment?

Each new NTIOL class is assigned an alpha-numeric HCPCS code that is prefaced by the letter “Q,” which identifies the predominant characteristic of the class. For example, the HCPCS code Q1003 is

used to designate an NTIOL class whose predominant characteristic is reduced spherical aberration. CMS also identifies by manufacturer, name, and model number each lens approved as belonging to a designated NTIOL category. When an ASC furnishes a lens approved for the NTIOL adjustment, the ASC submits a claim that specifies the CPT code for the lens insertion procedure and the Q-code for the NTIOL category to which the inserted lens belongs. Only lenses approved by CMS for the NTIOL adjustment may be reported using the designated Q-code.

Where can I find more information about past or current lenses approved for the NTIOL adjustment?

A list of codes assigned to NTIOL categories, both past and current, will be maintained on the ASC web site, currently at http://www.cms.hhs.gov/ASCPayment/05_NTIOls.asp#TopOfPage.

PART 3—CONTENT OF A REQUEST FOR REVIEW

To enable CMS to make an appropriate determination as to whether the criteria for approving a new class of NTIOLs are met, a request for review **must** include all of the information listed below. A separate application is required for each distinct IOL for which a review is requested. The submission of all credible evidence, whether published or not, is encouraged. Published, peer-reviewed literature is strongly encouraged to demonstrate substantial clinical improvement with use of the candidate IOL over use of currently available IOLs.

An application for review is not considered complete until—

- All required information has been submitted, AND
- All questions related to such information have been answered.

CMS can act only on applications that include all of the following information:

1. Proposed name or description of a new class of NTIOLs.
2. Trade/brand name, manufacturer, and model number of the IOL for which the request to establish a new NTIOL class is being made. (Applications must include the name and description of at least one marketed IOL that would be placed in the proposed new NTIOL class.)
3. A list of all active or expired NTIOL classes that describe similar IOLs. For each active or expired class, provide a detailed explanation as to why that class would not describe the candidate IOL.
4. Detailed description of the FDA approved clinical indications for the candidate IOL.
5. Description of the IOL—
 - a. What is it? Provide a complete physical description of the IOL, including its components, for example, its composition; coating or covering; haptics; material; and construction.
 - b. What does it do?
 - c. How is it used?
 - d. What makes it different from other currently available IOLs?
 - e. What makes it superior to other currently available IOLs used for similar indications?
 - f. What are its clinical characteristics, for example, is it used for treatment of specific pathology; what is its life span; what are the complications associated with its use; and for what patient populations is it intended?
 - g. Submit relevant booklets, pamphlets, brochures, product catalogues, price lists, and/or package inserts that further describe and illuminate the nature of the IOL.
6. If the candidate IOL replaces or improves upon an existing IOL, identify the trade/brand name and model of the existing IOL(s).
7. Full discussion of the clinically meaningful, improved outcomes that result from use of the candidate IOL compared to use of other currently available IOLs. This discussion must include evidence to demonstrate that use of the IOL results in measurable, clinically significant improvement over currently available IOLs in one or more of the following areas:

- a. Reduced risk of intraoperative or postoperative complication or trauma.
 - b. Accelerated postoperative recovery.
 - c. Reduced induced astigmatism.
 - d. Improved postoperative visual acuity.
 - e. More stable postoperative vision.
 - f. Other comparable clinical advantages, such as—
 - i. Reduced dependence on other eyewear (for example, spectacles, contact lenses, and reading glasses);
 - ii. Decreased rate of subsequent diagnostic or therapeutic interventions, such as the need for YAG laser treatment;
 - iii. Decreased incidence of subsequent IOL exchange; and
 - iv. Decreased blurred vision, glare or other quantifiable symptom or vision deficiency.
8. Provide the following information for the IOL(s) for which a new class is proposed:
- a. Dates the candidate IOL was first marketed, reporting inside the United States and outside the United States separately.
 - b. Dates of sale of the first unit of the IOL, reporting inside the United States and outside the United States separately.
 - c. Number of IOLs that have been sold up to the date of the application.
9. Provide the following information regarding approval of the candidate IOL by the U.S. Food and Drug Administration:
- a. A copy of the FDA's original approval notification.
 - b. A copy of the labeling claims approved by the FDA for the IOL, indicating its clinical advantages and/or the lens characteristics with clinical relevance.
 - c. A copy of the FDA's summary of the IOL's safety and effectiveness.
 - d. Reports of modifications made after the original FDA approval.

Where are applications to be sent?

Mail eight (8) copies of each completed application, at least one of which should be an unbound copy, to the following address:

ASC NTIOL Requests
Division of Outpatient Care Mailstop C4-05-17 Centers for Medicare and Medicaid
Services 7500 Security Boulevard Baltimore, MD 21244-1850

Because of staffing and resource limitations, we cannot accept applications by facsimile (FAX) transmission or by e-mail.

Questions pertaining to the NTIOL application process may be sent via e-mail to the Division of Outpatient Care mailbox, ASCP@cms.hhs.gov or by phone to 410-786-0378.