

# SUPPLEMENTAL QUESTIONNAIRE FOR CONDUCTIVE KERATOPLASTY ("CK")



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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 CK? **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 CK 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 Patients undergoing **treatment of hyperopia** must meet the following eligibility criteria:

- Patients must be over the **age** of 40.
- Patients can have no more than 0.75 diopters of **astigmatism**.
- Patients must have at least 0.75 diopters and no more than 3.00 diopters of **hyperopia** spherical equivalent.
- **Off-label** use 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: \_\_\_\_\_

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Patients undergoing **treatment of presbyopia** must meet the following eligibility criteria:

- Patients must be **age** 40 or older.
- Patients can have no more than 0.75 diopters of **astigmatism**.
- Patients must be **emmetropic or mildly hyperopic** and undergo spherical hyperopic treatment of 1 to 2.25 diopters.
- Patients must have had a **successful preoperative trial** of monovision or history of prior successful monovision wear documented in their medical record.
- Treatment must be in the **non-dominant eye unless** the contact lens trial demonstrated the patient prefers the dominant eye for reading. The contact lens trial and patient preference must be documented in the patient's medical record.

## INFORMED CONSENT

6 The informed consent document must be procedure-specific and adequately address the indications, alternatives, benefits, risks, and complications. OMIC and Refractec have jointly developed a sample consent form for CK. A copy is attached for your convenience. 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. Please confirm whether you will use  OMIC's sample consent form or  other equivalent form.

## OPERATIVE PROCEDURES

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

- Your office       Local physician-owned ASC       Commercial laser center       Academic facility

8 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:

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9 Do you intend to perform bilateral simultaneous CK?  Yes  No

**If yes**, bilateral simultaneous CK patients must read and sign the **Addendum to Informed Consent for Bilateral Simultaneous CK** developed by OMIC or a similarly acceptable consent form. In addition, presbyopic patients must be given the opportunity to select monovision as a surgical alternative. This option must be documented in the medical record.

## POSTOPERATIVE CARE

10 Do you co-manage?  Yes  No

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

## ADVERTISING

11 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 conductive keratoplasty ("CK") 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.)*