

SUPPLEMENTAL QUESTIONNAIRE FOR PHAKIC IMPLANTS FOR REFRACTIVE PURPOSES



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OMIC requires special underwriting review of physicians requesting coverage for the performance of refractive surgical procedures. **Coverage is not included under the policy until and unless approved and specifically endorsed.**

TRAINING AND EXPERIENCE

1 What training did you receive specific to the performance of phakic implants? **Attach a copy of your certificate of completion of training.**

Course Title	_____	_____	_____
Dates	_____	_____	_____
Location	_____	_____	_____
Sponsor	_____	_____	_____
Instructor	_____	_____	_____

2 During your training, how many cases did you:

	Observe?	Assist?	Perform?
A. Live	_____	_____	_____
B. Animal	_____	_____	_____
C. Human Cadaver	_____	_____	_____

3 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?	_____

PATIENT SELECTION

4 Who conducts the preoperative evaluations? (Check all that apply.)

Surgeon Surgeon's non-physician staff Surgery center staff Referring optometrist

- 5 A. For implants FDA-approved for phakic use, criteria for age, 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. Exceptions may be requested only in extenuating circumstances. 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 the attached **Exception Request** form and return it to OMIC for consideration prior to scheduling surgery.

- B. For cases performed during the course of clinical trials, patients must fall within the patient selection criteria established by the trial protocol.
- C. Off-label use for the treatment of keratoconus or amblyopia may be approved with appropriate informed consent. Please explain what off-label procedures, if any, you may perform and attach your off-label consent language:

NOTE: An **Exception Request** form is not required for the off-label treatment of keratoconus or amblyopia.

INFORMED CONSENT

- 6 The informed consent document must be procedure-specific and adequately address the indications, alternatives, benefits, risks, and complications. OMIC has developed a sample consent form for phakic implants. A copy is attached. 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.

Which consent form will you use? OMIC's Another equivalent form

A separate consent form is required for LASIK surgery performed in conjunction with or following phakic implant surgery ("Bioptics" procedures).

OPERATIVE PROCEDURES

- 7 Do you perform phakic implant procedures under an FDA study or IDE? Yes No

- 8 A. Do you use only those lenses specifically designed and approved for phakic implant? Yes No

B. Which lenses do you use? Staar Visian ICL Ophtec/AMO Verisyse Medennium PRL
 Alcon AcrySof Phakic IOL Other: _____

- 9 Where do you perform this procedure? (Please check all that apply.)

Accredited ASC Non-accredited outpatient surgery center approved for cataract surgery Hospital

Please note that 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. OMIC requires that this surgery be performed only in a hospital or outpatient surgery center approved for cataract surgery. Full sterile technique must be followed.

10 Do you perform this procedure in any states/counties other than the county and state of your primary practice location? Yes No

If yes, please indicate which state(s)/county(ies), how frequently you travel to that location, and for what duration:

11 There must be a **minimum interval** of five days **between primary procedures**.

12 The post-implant refraction must be stabilized before an **enhancement** can be performed.

POSTOPERATIVE CARE

13 Do you co-manage? Yes No

If yes, refer to OMIC's postoperative care guidelines.

ADVERTISING

14 Do you advertise your availability to perform this procedure? Yes No

Advertisements must comply with state law and FDA- and FTC-mandated guidelines. Ads and other patient information materials must not be misleading and must not make statements that guarantee results or cause unrealistic expectations. Similarly, satisfaction guarantees, warranties, and similar contracts are not permitted. Please refer to the attached **Review of Advertisement for Medical Services** form so that you may evaluate and monitor your compliance with OMIC's underwriting requirements with respect to advertising.

"I have read and hereby agree to comply with OMIC's underwriting requirements specific to phakic implants for refractive purposes and with OMIC's standard refractive surgery 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 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.)