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. 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.

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.

1. **Training and Experience**
   - The surgeon must be appropriately trained and certified on the CK system. Please submit your certificate(s) of training.

2. **Patient Selection**
   - Patients must undergo a comprehensive baseline eye exam, including cycloplegic refraction, slit lamp exam, corneal topography, and dilated fundus exam. Keratometry readings, corneal pachymetry, and endothelial cell count on all patients are also recommended.
   - Prior to surgery, the surgeon must perform and document an independent evaluation to determine the patient’s eligibility for surgery. As part of the independent evaluation, the surgeon must personally examine the patient’s eyes and ocular adnexa, perform a slit lamp exam, and carefully review corneal topographies, pupil size, pachymetry, refractive stability, and eye health history. Whenever reasonably possible, a review of prior records is recommended.
   - The surgeon must 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 have realistic expectations.
   - Patients must be at least age 40.
   - Patients should have a clinically demonstrable refractive stability over a six-month period or documentation in the medical record explaining the rationale for the exception. A 12-month or longer period of refractive stability is ideal. (Refractive stability is defined as a change of one-half diopter or less.)
   - Rigid-contact lens wearers should remain contact lens-free until refractions and topography or keratometry readings are stable on successive readings, taken at least one week apart.
   - Patients undergoing treatment of hyperopia must meet the following eligibility criteria:
     A. Patients can have no more than 0.75 diopters of astigmatism.
     B. Patients must have at least 0.75 diopters and no more than 3.00 diopters of hyperopia spherical equivalent.
     C. Off-label use may be approved with appropriate informed consent.
   - Patients undergoing treatment of presbyopia must meet the following criteria:
     A. Patients can have no more than 0.75 diopters of astigmatism.
     B. Patients must be emmetropic or mildly hyperopic and undergo spherical hyperopic treatment of 1 to 2.25 diopters.
     C. Patients must have had a successful preoperative trial of monovision or history of prior successful monovision wear documented in their medical record.
     D. 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

- 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.

- Consent must be obtained in writing. The consent form must be signed and dated by the patient prior to surgery.

- 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 and Refractec have jointly developed a sample consent form for CK, available online at www.omic.com/conductive-keratoplasty. 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.

- You must write a note in the patient’s medical record that the risks, benefits, complications, and alternatives were discussed with each patient.

- Each patient must be offered a copy of the consent form prior to the day of surgery.

Operative Procedures

- To qualify for coverage of bilateral same-day procedures:
  A. The physician must discuss, demonstrate as needed, and afford presbyopic patients the opportunity to select, monovision as a surgical option. This must be documented in the medical record, and
  B. Bilateral same-day patients must read and sign the Addendum to Informed Consent for Bilateral CK developed by OMIC (available online at www.omic.com/conductive-keratoplasty), or an equivalent bilateral consent form.

Postoperative Care

- Although other health care professionals may participate in the postoperative management of patients, the surgeon or a designated ophthalmologist must perform the first postoperative visit. Please also refer to Exclusion III.A.16 of the OMIC policy regarding OMIC’s postoperative care requirements, excerpted below. OMIC has developed a sample co-management consent form, available online at www.omic.com/coordinating-care-with-optometrists-recommendations.

Section III. COMMON EXCLUSIONS—APPLICABLE TO ALL COVERAGE AGREEMENTS

A. No Defense or Payment of Damages or Supplementary Payments

OMIC will neither defend an Insured nor pay damages or supplementary payments because of a Claim that arises out of any of the following:

16. Postoperative Care. A professional services incident occurring postoperatively unless the following conditions are satisfied:

  a) the Insured operating ophthalmologist or an on-call or locum tenens ophthalmologist performs the patient’s postoperative care throughout the patient’s recovery period;
  b) the Insured operating ophthalmologist (i) refers the patient to a licensed ophthalmologist or other licensed physician as appropriate and (ii) obtains the patient’s informed consent for planned comanagement prior to surgery; or
  c) the Insured operating ophthalmologist (i) arranges for a portion of the outpatient postoperative care to be rendered by a non-physician provider who is clinically competent and lawfully able to provide that care and (ii) obtains the patient’s written informed consent for planned comanagement prior to surgery. Such delegated postoperative care must be provided under the Insured operating ophthalmologist’s supervision.

Physician means a medical doctor (MD) or a doctor of osteopathy (DO).

- The first postoperative exam must occur within the first 72 hours.

- Patients must be followed a minimum of 60 days.
Advertising

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 OMIC’s Review of Advertisement for Medical Services form, available online at www.omic.com/advertising-medical-services-recommendations, so that you may evaluate and monitor your compliance with OMIC’s underwriting requirements with respect to advertising.

2. 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? ______________

3. Where do you perform this procedure? (Please check all that apply)
   □ Your office  □ Local physician-owned ASC  □ Commercial laser center  □ Academic facility

4. 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), the approximate distance (in miles or time duration) between the primary practice location and alternate facility, how frequently you travel to the alternate location, and for what duration:

   __________________________________________________________________________________________
   __________________________________________________________________________________________
   __________________________________________________________________________________________

“I have read and hereby agree to comply with OMIC’s underwriting requirements for Conductive Keratoplasty (“CK”). 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.)