OMIC OPHTHALMIC MUTUAL INSURANCE COMPANY
(A Risk Retention Group)

Visian ICL™ Phakic Implant Surgery: Risk Management Recommendations

Anne M. Menke, R.N., Ph.D.
OMIC Risk Manager

PURPOSE OF RISK MANAGEMENT RECOMMENDATIONS

OMIC regularly analyzes its claims experience to determine loss prevention measures that our insured ophthalmologists can take to reduce the likelihood of professional liability lawsuits. OMIC policyholders are not required to implement these risk management recommendations. Rather, physicians should use their professional judgment in determining the applicability of a given recommendation to their particular patients and practice situation. These loss prevention documents may refer to clinical care guidelines such as the American Academy of Ophthalmology's *Preferred Practice Patterns*, peer-reviewed articles, or to federal or state laws and regulations. However, our risk management recommendations do not constitute the standard of care nor do they provide legal advice. If legal advice is desired or needed, an attorney should be consulted. Information contained here is not intended to be a modification of the terms and conditions of the OMIC professional and limited office premises liability insurance policy. Please refer to the OMIC policy for these terms and conditions.

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These risk management recommendations and sample consent form (at www.omic.com) provide information on risk reduction and coverage issues related to phakic implant surgery with the Visian ICL™

Approved uses

- The Visian ICL™ was approved by the FDA for:
  - the correction of myopia ranging from -3 to -15 D with ≤ 2.5 D astigmatism at the spectacle plane
  - the reduction of myopia ranging from -15 to -20 D anterior with ≤ 2.5 D astigmatism at the spectacle plane
  - in adults from 21 to 45 years of age
  - with an anterior chamber depth ≥ 3.00 mm, and a
  - stable refractive history within 0.5D for 1 year before implantation
    - **Any use outside these parameters constitutes "off-label" use of the device.** The ophthalmologist should weigh the risk/benefit ratio and inform the patient of the "off-label" status. The "off-label" status should be added to the procedure-specific consent form.

Possible contraindications

- Anterior chamber depth < 3.0 mm as determined by the eye doctor
- Anterior chamber angle < Grade II as determined by gonioscopic examination
- Patients who are pregnant or nursing
- Endothelial cell density as specified in the labeling.

OMIC coverage information

- OMIC's standard policy excludes refractive surgery. OMIC-insured ophthalmologists must apply for, and be granted, an endorsement to their OMIC policy in order to obtain coverage for phakic IOLs. Coverage is granted for on-label use.
    - Please contact the Underwriting Department at 800.562-6642, extension 639 for questions about coverage or off-label use.
    - The application form and refractive requirements are available at http://www.omic.com

Informed consent

- There is a sample consent form on the OMIC website in the refractive surgery section. Carefully review it and change it as needed to reflect your practice.
- OMIC encourages its insureds to inform their patients of their limited experience performing new surgical techniques. For additional information regarding this informed consent issue, please refer to OMIC's Hotline article, "Informing Patients About Your Surgical Experience," featured in the Spring 2004 Digest, and available at www.omic.com.

OMIC policyholders who have additional questions or concerns about practice changes are invited to call OMIC's confidential Risk Management Hotline at (800) 562-6642, extension 641.