**Process for Recognizing Intraocular Lenses Furnished by Ambulatory Surgery Centers (ASCs) as Belonging to an Existing 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 existing 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 existing NTIOL subset may seek inclusion of their IOLs into 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. We have not previously received any applications for such recognition.

To be considered for recognition as belonging to an existing 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 existing NTIOL subset if the FDA-approved labeling for the lens along with clinical data and evidence and other available information supports the claim of achievement of the same or greater subset-specific quantitative and qualitative clinical benefit as the NTIOL that established that subset.

Review Process

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

- Accepting requests throughout the year to review the appropriateness of recognizing an IOL as a member of an existing subset of NTIOLs.
- Determining by internal CMS review which IOLs meet the criteria to qualify for membership in an existing 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 30 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 other information that documents an equal or greater subset-specific quantitative and qualitative clinical benefit as the NTIOL that established that subset.

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 existing NTIOL subset.

Information Required to Request a Review

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

- The name of the manufacturer, the model number, and the trade name of the 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.
- Other information that supports the requestor's claim (including clinical trials, case studies, journal articles, etc.). Applicants should provide evidence supporting claims that the applicant's IOL achieves the same or greater subset-specific quantitative and qualitative clinical benefit as the first NTIOL recognized in that subset.