ORA SYSTEM® Intraoperative Wavefront Aberrometry Billing Fact Sheet

The ORA SYSTEM® uses wavefront aberrometry data in the measurement and analysis of the refractive properties of the eye. The ORA SYSTEM® method of determining the refractive state of the eye is performed intra-operatively during the aphakic state (after natural lens removal) during cataract surgery. This additional information provided by the ORA SYSTEM® can be collected only after the natural lens is removed and may contribute to the provider’s plan and patient’s outcome when seeking a refractive correction. Pre-operatively, a patient who has been diagnosed with a treatable refractive condition could elect to have the ORA SYSTEM® utilized during cataract surgery to allow the surgeon to measure the total corneal impact on refraction, and variables that may impede the refractive goal. Please see back page for Important Safety Information.

This guide does not contain legal advice. Providers should seek their own legal counsel for a review of their billing and charging processes.

Billing the patient for ORA SYSTEM® Testing

If, prior to surgery, the patient
1. has been pre-diagnosed with a refractive condition, and
2. has agreed and consented for ORA SYSTEM® testing and for refractive treatment via an ATIOL or a separate surgical procedure, and
3. understands and accepts responsibility of the charges for the test and subsequent treatment, then surgeons and facilities may charge a patient for use of the ORA SYSTEM®.

ORA SYSTEM® testing may verify the initial refractive treatment plan, or may yield information leading to a change in the refractive treatment plan.

• If the test reveals a visually significant degree of corneal astigmatism, and if the patient consented pre-operatively to have refractive treatment, then the provider may include the charge for the intraoperative test in the provider’s comprehensive charge for a non-covered, refractive service such as correcting astigmatism or correcting presbyopia.

• If the test reveals intraoperatively that the total degree of astigmatism does not warrant refractive treatment, the patient who has consented preoperatively for the test as part of the planned refractive treatment may be charged a separate fee for the ORA SYSTEM® test.

Typically, charges for non-covered services are not included on claims to payers because the payer will not reimburse non-covered services. If the provider is asked by the patient to file a claim in order to get documentation of the denial, or if the commercial provider/payer contract requires all services be billed, then the provider should file the claim with the appropriate modifiers to avoid an improper payment or denial.

Claims also include diagnosis codes. When submitting a claim for non-covered items and services, it is very important to assign the appropriate refractive diagnosis, not cataract, to the non-covered charges.

If the ORA SYSTEM® test is billed to a payer at the request of the patient, or as required by the payer, the test may be included with the line item charge that describes the other astigmatism or presbyopia correcting items or services provided.

Modifiers–GY (statutorily excluded from any benefit category), or –GA (waiver of liability statement on file), and –LT or – RT (left side or right side) and the appropriate refractive diagnosis (i.e., astigmatism or presbyopia) should be appended.

Coding and billing requirements of commercial payers vary and may be subject to the payer/provider contract.
Ora System® Intraoperative Wavefront Aberrometry
Billing Fact Sheet

Documentation

Patients are responsible for the charges of tests, services, and items that are used for their refractive treatment that are considered not medically necessary for treatment of cataract. It is important that the provider fully educate and inform the patient of their out-of-pocket responsibility prior to treatment.

For patients with fee-for-service Medicare, an Advanced Beneficiary Notice (ABN) is recommended. While services that are statutorily excluded from any benefit category by Medicare do not require that the patient sign an ABN, when a non-covered service is provided at the same time as a covered benefit (i.e., cataract surgery) it is highly recommended that the patient’s understanding of their financial responsibility be documented.

Medicare Advantage plans and some commercial payers do not permit providers to use the standard Medicare ABN or similar waivers of financial liability, and may require a prior authorization before collecting payment for non-covered services from beneficiaries. Providers should review each individual plan and follow the appropriate process specific to that payer.

The appropriate diagnosis for the refractive condition (secondary to the cataract diagnosis) should also be fully documented in the patient’s chart.

Ora System® – Important Product Information

CAUTION: Federal (USA) law restricts this device to the sale by or on the order of a physician.

INDICATIONS: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

INTENDED USE: The Ora System® uses wavefront aberrometry data in the measurement and analysis of the refractive power of the eye (i.e. sphere, cylinder, and axis measurements) to support cataract surgical procedures.

CONTRAINDICATIONS: There are no known contraindications for this device.

WARNINGS AND PRECAUTIONS: The following conditions may make it difficult to obtain accurate readings using the Ora System®:

- Patients having progressive retinal pathology such as diabetic retinopathy, macular degeneration, or any other pathology that the physician deems would interfere with patient fixation;
- Patients having corneal pathology such as Fuchs’, EBMD, keratoconus, advanced pterygium impairing the cornea, or any other pathology that the physician deems would interfere with the measurement process;
- Patients for which the preoperative regimen includes residual viscous substances left on the corneal surface such as lidocaine gel or viscoelastics;
- Visually significant media opacity, such as prominent floaters or asteroid hyalosis, will either limit or prohibit the measurement process; or
- Patients having received retro or peribulbar block or any other treatment that impairs their ability to visualize the fixation light.

In addition:

- Significant central corneal irregularities resulting in higher order aberrations might yield inaccurate refractive measurements.
- Post refractive keratectomy eyes might yield inaccurate refractive measurement.
- The safety and effectiveness of using the data from the Ora System® have not been established for determining treatments involving higher order aberrations of the eye such as coma and spherical aberrations.
- The Ora System® is intended for use by qualified health personnel only.
- Improper use of this device may result in exposure to dangerous voltage or hazardous laser-like radiation exposure. Do not operate the Ora System® in the presence of flammable anesthetics or volatile solvents such as alcohol or benzene, or in locations that present an explosion hazard.

ATTENTION: Refer to the Ora System® Operator’s Manual for a complete description of proper use and maintenance, as well as a complete list of contraindications, warnings and precautions.