CUSTOM*FLEX*® ARTIFICIAL*IRIS* GUIDE FOR REIMBURSEMENT

The device is a foldable iris prosthesis that is custom-made for each individual patient by HumanOptics AG (Erlangen, Germany). The CUSTOM*FLEX*® ARTIFICIAL*IRIS* prosthesis is manufactured from a commercially available ophthalmic silicone. Colorized silicone paste is applied by hand in a pattern to match the color of the natural iris using a photograph of the existing iris or, in the case of aniridia, the color of the photograph selected by the patient. The CUSTOM*FLEX*® ARTIFICIAL*IRIS* prosthesis is approved by the FDA to repair or replace missing or damaged iris tissue due to partial or total, congenital or acquired aniridia, congenital or acquired iris defects (such as iris removal due to iris melanoma), or for ocular albinism. The device comes in both "With Fiber" and "Fiber-Free" models, accommodating both sutured and sutureless implant techniques. The "With Fiber" model features an embedded polyester meshwork layer and is more robust to tighter sutures.

The CUSTOM*FLEX*® ARTIFICIAL*IRIS* prosthesis was granted breakthrough device status by the FDA. To qualify, a device must provide for more effective treatment or diagnosis of a life-threatening or irreversibly debilitating disease or condition, and meet one of the following criteria: the device must represent a breakthrough technology; there must be no approved or cleared alternatives; the device must offer significant advantages over existing approved or cleared alternatives; or, the availability of the device is in the best interest of patients.

Three (3) Category III CPT codes have been assigned for reporting surgeries with the CUSTO*MFLEX*® ARTIFICIAL*IRIS* prosthesis as of 7/1/20. They are:

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

(Do not report 0617T in conjunction with 66982, 66983, 66984)

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

(Do not report 0618T in conjunction with 66985, 66986)

(Do not report 0616T, 0617T, 0618T in conjunction with 66600, 66680, 66682)

Because the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is used in a variety of situations, often to repair serious injuries to the iris and adjacent tissues, it may be one part of a compound procedure that includes surgery of the cornea, anterior chamber angle, vitreous and retina.

In 2024, each Medicare Administrative Contractor determines the surgeon's reimbursement for 0616T, 0617T, and 0618T. CMS established 2024 payment rates for hospital outpatient departments (HOPD) and ambulatory surgery centers (ASC). These payments are inclusive of the device and facility fee. The payment rates listed are the national unadjusted rates; actual payment rates are geographically adjusted according to the wage index.

CPT Code	ASC	HOPD
0616T	$14,299	$16,548
0617T	$15,066	$16,548
0618T	$11,184	$16,548

HOPD will report the charges for the device (CUSTOMFLEX® ARTIFICIALIRIS) on a claim using HCPCS code C1839 (Iris prosthesis). C1839 is a non-payable code but must be reported, along with 1 of the artificial iris CPT codes, for the claim to be billed correctly.

ASC will only report the appropriate CPT code for the artificial iris implantation and will not report C1839.

Diagnosis code Q13.1, for aniridia, should be present on all artificial iris claims.

A claim for reimbursement needs to be supported by documentation in the beneficiary's medical record that describes the procedure and the medical rational for it. This may include:

- Eye exam with medical justification for planned procedures and absence of contraindications for them.
- Allied diagnostic testing supporting medical necessity for the iris prosthesis (e.g., endothelial cell count, corneal pachymetry, scanning computerized ophthalmic diagnostic imaging of the anterior segment).
- Clearance for surgery (e.g., history and physical) by the surgeon or other health care professional.
- Detailed operative report.

CAUTION: Federal (USA) law restricts this device to sale by, or on the order of, a physician. U.S. Federal law restricts this device to practitioners who have been trained and have experience in the surgical management and treatment of aniridia.
INTENDED USE: The CUSTOM*FLEX*® ARTIFICIAL*IRIS* is intended for use as an iris prosthesis for the treatment of iris defects. The CUSTOM*FLEX*® ARTIFICIALIRIS 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.
CONTRAINDICATIONS: The CUSTOM*FLEX*® ARTIFICIAL*IRIS* device is contraindicated in eyes with any of the following conditions: uncontrolled ocular inflammation (e.g., uveitis), severe chronic uveitis, microphthalmus, untreated retinal detachment, untreated chronic glaucoma, rubella cataract, rubeosis of the iris, proliferative diabetic retinopathy, Stargardt's retinopathy, pregnant women, and intraocular infections.
ATTENTION: Refer to the manufacturer's professional use information for a complete description of proper use of the CUSTOM*FLEX*® ARTIFICIAL*IRIS*. https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170039d.pdf

Distributed by:
VEO Ophthalmics
10184 International Blvd.
West Chester, OH 45246
(513) 872-1330