SANSUM - SANTA BARBARA
Medical Foundation Clinic
Ophthalmology & Ophthalmic Surgery

October 26. 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CAPT Michael Lyman, CMS-3144-NC
Mail Stop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Capt. Lyman,

My name is Dr. Douglas Katsev. I am an eye surgeon with over fifteen years of clinical practice, including a specialty interest in intraocular lens technology and cataract surgery. I am writing this letter in support of designating the Tecnis IOL for NTIOL status. Based on my personal experience with the lens, and the difference it has made for my patients' vision, I would like to urge you to grant NTIOL status to this unique IOL.

Clinical studies have demonstrated that the Tecnis IOL significantly improves both night vision and night driving ability relative to the current IOL market leader. Because of these results, the Tecnis has been granted unique labeling claims by the FDA for:

- Improved functional vision (real life vision in varying light conditions)
- Decreased spherical aberration
- Improved nighttime driving safety

Based on my own clinical experience, I can attest to the fact that the Tecnis lens provides the best quality of vision for my patients. Many patients today expect to be able to get rid of their glasses and so, I often perform a monovision procedure (correcting one eye for distance vision and one eye for near vision). To do this requires the best possible vision for the eye that will do all the distance work. The distance vision needs to be as sharp as possible.

Do to the unique modified prolate technology of the Tecnis, it does cost me extra—money that I lose compared to implanting a traditional IOL, but the difference in my patients' vision is worth it. **Realistically however, not all physicians and/or surgery centers are willing to lose money to achieve better quality of vision.**

With the introduction of the Tecnis intraocular lens there has been a dramatic improvement in the quality of life of my patients. The Tecnis IOL, which takes into consideration the importance of the correction of spherical aberration with cataract surgery, is one of the few truly major advances in intraocular lens technology over the past two decades. This lens has had a remarkable effect on night vision and the ability of my cataract patients to live more independent lives. This contribution to medicine and society as a whole deserves special recognition and designation.

Sincerely,

Doug Katsev, M.D.,
Santa Barbara, CA

WALLACE EYE SURGERY
LASER AND SURGERY CENTER

October 26, 2005

Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attn: CAPT Michael Lyman, CMS-3144-NC
Mail Stop C1-09-06
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Mr. Lyman:

I have been using AMO Tecnis IOLs and find them to offer superior optical clarity. Patients have been able to notice this difference. In looking over the research it is clear that the Tecnis IOL offers some advantages over standard monofocal lenses in regards to improvement in contrast sensitivity, which leads to more rapid reaction times, such as in driving in low light conditions. Other companies have made attempts to manufacture lenses of similar design, but this lens seems to offer the best approach to creating an optical system that mimics the youthful human eye. When purchasing examination equipment that incorporates optical lenses, I judge their quality by the sharpness of the optics. We should view intraocular lenses in the same manner.

Please consider the value this technology provides our patients and consider it being designated as a new technology IOL. If I can supply further information that you would find helpful, please do not hesitate to contact me.

Sincerely,

R. Bruce Wallace, III, MD

RBWIII/dm

4110 Parliament Drive • Alexandria, Louisiana 71303
(318) 448-4488 • 1-800-349-4488 • FAX (318) 448-9731

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University of Utah
Moran Eye Center

Randall J. Olson , MD
The John A. Moran Presidential Professor
and Chair of Ophthalmology
Director, John A. Moran Eye Center
Department of Ophthalmology and Visual Sciences
50 North Medical Drive
Salt Lake City, UT 84132
(801) 581-2352 Fax (801) 581-3357

October 21, 2005

Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Attn: CAPT Michael Lyman, CMS-3144-NC
Mail Stop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244-1850

To Whom It May Concern:

The Tecnis intraocular lens is being considered for new technology IOL status. I strongly encourage this designation for this lens. It is the first that has successfully utilized an aspheric design to improve functional vision. The present spherical lenses induce spherical aberration which, in particular, hurts our vision in low light situations. The fact that this lens has been shown to improve reaction time by as much as one-half a second with night driving means that it is an important advance and is the only lens that has been allowed by the FDA to make such a claim.

