MARS
MARKET ACCESS AND REIMBURSEMENT SERVICES

ORA SYSTEM® With VERIFEYE® Lynk Technology Billing Guide

Overview

The ORA SYSTEM® technology provides an integrated and optimized image-guided process for surgical planning, navigation, and intraoperative aberrometry to help surgeons achieve the desired cataract refractive outcomes (presbyopia and astigmatism correction). The ORA SYSTEM® technology pairs with the VERION® Image Guided System to address potential sources of error at each procedural step (imaging, planning, guidance, and verification) during the cataract procedure:

- Allows the user to account for cyclorotation with a digital overlay guiding incisions and the capsulorhexis, while helping to choose the ideal intraocular lens (IOL) with direct aphakic measurements and precise sphere, cylinder, and axis calculations
- Verifies and refines of the pre-op plan, with the ability to make a change intraoperatively

Billing Overview

Intraoperative aberrometry performed using the ORA SYSTEM® is non-covered for cataract patients in these three scenarios:

1. **Part of the premium IOL package or separate refractive procedure**
2. **The patient had given consent to a premium IOL, but intraoperatively the surgeon had to convert to a standard IOL**
3. **Post-refractive cases**

Note: This is based on the American Academy of Ophthalmology's (AAO) April 2020 updated guidance for the ORA SYSTEM®.

See Important Product Information on last page.

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Claim Submission

- Billing for noncovered services are not required by payers
- Some commercial or Medicare Advantage provider/payer contracts require all services to be billed to the plan; in those instances the provider should file the claim with the appropriate modifiers to avoid an improper payment or denial
  - 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 (ie, astigmatism or presbyopia) should be appended
- When submitting a claim for noncovered items and services, it is important to assign the appropriate refractive diagnosis code to the noncovered services in addition to the diagnosis code for the cataract procedure

Patient Documentation & Advanced Beneficiary Notice of Noncoverage (ABN)

The provider should fully educate and inform the patient of their out-of-pocket responsibility for non-covered services prior to treatment.

- Patients are responsible for the charges of tests, services, and items used for their refractive treatment that are considered not medically necessary for treatment of a cataract
- Practices should develop their own written explanation and associated costs for a patient to sign in agreement prior to cataract surgery
- Physicians should follow their standard office practice and refer to CMS guidance for appropriate documentation for astigmatism, presbyopia, and non-covered refractive services within a patient's health record

For Original (Fee-for-Service) Medicare Patients:

- The Advance Beneficiary Notice (ABN) is not required for Medicare Part B patients

For Medicare Advantage and Commercial Patients:

- A predetermination can be submitted to the payer to document noncovered services
- Providers should review each individual plan contract and follow the appropriate process specific to that payer

Sources: CMS 05-01: https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/CMSR0501.pdf
CMS 1536-R: https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/downloads/CMS1536R.pdf
Laser assisted cataract guidance: https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/downloads/cms-pc-ac-iol-laser-guidance.pdf

Refractive Procedures: Statutory Guidelines

The Centers for Medicare and Medicaid Services (CMS) issued 2 rulings which provided Medicare beneficiaries with a choice between:

- Cataract surgery with a conventional intraocular lens (covered service and supply), or
- Cataract surgery with an advanced technology intraocular lens (partially-covered service and partially-covered supply)

This payment methodology is commonly referred to as "two-aspect or dual-aspect" payment.

In addition, CMS issued a guidance memo in 2012 for laser-assisted cataract surgery that identified certain "imaging" as a component of the refractive service, which is a non-covered service.

	Covered	Noncovered	Patient's Responsibility
Physician	Surgery for treatment of cataract (66982, 66984)	• Physicians services attributable to the noncovered functionality of the astigmatism-correcting IOL (AC-IOL) and presbyopia-correcting IOL (PC-IOL) • Additional physician work and resources required for insertion, fitting, and vision acuity testing	Payment of charges for the physician services that exceed the physician charge for insertion of a conventional IOL
Facility	Surgery for treatment of cataract (66982, 66984)	• Astigmatism-correcting or presbyopia-correcting function of an IOL and any additional resources required for insertion, fitting, and vision acuity testing	Payment of charges for the facility charges that exceed the facility charge for insertion of a conventional IOL

ORA SYSTEM® Technology Important Product Information

Caution

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

Indications

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Intended Use

The ORA SYSTEM® technology utilizes wavefront aberrometry data to measure and analyze the refractive power of the eye (i.e. sphere, cylinder, and axis measurements) to support cataract surgical procedures.

Warnings and Precautions

The following conditions may make it difficult to obtain accurate readings using the ORA SYSTEM® technology:

- 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.
- Use of iris hooks during an ORA SYSTEM® technology image capture will yield inaccurate measurements.

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.
- ORA SYSTEM® technology 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.

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