Policy Name	Clinical Policy - Iris Prosthesis
Policy Number	1340.00
Department	Clinical Strategy
Subcategory	Medical Management
Original Approval Date	07/07/2021
Current MPC/CCO Approval Date	07/09/2025
Current Effective date	10/01/2025

Company Entities Supported (Select All that Apply):
X Superior Vision Benefit Management
X Superior Vision Services
X Superior Vision of New Jersey, Inc.
X Block Vision of Texas, Inc. d/b/a Superior Vision of Texas
X Davis Vision
(Collectively referred to as 'Versant Health' or 'the Company')

ACRONYMS	
AAO	American Academy of Ophthalmology®
FDA	U.S. Food and Drug Administration

PURPOSE

To provide the evaluation methodology for iris prosthesis. Applicable procedure codes are also defined.

POLICY

A. SUMMARY

Versant Health considers the use of prosthetic iris devices to be investigational. There is insufficient evidence in the form of randomized clinical trials or high quality meta analysis to confirm safety, efficacy and improved health outcomes.

B. Methodology for evaluating medical necessity

Articles from peer reviewed literature were evaluated, plus information from AAO, FDA, and the manufacturer. The organizing methodology to evaluate the quality of medical evidence is referenced by the American Academy of Ophthalmology (2020) and is consistent with the work of Guyatt in the 2008 GRADE study.[1] It states that randomized, controlled, double masked studies and/or systematic reviews with meta-analysis provide the best evidence regarding the efficacy of any intervention. Cohort studies, case-controlled studies, case series, and case reports provide lower levels of confidence in the efficacy of an intervention. The quality of the medical evidence will inform an evaluation of how this technology affects patient health outcomes, the magnitude of that effect and its applicability to clinical practice.

C. Conclusion on medical necessity

The literature reviewed contained individual case reports, small case samples of non-randomized retrospective and prospective cohort analyses. There are no randomized controlled clinical trials which were suitably masked. Additionally, there were no reports in the peer review literature of meta-analyses or multicenter randomized trials. For these reasons, Versant Health considers prosthetic iris devices to be investigational and may not be medically necessary.

D. PROCEDURE DETAIL

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

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[1] Guyatt, 2010.

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RELATED POLICIES AND PROCEDURES	
1323	Experimental & Investigational Services

DOCUMENT HISTORY		
Approval Date	**Revision**	**Effective Date**
07/07/2021	Initial policy; designates device as investigational.	01/01/2022
07/06/2022	Annual review; no criteria changes.	08/01/2022
07/12/2023	Add CPT C1839; all procedures and devices remain investigational status.	10/01/2023
07/10/2024	Annual review; no criteria changes.	09/01/2024
07/09/2025	Remove CMS deleted CPT codes 0616T, 0617T, 0618T and add new CMS CPT code 66683.	10/01/2025

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