



Dear Employer:

The employee presenting this information to you, or a dependent family member, suffers from a rare degenerative disease of the cornea, the clear front surface of the eye. Called Keratoconus, it severely impacts vision and can lead to blindness. Your employee and their corneal surgeon have determined that treatment with Intacs is the best option. Intacs is breakthrough treatment for Keratoconus which provides equal or superior improvement in vision versus the traditional cornea transplant, greatly improving quality of life.

Unlike a corneal transplant, the recovery period is relatively fast, the risk of complication is minimal and the cost of the procedure is substantially less. The accompanying material about Intacs for Keratoconus is for discussion with your third-party health care administrator (TPA) or your medical plan provider. While medicine is flush with new developments, these many times seem to only increase the cost of care instead of reducing it. All businesses, including ours, have been challenged by rising medical costs that erode profit margins and negatively impacts employee benefits. This is not the case with Intacs.

Intacs corneal implants were approved by the US FDA three years ago under a special Humanitarian Device Exemption (HDE), since it will be utilized in fewer than 4,000 patients per year. From a coverage standpoint, new treatments for obscure conditions, like Keratoconus, are often problematic for patients to receive reimbursement under the company health care plan. Typically, less common procedures are initially rejected by payers and TPAs. The Improvements in effectiveness of care they provide are not well understood and there is a presumption that treatment costs and procedure volume may increase. They use the HDE approval to label the procedure "investigational" or "research" even though FDA clearly states Intacs are safe, not considered investigational and are now supported by more than twenty peer reviewed studies including several showing long-term stability.

The key benefits of Intacs to the employee and company include:

- A new outlook on life and increased productivity
- A procedure that is half the cost of the alternative corneal transplant
- A significantly reduced recovery time measured in days, not months or more
- Elimination of significant potential complications associated with corneal transplant
- Elimination of costly short and/or long-term disability benefits

The attached materials provide a review of the specific nature of the Keratoconus disease and an understanding of the Intacs treatment option. Please review them and contact the patient's surgeon directly with any specific questions you may have. Intacs is a compelling medical breakthrough in the treatment of keratoconus that can provide satisfaction to the employee and cost effective medical care for the company.

Thank you for assisting your employee to improve their medical care.

Sincerely,

William Flynn  
President & CEO  
Addition Technology, Inc.

## **Evidence Based Talking Points For Medical Director Peer Review Consideration & Policy Review**

The following are for the purpose of providing more detail comparing Intacs to the alternative comparable procedure – a corneal transplant. These are clear reference points often misinterpreted and improperly used in denials and negative policies.

### **1. Keratoconus is a disease not a refractive error.**

- Bi-lateral, non-inflammatory, progressive ectasia of the cornea which can result in severe vision loss and requires cornea transplantation (penetrating keratoplasty or PK) for a subset of patients.
- PK is normally undertaken to restore functional vision and until recently was the only option for these patients. If untreated keratoconus can lead to blindness in 10% of sufferers and is often debilitating for a larger percentage.

### **2. The objective is to return functional vision with contacts or glasses.**

- Intacs for keratoconus is used to normalize the shape of the diseased cornea.
- Appropriate candidates are whose vision has deteriorated to such a point that eye glasses and contact lenses can no longer provide functional vision or cannot be tolerated throughout productive hours of the day. Continuing to fit contact lenses on steep, bulging corneas can cause permanent scarring and central corneal opacities.
- Both Intacs corneal implants and a corneal transplant are procedures whose objective is to restore functional vision by returning the patient to glasses or tolerant contact lens wear. Neither Intacs for keratoconus or a corneal transplant is an elective procedure.

### **3. Intacs corneal implants is a safer more cost-effective option than a corneal transplant for contact lens intolerant keratoconus sufferers**

- Intacs corneal implants are effective, less invasive and significantly less risky noting infection as one of the preventable complications treatable with topical antibiotic drops.
- Complications that have been documented for a corneal transplant are far more severe as opposed complications from a corneal lamellar out-patient procedure like Intacs for keratoconus.
- A corneal transplant has a 17.9% rejection rate and operative complications including expulsive hemorrhage, endophthalmitis, potential inducement of cataract, glaucoma, corneal ulcer, neovascularization, induced astigmatism, unstable vision and, risk of viral transference. Significant endothelial cell loss and a permanent weakening of the cornea is also important findings that potentially hinders the success of additional transplants in the future which is a primary concern with a younger population of patients.
- Potentially delaying a corneal transplant as long as possible is in the best interest of the patient versus the risks and complications associated with a corneal transplant.

