Policy Name	Clinical Policy - Iris Prosthesis
Policy Number	1340.00
Department	Clinical Product & Development
Subcategory	Medical Management
Original Approval Date	07/07/2021
Current MPC/CCO Approval Date	07/10/2024
Current Effective date	09/01/2024

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. 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 were no reports of 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.

1. **C1839** Iris prosthesis CustomFlex artificial iris – There is insufficient evidence based upon randomized controlled clinical trials and/or high-quality meta-analysis to demonstrate improved health outcomes.
2. **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 - There is insufficient evidence based upon randomized controlled clinical trials and/or high-quality meta-analysis to demonstrate improved health outcomes.
3. **0617T** as above + with removal of crystalline lens and insertion of intraocular lens - There is insufficient evidence based upon randomized controlled clinical trials and/or high quality meta-analysis to demonstrate improved health outcomes.
4. **0618T** as above + with secondary intraocular lens placement or intraocular lens exchange - There is insufficient evidence based upon randomized controlled clinical trials and/or high quality meta-analysis to demonstrate improved health outcomes.

Subject to applicable law, compliance with this Clinical Policy is not a guarantee of coverage or payment. Coverage is based on the terms of an individual's particular benefit plan document, which may not cover the service(s) or procedure(s) addressed in this Clinical Policy. The terms of the individual's specific benefit plan are always determinative.

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RELATED POLICIES AND PROCEDURES	
1346	Experimental & Investigational Services

DOCUMENT HISTORY		
Approval Date	**Revision**	**Effective Date**
07/07/2021	Initial policy; designates device as investigational and not medically necessary	01/01/2022
07/06/2022	Annual review; no criteria changes.	08/01/2022
07/12/2023	Update procedures to investigational status; add new device C1839 Iris prosthesis	10/01/2023
07/10/2024	Annual review; no criteria changes.	09/01/2024

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