CMS Rulings

Department of Health and Human Services

Centers for Medicare & Medicaid Services

Ruling No. CMS-1536-R Date: January 22, 2007

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, utilization and peer review by Quality Improvement Organizations, private health insurance, and related matters.

CMS Rulings are binding on all CMS components, Medicare contractors, the Provider Reimbursement Review Board, the Medicare Geographic Classification Review Board, and Administrative Law Judges who hear Medicare appeals. These Rulings promote consistency in interpretation of policy and adjudication of disputes.

This Ruling sets forth CMS policy concerning the requirements for determining payment for insertion of intraocular lenses that replace beneficiaries' natural lenses and correct pre-existing astigmatism following cataract surgery under the following sections of the Social Security Act (the Act):

- Section 1832(a)(2)(F) for services furnished in connection with surgical procedures performed in an Ambulatory Surgical Center (ASC).
- Section 1833(t)(1)(B)(iii) for implantable items described in paragraphs (3), (6), or (8) of section 1861(s) that are covered hospital outpatient department services.

• Section 1861(s)(1) for physicians' services.

• Section 1861(s)(2)(A) for services and supplies furnished incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either furnished without charge or included in the physicians' bills.

• Section 1861(s)(2)(B) for hospital services incident to physicians' services furnished to outpatients.

• Section 1861(s)(8) for one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.

• Section 1862(a)(7) where notwithstanding any other provision of this title, no payment may be made under Medicare Part A or Part B for any expenses incurred for items or services where such expenses are for ...eyeglasses (other than eyewear described in section 1861(s)(8)) or eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes.

MEDICARE PROGRAM

Supplemental Medical Insurance (Part B)

TITLE: Requirements for Determining Coverage of Astigmatism-Correcting Intraocular Lenses that Provide Two Distinct Services for the Patient: (1) Restoration of Distance Vision Following Cataract Surgery, and (2) Refractive Correction of Vision Due to Pre-existing Astigmatism, with Less Dependency on Surgical Correction, Eyeglasses, or Contact Lenses

PURPOSE: This Ruling sets forth the policy of the CMS concerning the requirements for determining payment made for insertion of astigmatism-correcting intraocular lenses following cataract surgery under the following sections of the Act:

- Section 1832(a)(2)(F) for services furnished in connection with surgical procedures performed in an Ambulatory Surgical Center (ASC).
- Section 1833(t)(1)(B)(iii) for implantable items described in paragraphs (3), (6), or (8) of section 1861(s) that are covered hospital outpatient department services.
- Section 1861(s)(1) for physicians' services.
- Section 1861(s)(2)(A) for services and supplies furnished incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either furnished without charge or included in the physicians' bills.
- Section 1861(s)(2)(B) for hospital services incident to physicians' services furnished to outpatients.
- Section 1861(s)(8) for one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.

• Section 1862(a)(7) where notwithstanding any other provision of this title, no payment may be made under Medicare Part A or Part B for any expenses incurred for items or services where such expenses are for ...eyeglasses (other than eyewear described in section 1861(s)(8)) or eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes.

CITATIONS: Sections 1832, 1833, 1861, 1862 of the Act; (42 U.S.C. 1395k, 1395l, 1395x, 1395y); (42 CFR 411.15, 489.32).

BACKGROUND

In general, items or services covered by Medicare must satisfy three basic requirements: (1) they must fall within a statutorily-defined benefit category; (2) they must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body part; and (3) the item or service must not be excluded from coverage.

A conventional intraocular lens (IOL) is covered when implanted following cataract surgery. A cataract is an opacity or cloudiness in the crystalline lens of the eye, blocking the passage of light through the lens, sometimes resulting in blurred or impaired vision. A conventional IOL is a small, lightweight, clear disk that replaces the distance focusing power of the eye's natural crystalline lens.

Medicare specifically excludes certain items and services from coverage, including eyeglasses and contact lenses. The Congress, however, has provided an exception for one pair of eyeglasses or contact lenses covered as a prosthetic device furnished after each cataract surgery with insertion of an IOL.

