



>> Example <<

Revised April 2009

Prepared For  
Intacs Reimbursement

## TABLE OF CONTENTS

|  |    |
|--|----|
| Instructions – How to Use Packet .....                                 | 3  |
| Pre-Determination – Operative Report Letter .....                      | 4  |
| Evidence Based Peer Review Information .....                           | 5  |
| Attachments .....  | 8  |
| Peer Review Literature List .....                                      | 8  |
| FDA Approval Letter .....  | 9  |
| FDA Say’s “Intacs are <u>not</u> investigational / experimental” ..... | 10 |
| 2008 Milliman Report Excerpts – Transplant Cost Estimates .....        | 11 |
| List of Insurance Carriers With Active Intacs Policy .....             | 12 |

**Instructions:**

Enclosed are various documents for you to use in the claims adjudication process for Intacs Corneal Implants. Use this packet when patients meet the selection criteria for Intacs for Keratoconus and:

- The patient's only other treatment option is a corneal transplant
- A carrier does not have a policy established to cover Intacs corneal implants
- A carrier has underpaid you for Intacs corneal implant procedure
- You are requesting, in good faith, a peer review of your claim
- You are requesting, in good faith, a policy review of your claim

**Important information to know when handling any response from the carrier:**

In every case, a corneal transplant is the alternative / comparable procedure – this is extremely important because the carrier may not be educated on both the evidence based clinical benefits of Intacs and the cost-effectiveness of Intacs as compared to a corneal transplant. In each scenario when a carrier may attempt to deny your claim, there is an opportunity to educate them through well documented response.

The letters in this packet are accompanied by sources from the FDA and leading industry authorities to assist you with your claims adjudication. If at any time you need assistance with your submission, don't hesitate to contact your ATI representative or contact us directly.

Addition Technology is dedicated to helping you and your patients with Intacs corneal implants.

**Corporate Office**

950 Lee Street, Ste. 210

Des Plaines IL 60016

Phone 847-297-8419

Fax 847-297-8678

Payer Name: <Carrier>

Case/Patient ID: 39483 - **Jane Patient**

Re: Pre-Determination, Not A Covered Benefit, Not Standard Care, Investigational / Experimental, Medical Necessity and/or Underpayment – Operative Report (**Choose based on your case...**)

Based on input from the American Medical Association (AMA) and physician representatives from the Medical Directors Association of America, enclosed is a comprehensive claim submission / operative report for **39483**:

Dr. **Joe Smith** has determined that 39483 - **Jane Patient** is contact lens intolerant with non-functional vision resulting from a diagnosis of **Keratoconus (ICD 9 - 371.6)**. The patient reports a history of **declining vision, visual distortion, glare, light sensitivity, ghosting, halo's, cloudy vision and double vision** resulting in contact lens intolerance. BCVA is **20/80**, UCVA is **counting fingers** in the **right** eye and **cannot wear glasses or contact lenses**. Keratoconus only afflicts 1 in 2000 young people in the U.S. and once contact lens intolerant, a corneal transplant has historically been their only option. Ophthalmologists would prefer *not* to do a corneal transplant due complications and significant endothelial cell loss.

**Evidence Based Consensus:** Medical and Financial evidence as to why carrier should pay the Intacs claim versus over-paying for a corneal transplant.

Safety and efficacy has been established for Intacs Corneal Implants through the 1999 & 2004 FDA approval process (see attached) and in over 100 published peer-reviewed publications (see attached). Since 1997, key Ophthalmic Physicians have overwhelmingly concluded that good medical practice has determined that Intacs is the preferred treatment for keratoconus versus a corneal transplant (See attached peer-reviewed references). Historically, a corneal transplant has been the standard of care however, the medical community also recognizes that 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 is also an important finding that potentially hinders the success of additional transplants in the future which is a primary concern with a younger population of patients.

The Intacs procedure is cost-effective compared to a corneal transplant. According to a 2008 Milliman Research Report on the cost estimates of tissue transplant (attached), there were 34,898 corneal transplants performed in 2008 whereby 5932 of them were due to keratoconus. The estimated average first year billed charges for a corneal transplant in 2008 was \$20,700. According to the 2008 report, insurance carriers received \$122.7 million dollars for claims for keratoconus indicated corneal transplants alone. My total billed charges to treat Keratoconus with Intacs corneal implants is \$xxxx representing less than half the billable charges compared to a corneal transplant. Comparatively, treating these same patients with Intacs would save a significant amount to the healthcare system.

If <Carrier> cannot decide to pay a reasonable amount for this claim based on the above evidence based information or, if <Carrier> decides to establish a policy for Intacs corneal implants for keratoconus (see attached policies as examples), please forward this entire packet and all attachments to **the Medical Director** as part of a comprehensive peer-review request.