I feel that this is the example of new technology which is already being copied by the other companies and should be awarded new technology status. I do hope you will view this application carefully.

Sincerely,

Randall J. Olson, MD
The John A. Moran Presidential Professor and
Chair of Ophthalmology and Visual Sciences
Director, John A. Moran Eye Center

RJO:jd

CSHP
Colorado Springs Health Partners, PC

Administrative Offices
209 South Nevada Avenue
Colorado Springs, CO 80903
(719) 475-7700
Fax (719) 475-1241

October 23, 2005

Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Attn: CAPT Michael Lyman, CMS-3144-NC
Mail Stop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Capt. Lyman:

I am writing this letter to convey my wholehearted support for the Tecnis IOL to receive NTIOL status.

In 14 years of practice, I have encountered many patients with a "perfect" postoperative clinical appearance, but a far from perfect clinical result. Typically, the description is of vague displeasure with the post-operative vision, despite demonstrating 20/20 acuity and an absolute lack of post-operative complications. This latter category of patient is well identified in the study by Pager[1] in which the standard VF-14 was used to assess pre-operative and post-operative subjective visual function. They demonstrated that a significant portion of individuals still had difficulty with night vision and small print, two areas of greatest concern for individuals contemplating cataract surgery.

The Tecnis IOL is remarkable for its ability to deliver improved vision for the patient, not just in terms of Snellen acuity, but also in terms of contrast sensitivity. Prior to adopting the use of the Tecnis in my practice, I thoroughly researched the available literature for any weaknesses this IOL might have in its routine performance. First, whether it is the original silicone Tecnis (based on the CeeOn 911 IOL platform), or the Tecnis Acrylic (based on the Sensar with OptiEdge IOL platform), the incidence of PCO with these three-piece IOLs with squared posterior edges is quite low[2]. This feature guarantees that PCO will not interfere with the improved function of the aspheric optic.

Second is the recognition that the function of these IOLs is dependent on proper centration. Significant improvements in the implantation of these IOLs have come in the form of the Emerald series Unfolders for the Tecnis Acrylic, and the Silver series for the silicone Tecnis. While I am comfortable that modern foldable IOLs do maintain good stability related to tilt and decentration regardless of insertion technique[3], I am even more confident that these

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1 Expectations and Outcomes in Cataract Surgery: A Prospective Test of 2 Models of Satisfaction
Chet K. Pager, Arch Ophthalmol. 2004;122:1788-1792.

2Buehl W, Findl O, Menapace R, Sacu S, Kriechbaum K, Koeppl C, Wirtitsch M. Long-term effect of optic edge design in an acrylic intraocular lens on posterior capsule opacification. J Cataract Refract Surg. 2005 May;31(5):954-61.

3Will tilt, decentration affect wavefront-corrected IOL result? Hoffman RS, Fine IH, Packer M, Ophthalmology Times, Oct 15, 2005, pp. 17-18

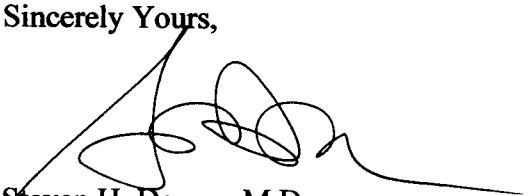
insertion systems will allow for an average surgeon to successfully implant the Tecnis IOLs on a consistent basis.

