Regence

NOTE: This policy is not effective until January 1, 2027

Medical Policy Manual Surgery, Policy No. 246

Iris Prosthesis

Effective: January 1, 2027

Next Review: August 2027
Last Review: August 2026

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

An artificial iris or iris prosthesis is used to treat a partial or total absence of the iris called aniridia.

MEDICAL POLICY CRITERIA

The use of an iris prosthesis (e.g., CustomFlex™ Artificial Iris) is considered **investigational** for any indication**.**

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Optical Coherence Tomography (OCT) of the Anterior Eye Segment, Medicine, Policy No. 133
2. Surgical Treatments for Glaucoma, Surgery, Policy No. 227

BACKGROUND

Aniridia is defined as a partial or complete absence of the iris and has either a congenital or acquired etiology. Congenital aniridia is a rare (1.8 per 100,000 births), typically autosomal

dominant disease which affects both eyes. Management of aniridia includes optimal refractive correction, amblyopia therapy, and correction of squint. Tinted contact lenses may reduce light sensitivity (photophobia), improve aesthetics, and improve vision. Such contact lenses also reduce nystagmus. Photochromatic or tinted glasses may be helpful. The Food and Drug Administration has approved an artificial iris implant which may reduce disabling glare and light sensitivity during day or night and enhance vision-related quality of life. However, there is a reported risk of development or worsening of glaucoma and limbal stem cell deficiency. [1]

REGULATORY STATUS

The FDA approved the CustomFlex® Artificial Iris (Clinical Research Consultants, Inc.) through the premarket approval process in May 2018. The CustomFlex® Artificial Iris 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. (P170039).[2] There are no other artificial iris devices currently approved by the FDA.

EVIDENCE SUMMARY

SYSTEMATIC REVIEWS

Gius (2023) published a systematic review (SR) evaluating the anatomical and functional outcomes of various prosthetic iris devices (PIDs) for the surgical correction of traumatic aniridia, with the goal of improving visual quality, compartmentalizing the anterior and posterior chambers, and restoring cosmetic appearance.[3] Of 185 articles identified in the literature, 70 met eligibility criteria, and five PID subgroups were analyzed: Ophtec (Ophtec BV), Morcher (Morcher GmbH), HumanOptics AG, artificial iris-intraocular lens prosthesis, and other prostheses. Both glare and aesthetic outcomes improved postoperatively across device types; however, complication profiles differed by device, with intraocular pressure elevation occurring at a higher rate in the Morcher group (40%) and prosthesis dislocation occurring more frequently in the Ophtec group (39%). Limitations include focus on a single indication, traumatic aniridia, heterogeneity of the included studies and absence of detailed subgroup statistics beyond complication rates.

Romano (2023) published a SR evaluating the use of artificial iris implants in patients with congenital aniridia.[4] Outcomes included surgical implantation techniques, clinical outcomes, complications, and risk of bias. Five studies were included, three retrospective case series and two retrospective cohort studies, comprising 144 eyes in 83 patients. Follow-up durations varied considerably across studies, ranging from 12 months to a maximum of 120 months, with three of the five studies reporting mean follow-up times greater than 24 months. Three prosthetic iris device (PID) types were evaluated: iris-lens diaphragm (ILD, n = 45 eyes, 31.2%), customized artificial iris (AI, n = 98 eyes, 68.1%), and capsular tension ring-based prosthetic iris device (CTR-based PID, n = 1 eye, 0.7%). Overall, 90 of 144 eyes (62.5%) demonstrated improved best-corrected visual acuity (BCVA) following implantation, while 39 of 144 eyes (27.1%) showed no change and 13 of 144 eyes (9.8%) experienced deterioration. BCVA improvement was reported in 71.2% of ILD cases and 59.2% of AI cases. Symptom reduction (glare and/or photophobia) was reported in 78 of 83 patients (94%), with AI demonstrating slightly higher symptom reduction (96%) compared to ILD (90%). Adverse events were common across all device types. Glaucoma progression in patients with pre-existing glaucoma occurred in 58.9% of cases (23 of 39 eyes), secondary glaucoma developed in 27.6% (29 of 105 eyes), progression of aniridia-associated keratopathy was noted in 27% (27 of 100 eyes), prosthesis decentration occurred in 10.6% (14 of 132 eyes), and endothelial