*In good faith* and in the interest of time, I've taken the liberty to attach all the necessary documentation, approvals, pre-written explanation appeal letters, and cost-effective justification sources for **the Medical Director** and <Carrier>'s review.

I will be calling **555-555-5555** on **7/15/2008** to check the status of 39483 - **Jane Patient**. If <Carrier> or **the Medical Director** needs to contact me before this date, I can be reached at **Doc-Phone** during business hours – please have me interrupted to take your call.

Sincerely,

**Joe Smith, M.D. (DON'T Forget to put your name on Page 7!!!)**

## **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 2008                       | 34,898                   |
| Keratoconus Transplant Procedures in 2008                 | 5,932                    |
| *Intacs Corneal Implant Procedure                         | \$6,000 - \$9,000        |
| *Billed Charges Corneal Transplant (1 <sup>st</sup> Year) | \$20,700                 |
| Estimated <i>Cost-Effective Savings Per Claim</i>         | \$11,700 - \$14,700      |

\*See 2008 Milliman Report – Excerpt included in this packet.

\*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 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.

7. **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).

8. **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.

**9. 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

**10. 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 5,932 corneal transplant procedures in the US for corneal ectasias according to US Eye Bank data and the 2008 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 for contact lens intolerant patients. Furthermore, immediate cost-savings to the payer and the health system has been established through scientific 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 and on behalf of our practice and patients covered by your plan – Thank You!

## Peer reviewed articles 2000 to 2009 For Keratoconus (Partial List)

1. Fontana L, Parente G, Sincich A, Tassinari G. Deep anterior lamellar keratoplasty after Intacs implantation in patients with keratoconus. *Cornea*. 2009 Jan;28(1):32-5.
2. Ertan A, Karacal H. Factors influencing flap and INTACS decentration after femtosecond laser application in normal and keratoconic eyes. *J Refract Surg*. 2008 Oct;24(8):797-801.
3. Shetty R, Kurian M, Anand D, Mhaske P, Narayana KM, Shetty BK. Intacs in advanced keratoconus. *Cornea*. 2008 Oct;27(9):1022-9.
4. Ertan A, Ozkilic E. Effect of age on outcomes in patients with keratoconus treated by Intacs using a femtosecond laser. *J Refract Surg*. 2008 Sep;24(7):690-5.
5. Smith KA, Carrell JD. High-Dk piggyback contact lenses over Intacs for keratoconus: a case report. *Eye Contact Lens*. 2008 Jul;34(4):238-41.
6. Ertan A, Kamburoğlu G. Intacs implantation using a femtosecond laser for management of keratoconus: Comparison of 306 cases in different stages. *J Cataract Refract Surg*. 2008 Sep;34(9):1521-6.
7. Alterations of extracellular matrix components and proteinases in human corneal buttons with INTACS for post-laser in situ keratomileusis keratectasia and keratoconus. *Cornea*. 2008 Jun;27(5):565-73.
8. Kaiserman I, Bahar I, Rootman DS. Optical coherence tomography provides insight into the effect of intacs in keratoconus. *Arch Ophthalmol*. 2008 Apr;126(4):571-2. No abstract available.
9. Zare MA, Hashemi H, Salari MR. Intracorneal ring segment implantation for the management of keratoconus: safety and efficacy. *J Cataract Refract Surg*. 2007 Nov;33(11):1886-91.
10. Hustler A, Manna A, Morris S, Obi A, Horgan S. Intacs for the correction of keratoconus. *J Cataract Refract Surg*. 2007 Aug;33(8):1354. No abstract available.
11. Rabinowitz YS. Intacs for keratoconus. *Curr Opin Ophthalmol*. 2007 Jul;18(4):279-83. Review.
12. Samimi S, Leger F, Touboul D, Colin J. Histopathological findings after intracorneal ring segment implantation in keratoconic human corneas. *J Cataract Refract Surg*. 2007 Feb;33(2):247-53.
13. Colin J, Malet FJ. Intacs for the correction of keratoconus: two-year follow-up. *J Cataract Refract Surg*. 2007 Jan;33(1):69-74.
14. Kymionis GD, Siganos CS, Tsiklis NS, Anastasakis A, Yoo SH, Pallikaris AI, Astyrakakis N, Pallikaris IG. Long-term follow-up of Intacs in keratoconus. *Am J Ophthalmol*. 2007 Feb;143(2):236-244. Epub 2006 Nov 30.
15. Rabinowitz YS. INTACS for keratoconus. *Int Ophthalmol Clin*. 2006 Summer;46(3):91-103. Review. No abstract available.
16. Alió JL, Shabayek MH, Artola A. Intracorneal ring segments for keratoconus correction: long-term follow-up. *J Cataract Refract Surg*. 2006 Jun;32(6):978-85.
17. Colin J. European clinical evaluation: use of Intacs for the treatment of keratoconus. *J Cataract Refract Surg*. 2006 May;32(5):747-55.
18. Uçakhan OO, Kanpolat A, Ozdemir O. Contact lens fitting for keratoconus after Intacs placement. *Eye Contact Lens*. 2006 Mar;32(2):75-7.
19. Nepomuceno RL, Boxer Wachler BS, Weissman BA. Feasibility of contact lens fitting on keratoconus patients with INTACS inserts. *Cont Lens Anterior Eye*. 2003 Dec;26(4):175-80.
20. Siganos CS, Kymionis GD, Kartakis N, Theodorakis MA, Astyrakakis N, Pallikaris IG. Management of keratoconus with Intacs. *Am J Ophthalmol*. 2003 Jan;135(1):64-70.
21. Colin J, Cochener B, Savary G, Malet F. Correcting keratoconus with intracorneal rings. *J Cataract Refract Surg*. 2000 Aug;26(8):1117-22.