Third, and most important, is the valid demonstration that the wavefront-designed optic of the Tecnis enhances visual performance when compared to standard spherical IOLs[4]. The Tecnis is the only currently available IOL designed specifically to correct the measured optical aberrations of the eye. Fundamentally, one of the challenges in the acceptance of this technology is that the improvement for the patient is not something visible to the surgeon at the slit lamp. Rather, the evidence for the enhanced visual function comes from fellow-eye studies comparing the Tecnis to spherical IOL designs. By reducing the spherical aberration, the improvement in performance amounts to an extra 45 feet in distance when using a pedestrian target in a driving simulation, or an extra half-second of reaction time when driving at 55 MPH. These parameters are better than the published data for standard safety improvements, such as the elevated center brake light, which provides between 0.2 and 0.35 seconds of increased reaction time.[5]

As an ophthalmologist in general practice, I hold high the importance of maintaining the standard of care within the community. The simple design change of the Tecnis IOL—the modified prolate optic—requires no modification in technique to successfully implant, nor any special testing equipment to recommend its use. Yet, it represents a tremendous improvement in visual function over standard IOLs, which have previously been deemed "good enough." I have been impressed that fewer patients in my practice are reporting vague dissatisfaction with their vision with the Tecnis IOL, and I am confident that this technology will result in improved function and safety for our patients, not only in night driving, but also in simple mobility in dim-light conditions.

Granting the Tecnis NTIOL status would undoubtedly bring the issue of visual function after cataract surgery to the forefront for study. Even more, it would provide the stimulus to advance the standard of care, with the secondary benefits of improved public safety through safer drivers. I would encourage the panel to endorse NTIOL status for the Tecnis based on the breakthrough technology this lens delivers.

Sincerely Yours,



Steven H. Dewey, M.D.
Chief, Ophthalmology Section, Penrose Hospital

4Visual acuity and contrast sensitivity comparison between Tecnis and AcrySof SA60AT intraocular lenses: A multicenter randomized study. Bellucci R, Scialdone A, Buratto L, et al. J Cataract Refract Surg. 2005 Apr;31(4):712-7.

5 Assessing the Significance of Optically Produced Reduction in Braking Response Time: Possible Impacts on Automotive Safety Among the Elderly, McBride K, May 2003.

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DRs. FINE & HOFFMAN & PACKER OPHTHALMOLOGISTS

I. HOWARD FINE, M.D.
Clinical Professor of Ophthalmology, Oregon Health & Science University
Diplomat American Board of Ophthalmology
Fellow American Academy of Ophthalmology
Certified American Board of Eye Surgery
Past President, American Society of Cataract & Refractive Surgery

RICHARD S. HOFFMAN, M.D.
Clinical Associate Professor of Ophthalmology, Oregon Health & Science University
Diplomat American Board of Ophthalmology
Fellow American Academy of Ophthalmology
Fellowship Trained in Corneal Surgery & External Disease

MARK PACKER, M.D., F.A.C.S.
Clinical Assistant Professor of Ophthalmology, Oregon Health & Science University
Diplomat American Board of Ophthalmology
Fellow American Academy of Ophthalmology
Fellow American College of Surgeons

October 20, 2005

Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Attn: CAPT Michael Lyman, CMS-3144-NC
Mail Stop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Capt. Lyman:

I am writing in support of New Technology Intraocular Lens (NTIOL) Status for the Tecnis Z9000 modified prolate IOL. I have had extensive clinical research experience with this device and would like to take this opportunity to outline the scientific data that form the basis for my support.

I served as Coordinating Investigator for the multicenter prospective randomized clinical investigation of the Tecnis IOL that underlies labeling approved by FDA. In this double masked study, subjects performed sequential monocular night driving simulation with one eye implanted with the Tecnis IOL and the fellow eye implanted with a control spherical IOL. As you know, FDA recognized significant improvement in functional vision for night driving and other activities of daily living performed under low light conditions for the Tecnis IOL. Independent evaluation of these findings by the Potomac Institute indicates that the Tecnis IOL provides 0.5 second of increased reaction time, a greater benefit than the third brake light mandated by DOT (0.3 second).

Although the FDA monitored clinical investigation did not meet its primary endpoint of significantly improved mesopic contrast sensitivity at 6 cycles per degree, there has been unusual unanimity in peer-reviewed publications regarding the Tecnis IOL. Every publication that has appeared in the scientific literature to date has demonstrated significant improvement in functional vision with the Tecnis IOL. The chart below lists these publications and provides a brief statement regarding their methods and results. These studies have allowed us to conclude that the Tecnis IOL not only eliminates mean residual spherical aberration after cataract surgery but also provides significantly better contrast sensitivity and contrast acuity than standard spherical IOLs.

