New Technology Intraocular Lenses (NTIOLS)

Application Process and Information Requirements for Requests for a New Class Of (NTIOLs) or Inclusion of an IOL In an Existing NTIOL Class

New Technology Intraocular Lenses (NTIOLs) are intraocular lenses that replace a patient's natural lens that has been removed in cataract surgery and that also meet the requirements listed in § 416.195.

NTIOL Application Cycle: Submitting Requests for a New Class of NTIOLs

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

- The annual deadline for each year's requests for review of a new class of NTIOLs is announced in the OPPS/ASC final rule with comment period updating the ASC and OPPS payment rates for that calendar year.

- The requests for review received in a calendar year and the deadline for public comments regarding the requests are announced in the OPPS/ASC proposed rule updating the ASC and OPPS payment rates for the following calendar year.

- Public comments regarding the requests must be submitted 30 days following the display date the proposed rule.

- **Announcement of CMS determinations regarding requests for review:**
    - CMS reviews the information submitted with a completed request for review, public comments submitted within 30 days of the proposed rule display date, and other pertinent information
    - CMS announces its determinations in the OPPS/ASC 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.

CMS accepts requests for recognition of IOLs as belonging to an existing, active NTIOL category on an ongoing basis, throughout a given calendar year, and such requests are approved or denied on a quarterly basis. Therefore, the timing of submission of requests described above does not apply to requests for recognition of an IOL belonging to an existing, active NTIOL category.

NTIOL Application Requirements

The requirements and evaluation criteria for NTIOLs are described at 42 CFR § 416.195. These criteria apply to both requests for a new NTIOL class and requests for membership in an existing class. To enable CMS to make an appropriate determination as to whether the criteria for approving a new class of NTIOLs or for membership in an existing NTIOL class are met, a request for review must include all of the information listed below. The submission of all credible evidence, whether published or not, is encouraged, but published, peer-reviewed literature is strongly encouraged to demonstrate substantial clinical improvement of the candidate IOL versus currently available IOLs. An application for review is

not considered complete until all the required information has been submitted and all of the questions related to such information have been answered.

Applications must include all the following information:

Proposed name or description of a new class of NTIOLs.	▪ If applying for membership in an existing class, then specify the NTIOL class.
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.
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.
Description of the IOL	▪ Provide a complete description of the IOL and its design and characteristics, including its components, for example, its composition; coating or covering; haptics; material; and construction. ▪ What is the candidate IOL's new characteristic in comparison to other currently available IOLs? ▪ What is the claim in the FDA-approved label of a specific clinical benefit imparted by the new IOL characteristic? ▪ Submit relevant booklets, pamphlets, brochures, product catalogues, price lists, and/or package inserts that further describe and illuminate the nature of the IOL.
If the candidate IOL replaces or improves upon an existing IOL, identify the trade/brand name and model of the existing IOL(s).	
Full discussion of the measurable, clinically meaningful, improved outcomes that result from the specific clinical benefit imparted by the new lens characteristic in comparison to other currently available IOLs.	▪ Improved outcomes include the following: ▪ Reduced risk of intraoperative or postoperative complication or trauma. ▪ Accelerated postoperative recovery. ▪ Reduced induced astigmatism. ▪ Improved postoperative visual acuity. ▪ More stable postoperative vision. ▪ Other comparable clinical advantages
Provide the following information for the IOL(s) for which a new class is proposed:	▪ Dates the candidate IOL was first marketed, reporting inside the United States and outside the United States separately. ▪ Dates of sale of the first unit of the IOL, reporting inside the United States and outside the United States separately. ▪ Number of IOLs that have been sold up to the date of the application.
Provide the following information regarding approval of the candidate IOL by the U.S. Food and Drug Administration:	▪ A copy of the FDA's original approval notification. ▪ A copy of the labeling claims approved by the FDA for the IOL. ▪ A copy of the FDA's summary of the IOL's safety and effectiveness. ▪ Reports of modifications made after the original FDA approval.

Application Submission and Questions

Completed applications for a new class of NTIOLs should be directed via email to *outpatientpps@cms.hhs.gov*.

Questions pertaining to the NTIOL application process may also be sent via e-mail to the Division of Outpatient Care mailbox, *outpatientpps@cms.hhs.gov,* or by phone to 410-786-4142.

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).