

**CMS-3144-NC-1 CY 2005 Review of the Appropriateness of Payment Amounts for
New Technology Intraocular Lenses (NTIOLs) Furnished by
Ambulatory Surgical Centers (ASCs)**

Submitter : Ms. Brette McClellan

Date & Time: 10/31/2005

Organization : Alcon Laboratories, Inc.

Category : Device Industry

Issue Areas/Comments

GENERAL

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Please see attachment.

CMS-3144-NC-1-Attach-1.DOC

October 24, 2005

Mark B. McClellan, M.D., Ph.D.
Centers for Medicaid and Medicare Services
Department of Health and Human Services
Attention: CAPT Michael Lyman
Mail Stop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244-1850

ALCON LABORATORIES, INC.
6201 South Freeway
Fort Worth, Texas 76134-2099
(817) 293-0450

RE: File Code CMS-3144-NC

Dear Dr. McClellan:

On behalf of Alcon Laboratories, we are pleased to submit these comments in support of the proposal to establish a new technology intraocular lens (NTIOL) category for Aspheric Optic IOLs.¹ As explained below, asphericity preserves individuals' ability to distinguish differences in contrast, thereby improving their functional vision. A lack of contrast sensitivity makes it difficult to read in dim lighting conditions or see street or traffic signs when driving at night.

Aspheric optic IOLs represent a class of new technology IOLs. The predominant characteristic of these IOLs that sets them apart from conventional IOLs is an aspheric optical curvature that aligns light rays in a manner that reduces positive spherical aberrations of the cornea that interfere with clarity and image quality. Positive spherical aberration occurs when light rays are refracted (bent) more at the periphery of an optical structure than they are at central portion of the optical structure.

Dr. Richard L. Lindstrom, the Chief Medical Editor of *Ocular Surgery News*, recently described the importance of aspheric IOLs in an AMO-sponsored educational supplement to *Ocular Surgery News*. In the review, he explained:

"The crystalline lens of young eyes has an overall negative spherical aberration that compensates for positive spherical aberration of the cornea. As individuals age, the crystalline lens loses the ability to compensate for corneal spherical aberration. Although replacing the aging crystalline lens with a traditional spherical IOL during cataract surgery can improve Snellen visual acuity, functional vision may not be maximized because spherical IOLs produce positive spherical aberrations, which may reduce contrast sensitivity. A reduction in contrast sensitivity can, in turn, reduce overall functional vision. The Tecnis . . . aspheric IOL features a wavefront-designed, modified

¹ Medicare Program; Calendar Year 2005 Review of the Appropriateness of Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers (ASCs), 70 Fed. Reg. 57297 (Sept. 30, 2005).

prolate anterior surface designed to improve both contrast sensitivity and functional vision by compensating for the positive spherical aberration of the cornea.”²

Thus, the shape of the cornea, a conventional spherical IOL, and an aging crystalline lens can increase spherical aberration and result in a reduction in contrast sensitivity and decreased visual function. An aspheric optic IOL, by comparison, produces negative spherical aberration which offsets the position spherical aberration of the cornea. It is the asphericity that allows light rays entering various parts of the optic to align toward a single focal point on the retina.

There are different means to incorporate prolate, aspheric optic technology into an IOL, and each of the three major manufacturers that currently market aspheric optic IOLs in the US utilize different means to achieve asphericity:

- The Alcon AcrySOF[®] IQ aspheric optic IOL (AcrySOF IQ Model SN60WF) features a flattened curvature on the posterior surface of the lens without adding mass to the peripheral portion. This design achieves asphericity without increasing the edge thickness of the IOL.
- The AMO Tecnis aspheric optic IOL (Tecnis*, Models Z9000, Z9001, and Z9003) features an anterior surface that has been flattened by elevating the peripheral portion of the anterior surface of the lens. Edge thickness is increased.
- The Bausch and Lomb SofPort AO IOL (SofPort AO* IOL, Model LI61AO) features an aspheric posterior surface and a steeper aspheric anterior surface. Both surfaces have uniform power from center to edge.³

Given that aspheric technology offers patients the opportunity to achieve a level of functional vision that is not available with conventional IOLs, Alcon believes that these lenses meet the standard for establishing a NTIOL category. The category should be titled “Aspheric Optic IOLs” and include each of the IOLs noted above.

Thank you for accepting our comments. Please feel free to contact me with questions.

Sincerely,



Brette McClellan
Director, Health Policy Government Relations

² “Wavefront-Designed IOL; Correcting Corneal Spherical Aberration for Safer, Sharper Vision,” supplement to the September 15, 2005 issue of *Ocular Surgery News*, pgs. 1, 2, 5, 7, 13.

³ Bausch & Lomb sales literature, reference #SU-3749.

A handwritten signature in black ink, appearing to read "Bob Stevens", is located in the upper left quadrant of the page.

Bob Stevens
Vice President, Research & Development, Surgical Products

cc: Allison Shuren, Arent Fox