4. In addition to the medical facts above, the total billed charges to the healthcare system for Intacs corneal implants have a significant cost-effective advantage over a corneal transplant.

Comparison	Estimated Billed Charges
Total Transplant Procedures in 2005	32,840
Ectasia Transplant Procedures in 2005	5,056
*Intacs Corneal Implant Procedure	\$6,000 - \$9,000
*Billed Charges Corneal Transplant (1 <sup>st</sup> Year)	\$19,100
Estimated <u>Cost-Effective Savings Per Claim</u>	\$12,100 – \$10,100

\*See 2005 Milliman Report

\*Random sample from practices across the U.S.

5. **Intacs Corneal Implants have a significantly faster recovery than a corneal transplant.**
- Intacs corneal implants typically require no more than a day or two away from work and patients are able to return to normal activities within one to two weeks. A corneal transplant requires extended disability absence for recovery of vision with sutures remaining in place for twelve to eighteen months.
6. **Intacs complications are related to minor vision symptoms**
- Glare, halos and light sensitivity is common with Intacs corneal implants and in corneal transplants.
  - Although extremely rare, unsatisfactory implant placement or infection (like any surgery) can occur and are easily managed through standard removal techniques and treated with standard medical eye drops.
7. **Intacs safety and efficacy for keratoconus has been established through the 1999 FDA approval process, the 2004 FDA clearance for use in treating myopia and astigmatism associated with keratoconus and in peer reviewed publications**
- Since Intacs corneal implants received FDA approval in 1999 and 2004 FDA clearance, more than one hundred peer reviewed publications and studies document the preponderance of clinical data supporting effectiveness of the procedure and its place as a standard of keratoconus care.
8. **As a Humanitarian Use Device and with a Humanitarian Device Exemption, Intacs Corneal Implants addresses a small yet impactful patient subset similar to other covered orphan drugs.**
- Given the 1999 FDA approval, the 2004 FDA clearance and the preponderance of clinical publications, Intacs Corneal Implants far exceeds the clinical data requirements of most Class III medical devices.
  - For clarity, IRB oversight is a FDA requirement and does not indicate that the device is investigational (see letter from the FDA).
9. **The Keratoconus Patient Lifecycle.**
- Historically, a contact lens intolerant keratoconus sufferer had a corneal transplant as their only option due to their inability to wear a contact lens or that the cornea has become scarred. Since 2004, Intacs corneal implants offer a safer standard of care for contact lens intolerant patients.

#### **10. Intacs inclusion criteria are well defined**

The subset of Keratoconus patients to be treated (defined in the FDA approval) are those:

- Who have experienced a progressive deterioration in their vision, such that they can no longer achieve adequate functional vision on a daily basis with their contact lenses or spectacles;
- Who are 21 years of age or older
- Who have clear central corneas
- Who have a corneal thickness of 450 microns or greater at the proposed incision site
- Who have only PK as the remaining option to improve functional vision

#### **11. Intacs for keratoconus has several limiting factors .**

- They are approved under an HDE and limited to 4,000 patients per year.
- Annually, there are between 4,800 to 5,056 corneal transplant procedures in the US for corneal ectasias according to US Eye Bank data and the 2005 Milliman Report.
- In the U.S. only a few hundred surgeons perform the procedure which must be completed under IRB supervision.

In summary, evidence based medical practice has determined Intacs corneal implants for the treatment of keratoconus is the preferred treatment option compared to a corneal transplant. Furthermore, immediate cost-savings to the payer and the health system has been established through factual comparative analysis. Enclosed is a list of peer reviewed publications and studies supporting the safety and efficacy of your decision to approve Intacs corneal implants for keratoconus. As a courtesy, I've attached a list of policies by other payer organizations that are enjoying the medical benefits and cost-effectiveness of Intacs corneal implants as the preferred option for keratoconus sufferers.