**FDA Approval Letter (Attached Here)**

## **FDA Say's Intacs Are “Not Investigational”**

I have excerpted a couple of the questions in this guidance to emphasize that FDA considers HDE-approved devices to be MARKETED products, that is approved for commercial distribution, and does NOT consider these devices to be investigational.

### **1. What is a Humanitarian Device Exemption (HDE)?**

A Humanitarian Device Exemption (HDE) is an application that is similar to a premarket approval (PMA) application, but exempt from the effectiveness requirements of a PMA. An approved HDE authorizes marketing of a Humanitarian Use Device (HUD).

### **19. Is informed consent required when treating/diagnosing a patient with a HUD?**

The Federal Food, Drug, and Cosmetic Act (the act) and the HDE regulation do not require informed consent because an HDE provides for marketing approval, and so use of the HUD does not constitute research or an investigation which would normally require informed consent. Although neither the act nor the regulation requires informed consent, there is nothing in the law or regulation that preempts a state or institution from requiring prospective informed consent. Most HDE holders, however, have developed patient labeling that incorporates information to assist a patient in making an informed decision about the use of the device. That is, the patient labeling contains a discussion of the potential risks and benefits of the device as well as any procedures associated with the use of the HUD. It also states that the device is a humanitarian use device for which effectiveness for the labeled indication has not been demonstrated.

If I can be of further assistance, please do not hesitate to contact me.

Sincerely,

**Elisa D. Harvey, D.V.M., Ph.D.**  
**(Former) Director, Investigational Device Exemption (IDE)**  
**and Humanitarian Device Exemption (HDE) Programs**  
**Office of Device Evaluation (ODE)**  
**Center for Devices and Radiological Health (CDRH)**  
**Food and Drug Administration**  
**9200 Corporate Boulevard (HFZ-403)**  
**Rockville, Maryland 20850**

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**Email:**



*Protecting and Promoting Public Health*

**Excerpts of Significance From the 2008 Milliman Research Report  
2008 US Organ and tissue Transplant Cost Estimates and Discussion**

**Page 4: Estimated US Average 2008 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      | 34,898   | \$20,700                            |

\*Page 10

**Page 5: Estimated US Average 2008 First-Year Billed Charges Per Transplant**

| Transplant | Hospital  | Physician | Total    |
|------------|-----------|-----------|----------|
| Cornea     | \$13, 200 | \$7,500   | \$20,700 |

**Page 11: Indications For Corneal Transplant**

| Indication | Keratoconus | Repeat Corneal Transplant | Post Cataract Surgery Edema |
|------------|-------------|---------------------------|-----------------------------|
| Cornea     | 17%         | 15%                       | 19%                         |

**Summary**

Of the 34,898 corneal transplants performed in 2008, 5,932 were diagnosed as keratoconus and 5234 additional were repeat corneal transplants. Estimated total first-year billed charges for corneal transplants for this diagnosis was an amazing \$122.7 Million dollars to the US healthcare industry – up nearly \$30 Million from the 2005 Milliman report. According to national statistics on failure rates for corneal transplants, 1061 (17.9%) will fail. It is also known that repeat corneal transplants have a higher failure rate.

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

**List of insurance carriers across the U.S. that have adopted a policy for Intacs corneal implants**

*Aetna*

*Blue Cross Blue Shield (various states)*

*Cigna*

*Excellus*

*Humana*

*United Health Care*

*Wellmark*

*Texas True Choice*

*And numerous other regional insurance carriers.*