The demonstration that elimination of spherical aberration in the aging eye improves contrast sensitivity to levels enjoyed by the younger population shows that decreases in functional vision associated with aging are in fact due to changes in the human lens and therefore reversible by cataract surgery and lens replacement. Cataract patients implanted with the Tecnis IOL enjoy improved highway safety and represent a potentially significant savings in morbidity and

mortality among drivers and pedestrians. These improvements in functional vision deserve recognition from CMS that the Tecnis IOL represents a significant advance in intraocular lens technology. I therefore respectfully recommend NTIOL Status for the Tecnis IOL.

Sincerely,

Mark Packer, MD, FACS

Author	***Journal***	***Date***	***Comparator IOL(s); Study Design***	***Results***
Packer	*J Refract Surg*	2002	AR40e; inter-individual; 21 eyes of 21 patients	Significantly better mesopic and photopic CST
Mester	*J Cataract Refract Surg*	2003	SI 40; intra-individual; 45 patients	Elimination of SA, significantly better low contrast VA and CST
Packer	*J Cataract Refract Surg*	2003	AR40e; inter-individual; 30 patients	Significantly better mesopic and photopic CST
Kershner	*J Cataract Refract Surg*	2003	Silicone plate haptic and single piece acrylic;221 eyes of 156 patients	Significantly better CST, enhanced retinal image contrast
Bellucci	*J Refract Surg*	2004	911 A, SA60AT, MA60BM, AR40e; inter-individual; 60 eyes of 60 patients	Elimination of SA, reduction of mydriatic myopic shift
Ricci	*Acta Ophthalmol Scand*	2004	911 A; intra-individual study of 12 patients	Significantly better mydriatic low contrast photopic VA for contrast ≤ 25%,
Kennis	*Bull Soc Belge Ophtalmol*	2004	AR40e, SN60AT; inter-individual; 98 eyes of 71 patients	Significantly better CST
Bellucci	*J Cataract Refract Surg*	2005	SA60AT; inter-individual study of 30 eyes of 30 subjects compared to 30 eyes of 30 matched subjects	Significantly better CST
Casprini	*Acta Ophthalmol Scand*	2005	MA30BA, AR40, SA30AL, Alcon; AR40e, Tecnis Z9000; 175 patients randomly recvd 1 type of lens	MA30BA has significantly more dysphotopsia and greater spherical aberration than the other lenses.
Martínez Palmer	*Arch Soc Esp Oftalmol*	2005	SA60AT; inter-individual; 32 Tecnis and 32 AcrySof	Significantly better VA; better CST

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MINNESOTA EYE CONSULTANTS, P.A.

CONSULTATIVE OPHTHALMOLOGY
Richard L. Lindstrom, M.D.
Thomas W. Samuelson, M.D.
David R. Hardten, M.D., F.A.C.S.
Elizabeth A. Davis, M.D., F.A.C.S.
William J. Lipham, M.D., F.A.C.S.
Patrick J. Riedel, M.D.
John E. Bergstedt, M.D.
Byron A. Teska, M.D., F.A.C.S.
Jane Haugen West, M.D.
Jason K. Darlington, M.D.

CONSULTATIVE OPTOMETRY
Marlane J. Brown, O.D., F.A.A.O.
Alyson L. Blakstad, O.D.
Mary Jo Femrite, O.D.
Timothy J. Goldsmith, O.D.
Wendy A. Goldsmith, O.D.
Deanna E. Harter, O.D.
Scott G. Hauswirth, O.D.
Neelu K. Hira, O.D., F.A.A.O.
Jodine L. Janzen, O.D.
Jodie S. Larson, O.D.
Jason B. Stowe, O.D.
Ahmad M. Fahmy, O.D.
Benjamin J. Fogal, O.D.

