Disclosures

No Financial Relationships to Disclose
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Topics

- Medicare Payment for IOLs
  - Default Payment Policy
  - Presbyopia-Correcting (PC) and Astigmatism-Correcting (AC) IOLs
  - New Technology IOLs (NTIOLs)
Default IOL Payment Policy

- Payment for IOL included in overall facility payment for cataract surgery procedure:
  - 2014 OPPS Payment = $1,766
  - 2014 ASC Payment = $976
2005 Presbyopia-Correcting IOL (PC-IOL) Ruling
2007 Astigmatism-Correcting IOL (AC-IOL) Ruling
  Part of the overall service is a Medicare covered benefit and part not a Medicare covered benefit
    • Covered part – “conventional cataract surgery” – Medicare pays
    • Noncovered part – “presbyopia correcting surgery” and “astigmatism correcting surgery” – Patient pays

PC-IOL = “corrects presbyopia” and provides relief from reading glasses

AC-IOL = corrects astigmatism and provides relief from astigmatic correction
NTIOL

- 20 year old statutory provision (1994)
- $50 separate payment for every NTIOL for 5 years
- 3 classes since 1999
  - Astigmatism-Correcting
  - Multifocal
  - Reduced Spherical Aberration
- Revised NTIOL Regulations at 42 CFR 416.195 in 2013
• NTIOL Criteria:
  – (1) The IOL is approved by the FDA.
  – (2) The IOL shall have a new lens characteristic in comparison to currently available IOLs. The labeling, which must be approved by FDA, shall contain a claim of a specific clinical benefit imparted by the new lens characteristic.
  – (3) The IOL is not described by an active or expired class of new technology IOLs; that is, it does not share a predominant, class-defining characteristic associated with improved clinical outcomes with members of an active or expired class.
  – (4) Any specific clinical benefit referred to in paragraph (a)(2) of this section must be supported by evidence that demonstrates that the IOL results in a measurable, clinically meaningful, improved outcome. Improved outcomes include:
• Improved outcomes include:
  – (i) Reduced risk of intraoperative or postoperative complication or trauma;
  – (ii) Accelerated postoperative recovery;
  – (iii) Reduced induced astigmatism;
  – (iv) Improved postoperative visual acuity;
  – (v) More stable postoperative vision;
  – (vi) Other comparable clinical advantages.
• Additional points:
  – EDOF IOLs as NTIOLs?
    ✓ If they can obtain “a claim of a specific clinical benefit” that results in an “improved outcome” for the beneficiary.
    ✓ Benefit/outcome possibly evaluated by validated visual function measurement tools.

• NTIOL timing:
  – 5-year clock starts with first IOL to establish NTIOL category
  – Claim can be established after initial IOL approval
Thank you

john.mcinnnes@cms.hhs.gov