**MEDICARE REIMBURSEMENT FOR CUSTOMFLEX® ARTIFICIALIRIS**

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

**ANSWER:** The CUSTOMFLEX ARTIFICIALIRIS is a silicone disc to replace a missing or damaged iris. 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. 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. 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 injected using the AMO [now J&J Vision] silver series IOL 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 to improve the functioning of a malformed body member." Other third party payers generally agree with this policy.

January 1, 2020

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.

© 2020 Corcoran Consulting Group. All rights reserved. No part of this publication may be reproduced or distributed in any form or by any means, or stored in a retrieval system, without the written permission of the publisher. CPT is a registered trademark of the American Medical Association.

Provided Courtesy of Veo Ophthalmics

© 2020 Corcoran Consulting Group (800) 399-6565 www.corcoranccg.com

© 2020 Corcoran Consulting Group (513) 872-1330 www.veo-ophthalmics.com
**QUESTION:** What CPT code is used to report implantation?

**ANSWER:** At present, there are limited choices.
- Use 66999 *(Unlisted procedure, anterior segment of eye)* to report insertion of artificial iris prosthesis in an aphakic or pseudophakic eye
- Use 66982 *(Complex cataract)* for *insertion* of artificial iris and concurrent cataract removal and IOL implantation; without endoscopic cyclophotocoagulation

In some cases, particularly after trauma, other ophthalmic procedures may be performed concurrently with implantation of an artificial iris such as: vitrectomy, keratoplasty, McCannel suture, or repair of laceration.

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

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

**QUESTION:** How does Medicare reimburse the surgeon?

**ANSWER:** For a specific CPT code, such as 66982, the Medicare Physician Fee Schedule (MPFS) applies. For a miscellaneous code, such as 66999, the MPFS does not specify a payment amount and that determination is made by the Medicare Administrative Contractor on an individual case-by-case basis. The surgeon does not bill for the artificial iris; the ASC or HOPD does.

**QUESTION:** What is the Medicare payment to the ASC?

**ANSWER:** Under the Medicare Outpatient Prospective Payment System (OPPS) in 2020, 66982 is allowed $1,013; 66999 is allowed zero. C1839 is assigned the “J7” indicator which means “OPPS pass-through device paid separately when provided integral to a surgical procedure on ASC list; payment contractor-priced.” There is no fee schedule for C1839 in an ASC, rather, payment is based on the manufacturer’s invoice. Copayments do apply in the ASC setting.

**QUESTION:** What is the Medicare payment to the HOPD?

**ANSWER:** Under the Medicare Outpatient Prospective Payment System (OPPS), 66982 is assigned a comprehensive ambulatory payment classification, C-APC 5491. Status indicator J1 is assigned which means there is a single payment for a C-APC; other concurrent procedures are included. The HOPD allowed amount is $2,022.

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)* and the usual 20% copayment is omitted although deductibles still apply.

---

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)
5. FDA Breakthrough Devices Program [Link here.]

---

January 1, 2020

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.

© 2020 Corcoran Consulting Group. All rights reserved. No part of this publication may be reproduced or distributed in any form or by any means, or stored in a retrieval system, without the written permission of the publisher. CPT is a registered trademark of the American Medical Association.

Corcoran Consulting Group (800) 399-6565 www.corcoranccg.com

**Provided Courtesy of Veo Ophthalmics (513) 872-1330 www.veo-ophthalmics.com**

S:\Monographs_FAQFAQ_Veo Artificial Iris_010120.docx