TOLL FREE
800-EYE-TO-EYE
1-800-393-8639

INTERNET
www.mneye.com

October 27, 2005

Centers for Medicare
& Medicaid Services
Department of Health & Human Services
ATTN: Capt. Michael Lyman, CMS/3144/NC
Mailstop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Capt. Lyman:

This letter is to support approval of the Tecnis intraocular lens for NTIOL reimbursement (an additional $50). The reasons for this are as follows:

(1) The Tecnis IOL has a unique Wavefront design that leads to reduction in overall ocular spherical aberration.
(2) Reducing spherical aberration in the eye leads to improved functional vision for patients. It improves their ability to function in various tasks with varying lighting conditions.
(3) The visual advantage provided by the Tecnis is similar to the optical improvement of an image taken with an expensive camera lens as compared to a disposable camera.
(4) The Tecnis was demonstrated to provide a significant advantage over a standard spherical IOL in a driving simulation study. Patients were able to see the pedestrian hazard 45 feet sooner with their eyes that were implanted with Tecnis lenses. At 55 miles per hour, this difference equates to an additional 0.5 seconds to react to the hazard.
(5) While the initial driving stimulator study did not show a statistically significant difference in contrast sensitivity between Tecnis and a standard spherical IOL, numerous subsequent studies have shown an improvement in contrast sensitivity for the Tecnis IOL.

I have seen in my own personal experience improvement in contrast sensitivity and improvement in functional vision. Particularly, my older patients feel safer and more mobile at nighttime. I have been implanting Tecnis lenses for two years, and these have certainly elevated the standard of care for our patients.

If you have any questions, please do not hesitate to contact me at 952.885.2467. I look forward to your support of the NTIOL status for the Tecnis lens.

Sincerely,

EDavis, M.D.

Elizabeth A. Davis, M.D., F.A.C.S.
Corneal, Cataract, and Refractive Surgeon
Partner, Minnesota Eye Consultants, P.A.
Assistant Clinical Professor, University of Minnesota

EAD/djh

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Chu *Vision*

INSTITUTE

October 28, 2005

Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Attn: CAPT Michael Lyman, CMS-3144-NC
Mail Stop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: NTIOL application for the Tecnis intraocular lens

Dear Captain Lyman,

I am writing to you in support of the NTIOL application for the Tecnis intraocular lens. The Tecnis lens is unique in that it has a wavefront design that leads to an overall reduction in ocular spherical aberration. This reduction in spherical aberration leads to improved functional vision, which helps real-world vision in various tasks in varying lighting conditions.

The visual advantage provided by the Tecnis is similar to the optical improvement of an image taken with an expensive camera lens versus a disposable camera. The Tecnis is the only lens with FDA human clinical data that demonstrated a significant advantage over a standard spherical IOL in a driving simulation study. In this study, patients are able to see the pedestrian hazard 45 feet sooner with their Tecnis eye. At 55 mph this difference equates to an additional 0.5 seconds to react to a hazard, or about 4 car lengths. While this initial driving simulator study did not show us a statistically significant difference in contrast sensitivity between Tecnis and a standard spherical IOL, numerous subsequent studies have shown an improvement in contrast sensitivity for the Tecnis.

In my personal experience, it has become very common for elderly cataract patients to desire safety and comfort during their daily activities, which make them more mobile, thus having a more active and happier lifestyle. They feel like the clock has been turned back and that their vision has been restored to the type of vision they had when they were much younger. We have implanted over 2500 Tecnis lenses over the last two and a half years and feel that this truly represents an increased standard of care for patients because it not only improves Snellen visual acuity for elderly cataract patients, but it also improves the safety benefit that these patients have when they function in low light conditions such as night driving. I therefore strongly encourage you to support the NTIOL application for the Tecnis lens so that more patients will benefit from this advanced technology.