cell loss was reported in 9% (13 of 144 eyes), exclusively in ILD cases. Glaucoma was the most common complication requiring additional surgery (53.8%; 28 of 52 eyes). Secondary glaucoma occurred in 28.7% of AI cases and 25.6% of ILD cases, while prosthesis decentration was noted in 9.2% of AI cases and 14.7% of ILD cases. Endothelial cell loss was reported only with ILD (28.8%; 13 of 45 eyes). Limitations include the retrospective design of all included studies, small sample sizes, absence of control groups, single-surgeon methodology, lack of standardized follow-up periods, heterogeneous patient populations, inconsistent reporting of baseline comorbidities, and the confounding effect of simultaneous cataract surgery performed in 97% of cases.

Randomized Controlled Trials

No randomized controlled trials were identified.

Nonrandomized Studies

Ayres (2022) published a multicenter, prospective, nonrandomized interventional clinical trial evaluating the safety and efficacy of the CustomFlex Artificial Iris (HumanOptics AG) for the treatment of congenital and acquired iris defects in patients with photophobia and glare.[5] The study enrolled patients across multiple U.S. centers, with implantations using one of four surgical techniques, with follow-up assessments at one day, one week, and one, three, six, and 12 months postoperatively. Outcomes included corrected distance visual acuity (CDVA), endothelial cell density (ECD), the 25-item National Eye Institute Visual Function Questionnaire (NEI VFQ-25), and the Global Aesthetic Improvement Scale. At 12 months, statistically significant reductions were observed in marked-to-severe daytime light sensitivity (59.7% reduction; $p < 0.0001$), nighttime light sensitivity (41.5% reduction; $p < 0.0001$), daytime glare (53.1% reduction; $p < 0.0001$), and nighttime glare (48.5% reduction; $p < 0.0001$). The NEI VFQ-25 total score improved by 15.4 points ($p < 0.0001$), and 93.8% of patients reported cosmetic improvement on the Global Aesthetic Improvement Scale. No device-related loss of CDVA greater than two lines was observed. Median ECD loss was 5.3% at six months and 7.2% at 12 months. The device met all key safety and efficacy endpoints. Limitations include the nonrandomized, unmasked design, absence of a control group, and a follow-up period limited to 12 months, which may not capture longer-term complications such as glaucoma progression or sustained endothelial cell loss.

PRACTICE GUIDELINE SUMMARY

No evidence-based clinical practice guidelines recommend the use of iris prosthesis (e.g., CustomFlex Artificial Iris) for any indication.

SUMMARY

There is not enough research to show that artificial iris devices improve health outcomes or guide treatment decisions. No clinical guidelines based on research recommend artificial iris devices. Therefore, artificial iris devices (e.g., CustomFlex Artificial Iris) are considered investigational.

REFERENCES

1. Tripathy K, Salini B. Aniridia. StatPearls. Treasure Island (FL): StatPearls Publishing Copyright © 2026, StatPearls Publishing LLC., 2026.
2. FDA Approval Order; CustomFlex Artificial Iris: Premarket Approval Application (PMA) Number: P170039. [cited 07/21/2026]. 'Available from:' https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170039A.pdf.
3. Gius I, Tozzi L, De Biasi CS, et al. Artificial iris: state of the art. *J Cataract Refract Surg.* 2023;49(4):430-37. PMID: 36719472
4. Romano D, Bremond-Gignac D, Barbany M, et al. Artificial iris implantation in congenital aniridia: A systematic review. *Surv Ophthalmol.* 2023;68(4):794-808. PMID: 36379301
5. Ayres BD, Fant BS, Landis ZC, et al. Results of the United States Food and Drug Administration Clinical Trial of the CustomFlex Artificial Iris. *Ophthalmology.* 2022;129(6):614-25. PMID: 35131359

CODES

Codes	Number	Description
CPT	66683	Implantation of iris prosthesis, including suture fixation and repair or removal of iris, when performed
HCPCS	C1839	Iris prosthesis

Date of Origin: *August 2026*