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OMIC requires special underwriting review of physicians requesting coverage for the performance of intraocular refractive surgery procedures. **Coverage is not included under the policy until and unless approved and specifically endorsed.** Valid reasons may exist for exceptions to these criteria. OMIC is willing to consider such exceptions on a patient-by-patient basis, provided they are well documented and supported in the medical record.

1 To qualify for coverage, insureds must comply with each of the underwriting requirements listed below. Please initial each item to confirm your understanding and agreement to abide by these requirements.

Patient Selection

- _____ Prior to surgery, the surgeon must perform and document an **independent evaluation**, which includes a personal and independent examination of the patient's eyes and ocular history, to determine the patient's eligibility for surgery and carefully analyze and discuss the **patient's expectations**. This should include discussion of monovision, when appropriate. (This discussion must be documented in the medical record or consent form.)
- _____ Patients must be **at least age 18**. For refractive surgery performed on patients between the ages of 18 and 21, refractions must be stable a minimum of 12 months, and the patient must be informed of the additional risk of progressive myopia and under-correction. This discussion must be documented in the medical record or consent form.
- _____ **For implants FDA-approved for phakic use**, criteria for degree of myopia and astigmatism and for anterior chamber depth must fall within FDA-approved guidelines. OMIC is willing to consider exceptions to these patient selection criteria on a patient-by-patient basis due to special situations. However, insureds are encouraged to limit their performance of phakic implant surgery to cases that fall within the FDA-approved guidelines. If you have a patient who falls outside of the FDA-approved patient selection criteria but for whom you believe phakic implants are the most appropriate option, please complete an **Exception Request Form** and return it to OMIC for consideration prior to scheduling surgery.
- _____ **Off-label treatment of patients between the ages of 18 and 21 or over age 45** is permitted subject to special consent language.
- _____ **For cases performed during the course of clinical trials**, patients must fall within the patient selection criteria established by the trial protocol.

Informed Consent

- _____ The surgeon must have an informed **consent discussion** with each patient. Although other health care professionals may be involved in the informed consent process, this duty may not be delegated exclusively to non-physician staff.
- _____ The **consent document** must be procedure specific, explain the nature of the procedure, and adequately address the procedure's indications, alternatives, benefits, risks, and complications. OMIC has developed sample consent forms for phakic implants, available online at www.omic.com/phakic-implants. If you will use a consent document other than OMIC's sample consent, please carefully review your consent form to ensure that it is equivalent.
- _____ A **separate consent** form is required for LASIK surgery performed in conjunction with or following phakic implant surgery ("Bioptics" procedures).

Operative Procedures

- _____ The lenses used must be specifically **designed and approved** for phakic implant.
- _____ **If the lens used is not yet approved by the FDA**, coverage will be extended only if the surgeon participates in an FDA study or IDE.
- _____ This surgery must be performed in a **hospital or outpatient surgery center approved for cataract surgery**. Phakic implant procedures may not be performed in the physician's office, laser refractive center, or other facility that does not meet the standards for sterile conditions as required for accreditation. Full sterile technique must be followed.
- _____ The post-implant refraction must be stabilized before **repeat surgery** can be performed.

Immediately Sequential Bilateral Surgery

_____ Patients undergoing immediately sequential bilateral intraocular refractive surgery (ISBIRS) must be at **low risk for surgical complications**. Treatment of both eyes on the same day is not permitted for “complex” surgical cases, such as in patients with amblyopia, pseudoexfoliation syndrome, eyes with previous ocular trauma, or eyes with active macular SRNVM with leakage or significant diabetic retinopathy, or in patients at higher risk of infection, such as patients who are immunocompromised or have poorly controlled diabetes.

_____ ISBIRS is not recommended in patients for whom there is a greater than normal risk of having difficulties **calculating or selecting the appropriate IOL power**. These types of patients include those who have previously undergone refractive surgery (e.g., LASIK, PRK, CK, and RK), have significant corneal scarring or keratoconus, have extremely long or short axial lengths, or have conditions that make it difficult to cooperate for the optical or ultrasonic biometry (e.g., nystagmus or dementia).

_____ Immediately sequential bilateral patients must **read and sign the Addendum** for Bilateral Same Day Phakic Implant Surgery, developed by OMIC (available online at www.omic.com/bilateral-phakic-implant-consent-addendum) or an equivalent bilateral consent addendum.

_____ The physician must develop and follow **appropriate protocols** to reduce the risks for right-left eye errors and errors in IOL insertion.

_____ There must be **complete aseptic separation** of the first and second eye surgeries, including use of separate instrument trays that have undergone separate sterilization cycles; complete, repeat surgical scrub and draping; and separate intraocular irrigating fluids and drops with different lot numbers.

_____ **Antibiotics** must be appropriately administered at sufficient dosages to reduce the risk of endophthalmitis.

_____ **Any complication** with the first eye must be resolved before proceeding with surgery on the second eye.

Postoperative Care

_____ Some states have passed legislation regarding comanagement and the surgeon’s duties and responsibilities relating to the postoperative care of surgical patients. The surgeon must follow all postoperative care **requirements of his/her state**.

2 How many phakic implant procedures have you performed as primary surgeon (rough estimates are acceptable):

A. Since completion of your training? _____

B. In the past 12 months? _____

C. Anticipated for the next 12 months? _____

3 Do you perform phakic implant procedures under an FDA study or IDE? _____

Yes No

4 Which lenses do you use?

Staar Visian ICL

Ophtec/AMO Verisyse

Medennium PRL

Alcon AcrySof Phakic IOL

Other: _____

I have read and hereby agree to comply with OMIC’s underwriting requirements specific to phakic implants for refractive purposes. I will obtain prior approval from OMIC on a case-by-case basis for any deviation from the company’s underwriting requirements. I also agree to notify OMIC prior to implementing any intended changes to my responses above. **I understand that failure to comply with OMIC’s underwriting requirements (other than deviations specifically approved by OMIC) or to notify OMIC promptly of changes in my protocol may result in uninsured risk or termination of coverage.”**

Applicant’s Signature (Please do not use signature stamp.)

Date

Applicant’s Name (Please type or print.)