Sincerely,

Y. Ralph Chu, M.D.

Y. Ralph Chu, M.D. Jessica Matsumoto, O.D. Dan Davis, O.D. Jacob Lang, O.D.

7760 France Avenue South, Suite 140, Edina MN 55435
866-400-EYES p: 952-835-1235 f: 952-835-0534

DRs. FINE & HOFFMAN & PACKER OPHTHALMOLOGISTS

I. HOWARD FINE, M.D.
Clinical Professor of Ophthalmology, Oregon Health & Science University
Diplomat American Board of Ophthalmology
Fellow American Academy of Ophthalmology
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Clinical Associate Professor of Ophthalmology, Oregon Health & Science University
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Fellow American Academy of Ophthalmology
Fellowship Trained in Corneal Surgery & External Disease

MARK PACKER, M.D., F.A.C.S.
Clinical Assistant Professor of Ophthalmology, Oregon Health & Science University
Diplomat American Board of Ophthalmology
Fellow American Academy of Ophthalmology
Fellow American College of Surgeons

October 21, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CAPT Michael Lyman, CMS-3144-NC
Mail Stop CI-09-06
7500 Security Blvd
Baltimore, MD 21244-1850

Dear Captain Lyman,

I am writing to you to strongly support the designation of the Tecnis intraocular lens as a new technology IOL. This lens, as you know, has many advantages that have already been documented, the most important of which is the increased safety in driving for pseudophakic senior citizens. This has enormous social and economic relevance to our society and that, in itself, is the strongest indication for such a designation.

In our own practice, we participated in the FDA-monitored core investigation of this IOL and actually documented with research in our group of patients that contrast sensitivity in seniors with the Tecnis IOL were similar to, or compared favorably to, 30 year-olds who never had a cataract. In addition, mesopic contrast sensitivity was better in patients with the Tecnis IOL than the photopic contrast sensitivity in patients implanted with standard spherical IOLs. We have continued to use this IOL since the initiation of the clinical trials several years ago and have published our experiences with this IOL in peer reviewed journals[1,2].

Once again, I am strongly in support of a new technology IOL designation for this lens. It is important that it be made available to as many cataract patients as possible.

Respectfully submitted,

I. Howard Fine, MD

IHF/slb

[1] Packer M, Fine IH, Hoffman RS, Piers PA. Prospective randomized trial of an anterior surface modified prolate intraocular lens. *J Refract Surg* 2002; 18:692-696.

[2] Packer M, Fine IH, Hoffman RS, Piers PA. Improved functional vision with a modified prolate intraocular lens. *J Cataract Refract Surg* 2004; 30:986-992.

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ASSIL EYE INSTITUTE

KERRY K. ASSIL, M.D., INC.

Kerry K. Assil, M.D.
Gila Golchet, O.D.
Philip Kwok, O.D.
Richard Lin, O.D.
Emily Livieratos, O.D.
Loren Yasunari, O.D.

Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attn: CAPT Michael Lyman, CMS-3144-NC
Mail Stop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244-1850

To Captain Lyman,

Spherical aberration can decrease the quality of vision. Symptoms include poor contrast vision, decreased night vision, and debilitating glare. Even if a patient tests well in an exam chair reading high contrast charts, they can be very disabled in real life situations for various tasks, under various lighting conditions. Spherical aberration can be the result of unusually flat corneas and in patients with a history of radial keratotomy or myopic LASIK.

At the time of cataract extraction, an intraocular lens is chosen based on its dioptric power to correct refractive error. This was sufficient in the past, but now with the advent of newer intraocular lenses, the surgeon must also consider a lens that can reduce overall spherical aberration when indicated. This decision will become more prevalent as more patients are undergoing refractive surgery procedures. Another consideration is for patients who suffer from age-related macular degeneration. They can receive benefits of reduced spherical aberration by improving their contrast vision. Yet another consideration is for patients with early cataract changes, who complain of glare problems while driving at night. Surgeons should not have to use a substandard lens when better lenses are available.