ASTIGMATISM-CORRECTING IOLS

Regular astigmatism is a visual condition where part of an image is blurred due to uneven corneal curvature. A normal cornea has the same curvature at all axes, whereas the curvature of a regular astigmatic cornea differs in two primary axes, resulting in vision that is distorted at all distances. As noted above, except following cataract surgery with insertion of an IOL, Medicare does not cover eyeglasses or contact lenses. Additionally, Medicare does not cover the surgical correction or cylindrical lenses of eyeglasses or contact lenses that may be required to compensate for the imperfect curvature of the cornea.

An IOL that also corrects for pre-existing astigmatism is indicated for primary implantation in the capsular bag of the eye for the visual correction of aphakia (absence of the lens of the eye) in patients with pre-existing astigmatism, and is also intended to provide improved near, intermediate, and distance vision. For some patients, the astigmatism-correcting IOL may improve vision, especially distance vision, so much that no other vision enhancing intervention or support is required to provide adequate vision at certain distances. In some cases, a single IOL that also corrects pre-existing astigmatism may provide what is otherwise achieved by two separate items: the implantable conventional IOL that is covered by Medicare and the surgical correction, eyeglasses, or contact lenses for treatment of pre-existing astigmatism that are not covered by Medicare.

CONCLUSION

The statute specifically states that one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an IOL is covered. A single IOL that also corrects for pre-existing astigmatism may provide what is otherwise achieved by two separate items: an implantable conventional IOL (one that is not astigmatism-correcting), and surgical correction, eyeglasses, or contact lenses. Although astigmatism-correcting IOLs may serve the same function as eyeglasses or contact lenses furnished following cataract surgery, IOLs are neither eyeglasses nor contact lenses. Therefore, the astigmatism-correcting functionality of an IOL does not fall into the benefit category and is not covered. Any additional provider or physician services required to insert or monitor a patient receiving an astigmatism-correcting IOL are also not covered. For example, eye examinations performed to determine the refractive state of the eyes following insertion of such an IOL are non-covered.

Facility Charge

The payment for insertion of a conventional IOL furnished in a hospital outpatient department or in a Medicare-approved ambulatory surgical center is packaged or bundled into the payment for the surgical procedure performed to remove a cataractous lens. A beneficiary may request insertion of an astigmatism-correcting IOL in place of a conventional IOL following cataract surgery. In this case, the facility charge for insertion of the astigmatism-correcting IOL is considered partially covered. The beneficiary is responsible for payment of that portion of the facility charge that exceeds the facility charge for insertion of a conventional IOL following cataract surgery. In addition, the beneficiary is responsible for the payment of facility charges for resources required for

fitting and visual acuity testing of an astigmatism-correcting IOL that exceed the facility charges for resources furnished for a conventional IOL following cataract surgery.

Physician Services Charge

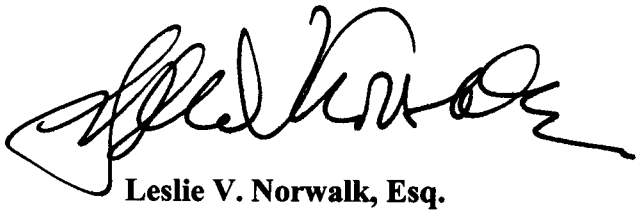
The payment for a conventional IOL furnished in a physician's office is not bundled with the procedure to insert the IOL following cataract surgery. The payment amounts for the IOL device and insertion procedure are two separate charges. A beneficiary may request insertion of an astigmatism-correcting IOL in place of a conventional IOL following cataract surgery. In this case, the astigmatism-correcting IOL device is considered partially covered. The beneficiary is responsible for payment of that portion of the physician's charge for the astigmatism-correcting IOL that exceeds the physician's charge for a conventional IOL following cataract surgery.

Regardless of site-of-service for insertion of an astigmatism-correcting IOL, the beneficiary is responsible for payment of physician services attributable to the non-covered functionality of an astigmatism-correcting IOL inserted following cataract surgery. In determining the physician service charge, the physician may take into account the additional physician work and resources required for insertion, fitting, and visual acuity testing of the astigmatism-correcting IOL compared to insertion of a conventional IOL. The beneficiary is responsible for payment of the charges for physician services that exceed the physician charge for insertion of a conventional IOL following cataract surgery.

EFFECTIVE DATE

This Ruling is effective January 22, 2007

Dated: _____



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Services.