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MEDICARE REIMBURSEMENT AND ZEPTO

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1 ***QUESTION:*** What is the ZEPTO IOL Positioning System™?

ANSWER: The ZEPTO IOL Positioning System™ is the first and only device that creates an instantaneous capsulotomy for precise, 360-degree IOL overlap and improved outcomes.

2 ***QUESTION:*** How does ZEPTO® work?

ANSWER: After insertion into the anterior chamber through a ≥2.2mm incision, the ZEPTO handpiece is centered on the first Purkinje image. Suction, delivered from the ZEPTO power console, brings the ZEPTO tip with nitinol ring into apposition against the lens capsule. Twelve micropulses of energy are applied in four milliseconds, and a capsulotomy is automatically formed. The device is removed through the main corneal incision.[1]

3 ***QUESTION:*** How is a precise, instantaneous capsulotomy beneficial?

ANSWER: It provides optimal positioning of the capsulotomy to improve intraocular lens centration especially for aspheric optics. It reduces the potential for capsule tears, asymmetric capsulotomies, crystalline lens dislocation, zonule dehiscence, decentered IOL, and endothelial cell loss, particularly in risky complex cases. ZEPTO is faster and less expensive than an automated capsulotomy with a femtosecond laser.

4 ***QUESTION:*** What is the indication for ZEPTO precision capsulotomy system?

ANSWER: It is indicated for use in performing anterior capsulotomy during cataract surgery.[2]

5 ***QUESTION:*** Which patients are ideally suited for ZEPTO?

ANSWER: Patients: with white cataracts, with suspicious zonules, with a history of difficult cataract surgery in the fellow eye, or who are receiving an aspheric IOL or advanced technology IOL (AT-IOL), are ideally suited for ZEPTO. It permits a better outcome with fewer adverse events.

6 ***QUESTION:*** What additional services are indicated to identify patients who are candidates for ZEPTO?

ANSWER: B-scan for dense cataracts[3] and specular microscopy for low endothelial cell count[4] are indicated and covered by Medicare. Patients with a history of difficult cataract surgery in the fellow eye with an unfortunate outcome or who may want an AT-IOL should be evaluated for higher order optical aberrations with wavefront aberrometry; this is not a covered test.[5] Corneal topography is indicated in planning for a toric IOL or other astigmatism correction; it is not covered as an element of refractive surgery.[6,7] For an optimal surgical outcome, particularly with AT-IOLs or in risky cases, patients should be screened for other diseases that might compromise the results such as macular degeneration and dry eye disease. Screening services not explicitly covered in the Social Security Act §1862(a)(1) are not covered.[8]

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7 ***QUESTION:*** Is additional diagnostic testing prior to cataract surgery indicated for all patients?

ANSWER: No. The American Medical Association states, "*Physicians should not recommend, provide, or charge for unnecessary medical services; nor should they make intentional misrepresentations to increase the level of payment they receive or to secure non-covered health benefits for their patients.*"[9] Ordered tests require a justifiable rationale, whether covered by health insurance or not.

8 ***QUESTION:*** Does Medicare pay an ASC or HOPD separately for ZEPTO?

ANSWER: No. A surgeon may choose any instrument to perform a capsulorhexis; however, the cost of the instrument is covered by the Medicare reimbursement of the facility fee for cataract surgery.

9 ***QUESTION:*** What circumstances warrant higher payment to a cataract surgeon?

ANSWER: A surgeon receives higher reimbursement for complex cataract surgery (66982).[10] When cataract surgery is performed and a presbyopia-correcting or astigmatism-correcting IOL implanted, there are additional noncovered physician fees.[11]

10 ***QUESTION:*** May an ASC or HOPD charge a surgeon a fee to use ZEPTO in cataract surgery?

ANSWER: No. Under the terms of its participation agreement with Medicare (or other third-party payor), the facility has already been reimbursed for all instruments and supplies used in cataract surgery.[12] A charge to a surgeon would represent a duplicate payment.

11 ***QUESTION:*** How do Medicare's rules differ for FLACS and ZEPTO?

ANSWER: A continuous curvilinear capsulorhexis (CCC) is standard in modern cataract surgery – no separate charge is made regardless of the instrument that is used to achieve it.

When the femtosecond laser is used to make two tabs 180° apart in the anterior capsule for alignment of a toric IOL, then a separate charge is justified.[13,14] When a femtosecond laser is used for corneal or limbal relaxing incisions, that is part of refractive surgery, a separate charge to the patient is warranted.

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1 Centricity website. Directions for use. Link here.
2 DHS 510(k) K210827 Indication for Use Link here.
3 NCD 10.1 Link here.
4 NCD 80.8 Link here.
5 SSA 1862(a)(7) Link here.
6 NCD 80.7 Link here.
7 SSA 1862(a)(10) Link here.
8 For more information, see our FAQ , Noncovered
9 AMA Code of Ethics 11.3.1 Link here.
10 For more information, see our FAQ
11 For more information, see our monograph
12 42 CFR 416.61(a)(3) Link here.
13 CMS Memo Laser Assisted Cataract Surgery, November 16, 2012. Link here.
14 Packer, M. *Image-guided femtosecond laser capsular marks for toric intraocular lens alignment – the refractive capsulorhexis*. January 2019. US Ophthalmic Review 12(2):60 Link here.

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