The Tecnis Z9000, Z90001 and ZA9003 have the ability to reduce overall ocular spherical aberration with their unique wavefront design. Studies have shown a visual advantage for patients in a driving simulator with the Tecnis intraocular lenses. Numerous other studies have shown an improvement in contrast sensitivity. As a result, the Tecnis lenses should receive NTIOL status.

Thank you,

Kerry Assil, M. D.
Assil Eye Institute

2232 Santa Monica Blvd. • Santa Monica, California 90404 • 310.453.8911 • 310.453.2519 fax
www.assileyeinstitute.com

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Eye Laser Consulting

Robert M. Kershner, M.D., M.S., F.A.C.S.

Wednesday, October 19, 2005

Attn: CAPT Michael Lyman, CMS-3144-NC
Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Mail Stop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on the Application of Advanced Medical Optics, Inc., Santa Clara, CA USA *Request for Review for Designation as a New Technology Intraocular Lens Furnished by Ambulatory Surgical Centers for the Tecnis® Foldable Posterior Chamber Intraocular Lens. File Code CMS-3112-NC2.*

Dear Captain Lyman:

I am an ophthalmologist, eye physician and surgeon, Clinical Professor of Ophthalmology, research scientist, a widely published and internationally recognized educator in ophthalmic surgical technique and a specialist in intraocular lenses. I am taking this opportunity to comment on the Tecnis, a modified prolate anterior surface intraocular lens (IOL) for cataract surgery that has been submitted to CMS for NTIOL approval. I have personally surgically implanted hundreds of these lenses in my patients since FDA approval. There is no question, based upon my extensive experience, that this IOL should be granted NTIOL status following review.

The Tecnis IOL is the first FDA approved IOL that contains a highly sophisticated wavefront-designed modified prolate anterior surface optic that has been shown to reduce spherical aberration in the human eye[1]. Much as a modified prolate lens in a camera improves image quality on the film, the Tecnis is designed to neutralize the positive spherical aberration of the human cornea. The FDA clinical trial of the Tecnis IOL compared it to the most commonly implanted IOL in the United States, a conventional spherical IOL made from an acrylic material. The Tecnis significantly reduced ocular spherical aberration, the most common optical aberration of the human eye, resulting in improved functional vision for cataract patients[2]. The Tecnis also was demonstrated to significantly improved simulated night driving performance of patients implanted with the IOL.[3]

Today, there are dozens of peer reviewed studies to corroborate the manufacturer's claims that the Tecnis IOL creates better uncorrected acuity for the cataract patient, reduces spherical aberration, improves contrast perception and improves driving safety[2]. What does this mean for cataract patients in the real world? Elderly drivers are more likely to have age-

Diplomate • American Board of Ophthalmology
Diplomate • American Board of Eye Surgery
Fellow • American College of Surgeons

Two Avery Street • Suite 19E • Boston, MA 02111-1003 • (978) 270-3835 • FAX (617) 357-5077
kershner@eyelaserconsulting.com

related cataracts affecting their vision, are at greater risk of automobile accidents than their children, and have an increased risk of dying in those accidents[4]. A demonstrated 47-foot stopping advantage at 55 miles per hour for those implanted with the Tecnis IOL translates into a one-half second of added safety[5]. No other IOL approved by the FDA has been shown to result in this direct benefit for the patient.

All of today's IOLs do a good job of providing clear vision for most postoperative cataract patients. The technology of today's IOLs does not address the untreated spherical aberration that remains following cataract surgery. My own independent studies, published in the *Journal of Cataract and Refractive Surgery* in October of 2003, compared the Tecnis IOL with conventional single piece spherical, silicone and acrylic IOLs[2]. Functional vision was improved under all photopic and scotopic conditions for patients implanted with the Tecnis IOL. The studies also demonstrated improved image contrast of funduscopic photographs in patients with the Tecnis IOL compared to conventional spherical IOLs.

The advanced technology that went into the design of the Tecnis IOL is substantial. The developers of the lens painstakingly measured the average corneal spherical aberration in a group of cataract patients and designed the Tecnis IOL optic with a modified prolate anterior surface to accurately neutralize that aberration in over 96% of patients implanted with the IOL. This new technology works. The Tecnis IOL *should* be granted NTIOL status.

