

## **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 examples of appropriately written 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!

**Your name**