**CMS-3112-NC-1**

**Submitter :** Dr. Robert Cionni **Date & Time:** 08/23/2004 12:08:44

**Organization :** Cincinnati Eye Institute

**Category :** Physician

**Issue Areas/Comments**

**Issues**

NTIOL Application for Alcon Laboratories, Inc. Model Numbers: ACRYSOF Natural IOL; Models: SB30AL and SN60AT

Word file attached

CMS-3112-NC-1-Attach-1.doc

**ATTACH # 001**

Robert J Cionni M.D.
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Cincinnati Eye Institute
10494 Montgomery Road
Cincinnati, Ohio 45242

Department of Health and Human Services
Centers for Medicare and Medicaid Services

Re: CMS-3112-NC2

To whom it concerns:

I am writing this letter in support of NTIOL designation for Alcon's AcrySof Natural IOLs (Models SB30AL and SB60AT) based on their ability to filter blue wavelength light and thereby protect the retina from high-level exposure to blue light following cataract surgery. Macular degeneration is one of the leading causes of disabling blindness in the USA. The devastation this disease process brings to our elderly patients is all too common. The cost to society and to the Medicare program is enormous. The AcrySof Natural IOLs have the potential to decrease the incidence of developing severe macular degeneration following cataract surgery.

Epidemiological studies differ on the contribution of blue light exposure to the development and progression of macular degeneration. This is not surprising as trying to unravel the mysteries of such a complex, multifactorial, biologic process is always problematic. Therefore, laboratory studies are essential in helping to elucidate contributory factors in this sight-threatening process.

At Columbia University, Dr Sparrow exposed cultured human retinal pigment epithelial cells to blue light and observed extensive cell death. Dr Sparrow then placed different colorless, UV blocking IOLs or AcrySof Natural IOLs in the path of the blue light to see if any of the IOLs would provide a protective effect. The results of this study demonstrated that cell death was still extensive with all UV blocking colorless IOLs but very significantly diminished with the AcrySof Natural IOLs.[1] Although these experiments are laboratory in nature and speak more to acute light damage rather than chronic long-term exposure, they clearly demonstrate that by filtering blue light with an IOL, RPE cells can survive the photo-toxic insult of the blue light. This is just one of a multitude of laboratory studies found in the literature over the last few decades, which concludes that exposing the retina to high levels of blue wavelength light may lead to the progression of macular degeneration.

It is well known that the natural human crystalline lens blocks, not only UV light, but also much of the high frequency blue wavelength light. In fact, when a cataract is removed and replaced by a UV blocking colorless IOL, more blue-wavelength light

reaches the retina than ever before in that patient's life. The growing body of literature warning of the dangers of blue wavelength light has convinced me that every patient undergoing cataract extraction should be offered the opportunity to receive an IOL that filters blue light in a similar fashion to their natural crystalline lens. Since the early 1970s, IOL manufacturers have researched methods for filtering blue wavelength light waves in efforts to incorporate blue-light protection into IOLs. Not until the introduction of the AcrySof Natural IOL has this technology become available to patients in the USA. Unfortunately, the price of this IOL limits its use, especially in the Medicare population. We understand Alcon's need to charge a premium for this IOL considering the years of research and development required to bring the AcrySof Natural to market. However, there are few ASCs that will allow their surgeons to use higher priced IOLs that do not receive the increased reimbursement associated with NTIOL status. Therefore, many of our elderly patients will likely not receive this blue light filtering IOL because its reimbursement is simply too low.

By providing NTIOL status to this innovative IOL design, the AcrySof Natural would become more readily available to the majority of our cataract patients. If the use of blue light filtering IOLs begins to decrease the incidence of severe macular degeneration, not only will our patients be spared this devastation, but the Medicare program will benefit as well. All one needs do to understand this thinking, is to look at the cost of a single photodynamic therapy treatment relative to the additional reimbursement of an IOL. The cost savings to Medicare could be quite substantial.

In closing, let me reiterate that the AcrySof Naturals has the ability to filter blue light following cataract surgery, similar to the normal human lens before cataract developed. No other IOL in the USA has that ability. There is substantial evidence that increased exposure to blue light following cataract surgery may be a factor in the worsening of macular degeneration. By granting NTIOL status to the AcrySof Natural IOLs, more of our patients will be able to receive this IOL and less may go on to develop severe macular degeneration.

Sincerely,

Robert J. Cionni M.D.

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[1]Sparrow, J, Miller, A, Zhou, J. Blue light-absorbing intraocular lens and retinal pigment epithelium protection in vitro. J Cataract Refract Surg 2004; 30:873–878