Very truly yours,

MD, MS, FACS

Robert M. Kershner, M.D. M.S., F.A.C.S.
Clinical Professor of Ophthalmology,
Eye Physician and Surgeon

Enclosures:

References:

1. Bellucci, R, Morselli, S, Piers, P. Comparison of wavefront aberrations and optical quality of eyes implanted with five different intraocular lenses. *J Refract Surg.* 2004;20:297-306.

2. Kershner RM. Retinal image contrast and functional visual performance with aspheric, silicone, and acrylic intraocular lenses. *J Cataract Refract Surg.* 2003;29:1684-1694.

3. Mester U, Dillinger, P. Anterist, N. Impact of a modified optic design on visual function: Clinical Comparative Study. J Cataract Refract Surg. 2003;29(4):652-660.

4. Owsley C, Stalvey B, Wells J, Sloane ME. Older drivers and cataract: driving habits and crash risk. *J Gerontology* 1999;54A:M203-11.

5. McBride DK, Matson W. Assessing the Significance of Optically Produced Reduction in Braking Response Time: Possible Impacts on Automotive Safety Among the Elderly. *Potomac Institute for Policy Studies Report*. April 1, 2003.

HEALTHSOUTH

October 31, 2005

VIA HAND DELIVERY

Mark B. McClellan, M.D., Ph.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3144-CN
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-3144-CN - Medicare Program; Calendar Year 2005 Review of the Appropriateness of Payment Amounts for New Technology Intraocular Lenses (NTIOLs) Furnished by Ambulatory Surgical Centers (ASCs)

Dear Dr. McClellan:

On behalf of the Surgery Division of HealthSouth Corporation, I am pleased to submit the following comments regarding the calendar year 2005 applications for new technology intraocular lenses (NTIOLs). 70 Fed. Reg. 57297 (September 30, 2005).

Advanced Medical Optics has submitted application for a payment adjustment for the Tecnis® Models Z9000, Z9001 and ZA9003 intraocular lenses as a class of new technology intraocular lenses.

Under 42 CFR 416.180, an intraocular lens may be classified as a new technology intraocular lens if claims of specific clinical advantages over existing intraocular lenses have been approved by the Food and Drug Administration (FDA) for use in labeling and advertising. Tecnis® Models Z9000, Z9001 and ZA9003 intraocular lenses all have FDA-approved product labeling claiming improved functional vision and compensation for corneal spherical aberration.

CMS has requested data showing functional clinical improvements as opposed to improvements with mere statistical significance. The anterior prolate surface design of these lenses offers tangible clinical benefits to patients. A clinical study[1] simulating night driving conditions found that pseudophakic eyes implanted with the Tecnis lens experienced an improved ability to detect and identify highway signs and pedestrian hazards, even with glare. Patients viewing a rural road through a Tecnis lens under minimum ambient lighting identified a pedestrian 45 feet sooner at 55 miles per hour. The Potomac Institute for Policy Studies found

[1] TECNIS™ Foldable Posterior Chamber Intraocular Lens Package Insert. Advanced Medical Optics.

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205 967-7116
http://www.healthsouth.com

that under these conditions, patients had an average of 0.5 seconds longer to identify and react to a pedestrian hazard. This suggests a safety advantage for night driving.

In summary, the Tecnis® Models Z9000, Z9001 and ZA9003 intraocular lenses meet CMS's requirements for FDA-approved product labeling claims as well as demonstrating clinical benefits with functional significance. We therefore support the classification of these lenses as new technology intraocular lenses.

Thank you for considering our comments.

Sincerely,

Kimberly L. Wood, M.D.
HealthSouth Corporation
One HealthSouth Parkway
Birmingham, AL 35243
ATTN: Vanna Zimmerman
Phone: 828-236-3027 Fax: 205-262-3794
Email: kimberly.wood@healthsouth.com