Policy Name	Clinical Policy – Experimental and Investigational Services
Policy Number	1323.00
Department	Clinical Strategy
Subcategory	Medical Management
Original Approval Date	04/25/2018
Current MPC/CCO Approval Date	04/09/2025
Current Effective Date	06/01/2025

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 and Definitions	
CPT® Category III Codes	Category III codes are temporary codes created to track safety and usage data of new, and emerging therapies and tests. All Category III Codes have a sunset date, at which time the CPT® editorial panel may convert it to a Category I code or delete the code if widespread use of the service has not materialized, or they may extend the code as Category III for several more years. See "Sources" for CPT® III criteria.
CPT® Category III/T Codes	Referred to as temporary codes to track utilization of emerging technologies, services, or procedures. Oftentimes, the subsequent permanent code has identical numbers and characters with no change.
DHHS	U.S. Department of Health and Human Services
FDA	U.S. Food and Drug administration which approves pharmaceuticals and devices for the initial investigational use.
FDA Categories Experimental	Category A. - Safety and efficacy has not been established. Category B - Safety and efficacy have been established but criteria for medical necessity and evidence of improved health outcomes have not been established.
Investigational	Therapies or diagnostics that are not recognized as standard medical care for the condition, disease, illness, or injury being treated.

Technology Assessment Reports	Formal documents resulting from the industry and scientific review of new or not widely adopted therapies and diagnostics.

PURPOSE

To define the medical necessity criteria to support the indication(s) for experimental and investigational procedures, medications, diagnostic tools, and devices, plus AMA designated CPT® Level 3 codes.

POLICY

A. BACKGROUND

The Versant Health Medical Policy Council regularly reviews experimental, investigational, and relatively unproven therapies that include CPT® Code III procedures, plus FDA approved drugs and devices that are not yet in widespread use, CMS released new technologies, and the use of FDA approved drugs or procedures for an unapproved (off label) use. These reviews may result in a formal technology assessment report.

1. The new technology assessment reports establish either:

    a. That the new or existing technology is considered experimental and/or investigational, thus, not adopted into the program services, or
    b. That the new or existing technology will be included as a therapeutic service.

2. Technologies which are not adopted as medically necessary treatments are retained on the new technology/CPT® III code tracker for ongoing tracking and future review.

3. The assessment of experimental and investigational services for program inclusion includes research from the following sources:

    a. Medicare/CMS Technology Assessments
    b. Client health plan criteria for alignment with specific CPT® III code, drug, diagnostic tool, or device.
    c. Industry coverage and commentary of the specified technology.
    d. Studies presented in peer-reviewed literature.
    e. Published study results in NIH clinical trials.

B. Medically Necessary

Review of a request for an experimental, or investigational service includes the information stated above plus a review of the member's individualized medical record and plan of care. Consideration also includes the member's regional variation and access to care, as follows:

1. General acceptance of the treatment by the medical community as safe and effective in treatment of the condition in the setting for which the use is proposed; and,
2. Access to medical expertise to provide the diagnosis, direct care and treatment of the patient's condition, and,
3. Is in accordance with professional, evidence based medical and recognized standards of good medical practice and care; and,
4. Provided at a level of duration and/or dosage that is individualized and medically appropriate and,
5. Not furnished primarily for the convenience of the patient, the physician, or supplier; and,
6. Treatment consensus is obtained with the member's health plan, as contractually required.
7. Versant Health will provide medical review of excluded experimental and investigational treatments for expanded use, i.e. compassionate use, when no comparable or satisfactory alternative therapy options are available. [1] [2]

C. Not Medically Necessary

1. Versant Health does not consider any experimental device, procedure, drug, therapy, treatment, biologic product or instrument to be medically necessary.

2. In rare circumstances investigational devices, procedures, or drugs may be considered medically appropriate. No investigational devices, drugs, or procedures are included in Versant Health programs except as documented in the formal clinical policies.

3. Versant Health considers any device, procedure, protocol, drug, therapy, treatment, biologic product or instrument to be experimental and/or investigational if it meets any of these criteria:

    a. It has not received final approval by the FDA, any interim approvals or instrument, drug or device investigative exemptions, Category A or Category B classifications are insufficient.
    b. Not proven to be safe and effective based upon authoritative peer reviewed literature.
    c. Performed under a protocol that requires or should require oversight by an institutional review board (IRB).
    d. Does not demonstrate improved health outcomes.
    e. If a comparable outcome can be achieved by a device, procedure, protocol, drug, therapy, treatment, biologic product or instrument that is not experimental and/or investigational and is already in common and accepted use in medical practice and appropriate for the patient.
    f. Furnished at a level, duration or frequency not supported by peer-reviewed medical literature.

[1] FDA, Expanded Access. 2024
[2] NCQA 2024 Utilization Management Standards

g. Not furnished in a setting (such as inpatient care at a hospital or skilled nursing facility, or physician's office or home care) appropriate to the patient's medical needs and condition.
h. Referred to as experimental, investigational, clinical trial, research project or similar language by other institutions studying the same or similar device, procedure, protocol, drug, therapy, treatment, biologic product or instrument.
i. It is not itself experimental and/or investigational but is being used for a purpose or route that is not included in the drug or device FDA labeling.

D. Documentation for Experimental or Investigational Services Request

Medical necessity must be supported by adequate and complete documentation in the patient's medical record that describes the procedure and the medical rationale as in requirements above. For any retrospective review, a full operative report and/or the clinical care plan is needed.

All medical record items must be available upon request to initiate or sustain previous payments. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, date(s) of service). Services provided or ordered must be authenticated by the physician, in a handwritten or electronic signature. Stamped signatures are not acceptable. For retrospective reviews, the full operative report and/or the clinical care plan is required.

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RELATED POLICIES AND PROCEDURES	
1324	Category III Services (retired 2020)

DOCUMENT HISTORY		
Approval Date	***Revision***	***Effective Date***
04/25/2018	Initial policy	04/25/2018
07/25/2019	Annual review; no criteria changes.	07/25/2019
06/03/2020	Combine with policy 1324.00 Category III codes.	07/01/2020
04/07/2021	Annual review; no criteria changes.	07/01/2021
04/06/2022	Annual review; no criteria changes.	05/01/2022
04/12/2023	Separate experimental and investigational procedures into two categories; add description of how investigational treatments may be included in the program.	07/01/2023
04/03/2024	Added compassionate use exception for medical review.	07/01/2024
04/09/2025	Update definitions of experimental and investigational services with FDA categories.	06/01/2025

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SOURCES

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