**1 QUESTION:** What is the CUSTOMFLEX® ARTIFICIALIRIS?

**ANSWER:** The CUSTOMFLEX® ARTIFICIALIRIS is a silicone disc to replace a missing or damaged iris.¹ The disc diameter measures 12.80 mm with a fixed 3.35 mm diameter pupil. The device is custom made for each patient; colorized silicone is applied to the front surface to simulate natural iris from a template photograph. The back surface is black for maximum light-blocking. Because eyes vary in size, it may be cut at the time of surgery for proper fit. The artificial iris can be placed with or without sutures. The device is available in two models: 1) With Fiber, and 2) Fiber Free. With Fiber has an embedded polyester meshwork for added strength to withstand suturing.

**2 QUESTION:** What is the FDA status of the device?

**ANSWER:** It was granted premarket approval by the FDA in May, 2018.² Additionally, FDA designated it a humanitarian use device in 2010.

**3 QUESTION:** What are the indications for use?

**ANSWER:** It is for treatment of iris defects.³ It is indicated for use in children and adults for the treatment of full or partial aniridia resulting from congenital aniridia, acquired defects, or other conditions associated with full or partial aniridia such as albinism.

**4 QUESTION:** How is the artificial iris implanted?

**ANSWER:** The CUSTOMFLEX® ARTIFICIALIRIS can be cut to a size that will fit a specific capsular bag or ciliary sulcus with a trephine. It can be implanted in addition to or at the same time as most commercially available IOLs with the exception of active accommodating IOLs. It is flexible, allowing it to be folded and inserted manually using forceps or with an auto injector. The device can be implanted using a sutured or sutureless technique. It can be used for either intracapsular, sulcus, or suture fixation, depending on pre-existing anatomy and the evolution of the individual patient’s surgical procedure. Furthermore, secondary suture fixation is possible late after the primary procedure in case progressive zonulopathy causes dislocation of the device.

**5 QUESTION:** Will Medicare cover the artificial iris and its implantation?

**ANSWER:** Yes. The treatment of aniridia with an FDA approved device meets the statutory coverage criteria of the Medicare program for “the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member”.⁴ Other third party payers generally agree with this policy.

**6 QUESTION:** What HCPCS code describes this prosthetic device?

**ANSWER:** Effective January 1, 2020, the CUSTOMFLEX® ARTIFICIALIRIS received separate Medicare payment under C1839 (Iris prosthesis).

July 1, 2020
What CPT codes are used to report implantation?

Effective July 1, 2020, three new Category III CPT codes apply.

- **0616T** – Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens
- **0617T** – Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens
- **0618T** – Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange

CPT instructs that 0617T not be billed in conjunction with 66982, 66983 or 66984, and that 0618T not be billed with 66985 or 66986. None of these codes may be billed with 66600, 66680 or 66682.

In some cases, particularly after trauma, other ophthalmic procedures may be performed concurrently with implantation of an artificial iris as needed such as: keratoplasty, synechialysis, or pars plana vitrectomy, among others.

How does Medicare reimburse the surgeon?

Category III codes do not have assigned values in the Medicare Physician Fee Schedule (MPFS); that determination is made by the Medicare Administrative Contractor on an individual case-by-case basis. The surgeon does not bill for the supply of the artificial iris; the ASC or HOPD does.

What is the Medicare payment to the ASC?

The ASC allowable amount for 0616T is $1,013; for 0617T and 0618T it is $1,836. Unlike in the HOPD, when multiple procedures are performed, additional payment is allowed, albeit at a reduced rate.

C1839 is assigned to APC 5491; the allowed amount is $2,202. 0617T and 0618T are assigned to APC 5492 and allowed $3,818. All three codes are assigned status indicator J1, which means there is a single payment; other concurrent procedures are included.

C1839 (Iris prosthesis) is assigned the status indicator "H" in the HOPD meaning "separate cost-based pass-through payment; not subject to copayment"; it is assigned to APC 2028. There is no fee schedule for C1839 in an HOPD. Instead, payment is a proportion of your charges. For example, if your HOPD cost-to-charge ratio (RCC) is 0.25, and your charge is $34,000, then the reimbursement is based on $8,500 (i.e., 0.25 times $34,000); the usual 20% copayment is omitted although deductibles still apply.

What is the Medicare payment to the HOPD?

Under OPPS, 0616T is assigned to APC 5491; the allowed amount is $2,202. 0617T and 0618T are assigned to APC 5492 and allowed $3,818. All three codes are assigned status indicator J1, which means there is a single payment; other concurrent procedures are included.

C1839 (Iris prosthesis) is assigned the status indicator "H" in the HOPD meaning "separate cost-based pass-through payment; not subject to copayment"; it is assigned to APC 2028. There is no fee schedule for C1839 in an HOPD. Instead, payment is a proportion of your charges. For example, if your HOPD cost-to-charge ratio (RCC) is 0.25, and your charge is $34,000, then the reimbursement is based on $8,500 (i.e., 0.25 times $34,000); the usual 20% copayment is omitted although deductibles still apply.

The reimbursement information is provided by Corcoran Consulting Group based on publicly available information from CMS, the AMA, and other sources. The reader is strongly encouraged to review federal and state laws, regulations, code sets, and official instructions promulgated by Medicare and other payers. This document is not an official source nor is it a complete guide on reimbursement. Although we believe this information is accurate at the time of publication, the reader is reminded that this information, including references and hyperlinks, changes over time, and may be incorrect at any time following publication.

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Social Security Act 1862(a)
1  Human Optics CUSTOMFLEX® ARTIFICIAL IRIS.  Link here.
2  US FDA Premarket Approval P170039.  Approval Date 05/30/18.  Link here.
3  Directions for Use.  Contraindications.  Link here.
4  Social Security Act 1862(a)