Thank you in advance for your thorough evaluation of the enclosed materials – Thank You!

## Peer Reviewed Literature, Intacs for Keratoconus

Title	Authors
Intracorneal Ring Segment Implantation for the Management of Keratoconus: Safety and Efficacy	Zare MA, Hashemi H, Salari MR.
Intacs for Keratoconus and Post-LASIK Ectasia : Mechanical Versus Femtosecond Laser-Assisted Channel Creation	Carrasquillo KG., Rand J., Talamo JH
Combined Intacs and Posterior Chamber Toric Implantable Collamer Lens Implantation for Keratoconic Patients with Extreme Myopia	Cokunseven, Onder, Kymuonis, Diakonis, Arslan, Tsiklis, Bouzoukis, Pallikaris
Intacs for the Correction of Keratoconus	Hustler A., Manna A., Morris S., Horgan S.
Intracorneal Rings for Keratoconus and Keratectasia	Ertan, Colin
Intacs for Keratoconus	Rabinowitz, YS
Sequential Intacs and Verisyse Phakic Intraocular Lens for Refractive Improvement in Keratoconic Eyes	El-Raggal, TM, Abdel Fattah AA
Comparison of outcomes of 2 channel sizes for intrastromal ring segment implantation with a femtosecond laser in eyes with keratoconus.	Ertan A., Kamburoglu G., Akgun U.
Penetrating keratoplasty versus intrastromal corneal ring segments to correct bilateral corneal ectasia; preliminary study.	Rodriguez LA, Guilen PB, Benavides MA, Garcia L., Porras D., Daqui-Garay RM
Implantation of Artisan toric phakic intraocular lens following Intacs in a patient with keratoconus.	Kamburoglu G., Ertan A., Bahadir M.
Histopathological findings after intracorneal ring segment implantation in keratoconic human corneas.	Samimi S., Leger F., Touboul D., Colin J.
Management of superior pellucid marginal degeneration with a single intracorneal ring segment using femtosecond laser.	Ertan A., Bahadir M.
Long-term follow-up of Intacs in keratoconus.	Kymionis GD, Siganos CS, Tsiklis NS, Anastasakis a., Yoo SH, Pallikaris AI, Astyrakakis N., Pallikaris IG
Topography-guided vertical implantation of Intacs using a femtosecond laser for the treatment of keratoconus	Bahadir, Memet, Ertan, Aylin
Reduced best spectacle-corrected visual acuity from inserting a thicker Intacs above and thinner Intacs below in keratoconus.	Chan CC, Boxer Wachler B.
Effect of inferior-segment Intacs with and without C3-R on keratoconus	Boxer Wachler, Chan, Franzco
Intacs for the correction of keratoconus: Two-year follow-up	Colin, Joseph, Malet, Florence J.
New Surgical approaches to the Management of Keratoconus and Post-Lasik Ectasia	Tan, Purcell, Torres, Schanzlin
Intacs insertion with femtosecond laser for the management of keratoconus: one-year results	Ertan A., Kamburoglu G., Bahadir M.
Optical coherence tomography to assess intrastromal corneal ring segment depth in keratoconic eyes	Lai MM, Tang M., Andrade EM, Li Y., Khurana RN, Song JC, Huang D.
INTACS inserts using the femtosecond laser	Rabinowitz YS, Li X., Ignacio TS, Maguen E.

