Payer Name: **Insurance Carrier**
Case/Patient ID: 39483 - **Jane Patient**
Re: Pre-Determination – Operative Report

Based on input from the American Medical Association (AMA) and physician representatives from the Medical Directors Association of America, enclosed is a comprehensive Pre-Determination - 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 facts 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). For the past 10 years, 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 2005 Milliman Research Report on the cost estimates of tissue transplant (attached), there were 32,840 corneal transplants performed in 2005 whereby 5056 of them were due to ectasia / corneal thinning. The estimated average first year billed charges for a corneal transplant in 2005 was $19,100. According to the 2005 report, insurance carriers received just under $100 million dollars for claims for ectasia 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.

Sincerely,

Joe Smith, M.D.