

Payer Name: BCBS
Case/Patient ID: 39483 - **Jane Patient**
Re: Response to "Investigational / Experimental" Denial

To Whom It May Concern:

Recently, we received a denial from you for 39483 - **Jane Patient** for Intacs corneal implants procedure for treating **Keratoconus (ICD 9 - 371.6)**. You state, "Investigational / Experimental".

Given the preponderance of clinical evidence showing Intacs corneal implant to be the overwhelmingly preferred clinical approach in treating patients suffering from keratoconus versus a corneal transplant, *we are requesting a formal peer review. In good faith* and in the interest of time, I've taken the liberty to attach all the necessary documentation, approvals, and cost-effective justification sources for peer review and consideration for policy review:

Evidence Based Consensus: Medical and Financial facts as to why carrier should pay Intacs claims versus continuing to over-pay for existing treatment – 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 only option and the medical community 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 for Intacs 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.

My professional medical opinion is that 39483 - **Jane Patient** meets selection criteria for the Intacs corneal implant procedure and that the alternative procedure, a corneal transplant, would not be in the best interest of the patient. Given the evidence based consensus provided in this appeal, I respectfully request approval to treat 39483 - **Jane Patient** with Intacs corneal implants.

Sincerely,

Joe Smith, M.D. or Your Name