compared to the mechanical spreader in the treatment of keratoconus	
Intrastromal ring segment insertion using a femtosecond laser to correct pellucid marginal corneal degeneration	Ertan A., Bahadir M.
After 5 Years Follow-Up: Do Intacs Help in Keratoconus?	Ibrahim, Tarek A.
Intacs Adjustment Surgery for Keratoconus	Pokroy, Levinger
Intracorneal Ring Segments for Keratoconus Correction: Long-term Follow-up	Alio, Shabayek, Artola
Analysis of Results Related to Good and Bad Outcomes of Intacs Implantation for Keratoconus Correction	Alio, Shabayek, Belda, Correas, Feijoo
European Clinical Evaluation: Use of Intacs for the Treatment of Keratoconus	Colin, Joseph
Are Intracorneal Rings Still Useful in Refractive Surgery?	Guell, Jose L.
Keratoconus Managed with Intacs	Levinger, Pokroy
Treating Keratoconus with Intacs Corneal Ring Segments	Hellsted, Makela, Uusitalo, Emre
Management of Pellucid Marginal Degeneration with Intracorneal Ring Segments	Barbara, Shehadeh-Masha'our, Zvi, Garzosi
One or 2 Intacs Segments for the Correction of Keratoconus	Alio, Artola, Hassanein, Haroun, Galal
Conservative Treatment of Early and Moderate Pellucid Marginal Degeneration: A New Refractive Approach with Intracorneal Rings	Mularoni, Torreggiani, di Biase, Laffi, Tassinari
Keratoconus: Current Surgical Options	Lemp, M.A.
Intrastromal Corneal Segments (intacs®) Safety in Keratoconic Eyes	Kymionis, Aslanides, Siganos, Pallikaris
Intacs for Early Pellucid Marginal Degeneration	Kymionis, Aslanides, Siganos, Pallikaris
Corneal Ring Segments (Intacs) for the Treatment of Asymmetrical Astigmatism of the Keratoconus. Follow-up after 2 Years	Tunc, Deveci, Sener, Bahcecioglu
Intracorneal Rings for the Correction of Pellucid Marginal Degeneration	Rodriguez-Prats, Galal, Garcia-Lledo, De La Hoz, Alio
Intacs for Keratoconus	Boxer Wachler, Christie, Chandra, Chou, Korn, Nepomuceno
Implantation of Intacs and a Refractive Intraocular Lens to Correct Keratoconus	Colin, Velou
Management of Keratoconus with Intacs	Siganos, Kymionis, Kartakis, Theodorakis, Astyrakakis, Pallikaris
Intacs Inserts for Treating Keratoconus: One-Year Results	Colin, Cochener, Savary, Malet, Holmes-Higgin
Correcting Keratoconus with Intracorneal Rings	Colin, Cochener, Savary, Malet

**Excerpts of Significance From the 2005 Milliman Research Report  
2005 US Organ and tissue Transplant Cost Estimates and Discussion**

**Page 3: Estimated US Average 2005 First-Year Transplant Costs Per Member Per Month (PMPM)**

Transplants	Total Estimated Number of Transplants In The US, All Ages*	Estimated First Year Billed Charges
Cornea	32,840	\$19,100

\*Page 10

**Page 5: Estimated US Average 2005 First-Year Billed Charges Per Transplant**

Transplant	Hospital	Physician	Total
Cornea	\$10,700	\$8,400	\$19,100

**Page 18: Most Common Primary Diagnoses by Transplant**

Tissue	Second-Most Common Primary Diagnosis and Prevalence
Cornea	Ectasias / thinnings (15.4%)

**Summary**

Of the 32,840 corneal transplants performed in 2005, 5,056 were diagnosed as ectasias or thinnings. Estimated total first-year billed charges for corneal transplants for this diagnosis was an estimated \$96 Million dollars to the US healthcare industry. According to national statistics on failure rates for corneal transplants, 905 (17.9%) failed.

*Given these evidence based facts, we look forward to you establishing a policy for Intacs as many others have?*

**List of insurance carriers that have already adopted a policy for Intacs corneal implants**

*2007 - 2007 Cigna Policy for Intacs Corneal Implants*

2006 BCBS Regence Oct Medical Policy Intacs Corneal Implants for Keratoconus

2006 BCBS Empire Aug Intacs Corneal Implants for Keratoconus

*2005 Aetna Policy for Intacs Corneal Implants for Keratoconus*

2004 BCBS TN MED POLICY - Intacs Corneal Implants for Keratoconus

2006 Sept MCAre Michigan Intacs Corneal Implants for Keratoconus

2006 July BCBS Excellus Intacs Corneal Implants for Keratoconus

2005 July Humana Intacs Corneal Implants for Keratoconus

2006 Aug BCBS California Intacs Corneal Implants for Keratoconus

2006 Sept BCBS Wellmark Intacs Corneal Implants for Keratoconus

2005 May Healthplan Nevada Intacs Corneal Implants for Keratoconus