Revised Process for Recognizing Intraocular Lenses Furnished by Ambulatory Surgery Centers (ASCs) as Belonging to an Active Subset of New Technology Intraocular Lenses (NTIOLs)

Background

New Technology Intraocular Lenses (NTIOLs) are Intraocular Lenses (IOLs) providing new clinical benefits. NTIOL classification is intended to enhance Medicare beneficiary access to improved IOL technologies. If CMS approves an IOL as an NTIOL that does not fit into an active new technology subset, that NTIOL will receive an additional $50 payment for a five-year period when provided to a Medicare beneficiary in an Ambulatory Surgical Center.
Coincident with the approval, a new technology subset (NTIOL subset) is created with the approved NTIOL as the defining first member.

Manufacturers of IOLs who believe their IOLs have the same characteristics as NTIOLs that are part of an active NTIOL subset may seek CMS approval to recognize their IOL as part of that subset. If approved, these other IOLs would receive the same $50 payment adjustment that applies to the first NTIOL approved for the applicable subset for the remainder of the 5-year payment period.

To be considered for recognition as belonging to an active NTIOL subset, an IOL must first be an FDA approved IOL with approved labeling and advertising for an indication that is consistent with a current NTIOL subset. We may recognize an IOL as belonging to an active NTIOL subset if there is evidence that—

- Use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs, and
- The IOL shares the predominant class-defining characteristic with the NTIOL that initially established the class, and
- The IOL has been approved by the FDA, and claims of specific clinical benefits and/or lens characteristics with established clinical relevance have been approved by the FDA for use in labeling and advertising.

Review Process

We will evaluate requests for the recognition of an IOL as belonging to an active NTIOL subset by doing the following:

- Accepting requests throughout the year to review the appropriateness of recognizing an IOL as a member of an active subset of NTIOLs.
- Determining by internal CMS review which IOLs meet the criteria to qualify for membership in an active NTIOL subset based on the FDA approved label, clinical data and evidence submitted for review, and other available information.
- Completing the internal review of a request within 90 days of receipt of the request.
- Notifying the requestor of our determination.
- Posting the result(s) of our determination on the CMS website.

• We will not accept a request for inclusion of an IOL into an NTIOL subset for which CMS has previously denied recognition through this process, unless the request includes new clinical evidence or new information to demonstrate that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs; that the IOL shares the predominant class-defining characteristic with the NTIOL which initially established the class; and, that the IOL has been approved by the FDA, and claims of specific clinical benefits and/or lens characteristics with established clinical relevance have been approved by the FDA for use in labeling and advertising.

Who May Request a Review

Any party who is able to furnish the information required may request that we review the appropriateness of including an IOL in an active NTIOL subset.

Information Required for Request to Recognize an IOL for Membership in an Active NTIOL Class

A request to review must include all of the following information:

- Name and description of active class of NTIOLs in which membership is requested.
- Trade/brand name, manufacturer, and model number of the IOL for which the request is being made.
- Description of the common characteristic(s) of the candidate IOL and the IOL that initially established the NTIOL class in which membership is requested, where that characteristic is associated with improved clinical outcomes.
- Detailed description of the approved clinical indications for the candidate IOL.
- A copy of the FDA's summary of the IOL's safety and effectiveness for the indication that would allow it to fit into a current NTIOL subset.
- A copy of the FDA-approved label for the IOL.
- A copy of the IOL's original FDA approval notification.
- Reports of modifications made after the original FDA approval.
- Description of the IOL:
    - What is it? Provide a complete physical description of the IOL including its components, e.g., its composition, coating or covering, haptics, material, construction, etc.
    - What does it do?
    - How is it used?
    - What makes it different from other currently available IOLs?
    - What makes it superior to other currently available IOLs used for similar indications?
    - What are its clinical characteristics, e.g., is it used for treatment of specific pathology, what is its life span, what are the complications associated with its use, for what patient populations is it intended?

    - Submit relevant booklets, pamphlets, brochures, product catalogues, price lists,

and/or package inserts that further describe and illuminate the nature of the IOL, and other information that supports the requestor's claim (including clinical trials, case studies, journal articles, etc.).

- If the candidate IOL replaces or improves upon an existing IOL, identify the trade/brand name and model of the existing IOL(s).
- A 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 use of currently available IOLs in one or more of the following areas:

· Reduced risk of intraoperative or postoperative complication or trauma;
1 Accelerated postoperative recovery;
2 Reduced induced astigmatism;
3 Improved postoperative visual acuity;
4 More stable postoperative vision;
5 Other comparable clinical advantages such as--

· Reduced dependence on other eyewear (spectacles, contact lenses, reading glasses, etc.)
1 Decreased rate of subsequent diagnostic or therapeutic interventions such as need for YAG laser treatment.
2 Decreased incidence of subsequent IOL exchange.

Where are requests to be sent?

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

OPPS New Technology IOL
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 requests by facsimile (FAX) transmission or by e-mail.

Questions pertaining to the process for requesting review of an IOL for inclusion in a previously designated active NTIOL subset may be sent via e-mail to division of outpatient care's ASC mailbox, ASCPPS@cms.hhs.gov or by phone to 410-786-0378.