CareSource

MEDICAL POLICY STATEMENT
Ohio Medicaid

Policy Name & Number	Date Effective
Digital Therapy Devices for Treatment of Amblyopia-OH MCD-MM-1841	11/01/2026
Policy Type	
MEDICAL	

Medical Policy Statements are developed from a review of the available evidence-based, clinical information based on and supported by clinical guidelines from medical specialties, peer-reviewed medical and scientific studies, nationally recognized utilization and technology assessment guidelines, and other medical management industry standards to aid in determining the medical necessity of a service. Medically necessary services are defined in the plan-specific Evidence of Coverage, Member Handbooks, Provider Manuals, Medical Policy Statements, and/or other plan policies and procedures.

Medical Policy Statements do not guarantee an authorization or payment of services. Please refer to the plan contract (e.g., Evidence of Coverage, Member Handbook) for the service(s) referenced in the Medical Policy Statement. Except as otherwise required by law, if there is a conflict between the Medical Policy Statement and the plan contract and/or provider agreement, then the plan contract and/or provider agreement will be the controlling document. Reasonable discretion may be used in interpreting and applying this Policy Statement to services provided in a particular case, and the policy may be modified at any time. Medical Policy Statements may be superseded by federal and state laws and regulations, as applicable. In the case of a discrepancy between the Policy Statement's effective date and any applicable legal or regulatory requirement, the law or regulation will govern.

Coverage for mental health and substance use disorder (MH/SUD) benefits are provided at the same level as coverage for medical and surgical (M/S) benefits, as required by the Mental Health Parity and Addiction Equity Act (MHPAEA). MH/SUD benefits are not subject to limits or requirements that are more restrictive than those that apply to M/S benefits.

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A. Subject

Digital Therapy Devices for Treatment of Amblyopia

B. Background

Amblyopia (often referred to as "lazy eye") is a neurodevelopmental disorder characterized by diminished visual acuity, usually in 1 eye, that is caused by inadequate visual processing in early childhood. When vision in 1 eye is abnormal, the brain will suppress signals from the weaker eye and rely on information from the stronger eye instead. Amblyopia is defined by the American Academy of Ophthalmology (AAO) as an interocular difference of ≥ 2 lines in acuity or acuity ≤ 20/30 with the best optical correction.

According to the AAO Preferred Practice Pattern® guidelines Amblyopia (2024), most children who have moderate amblyopia (20/40 to 20/80) respond to initial treatment consisting of 2 hours of daily patching or weekend atropine. The AAO Preferred Practice Pattern® guidelines (2024) state: “Refractive correction with eyeglasses is recommended as the initial step in care of children 0-17 years of age.” Additionally, occlusion of the non-amblyopic eye with eye patching or pharmacological treatment with blurring atropine eye drops are each recommended in the guideline as “an appropriate choice for amblyopia treatment in children who do not improve with refractive correction alone or who have incomplete resolution of their visual acuity deficit” (2024).

More recently, digital therapy devices have been developed to treat amblyopia in children with no strabismus or small angle strabismus with some binocularity using therapeutic dichoptic (binocular) visual stimuli. Images are presented using noninvasive, computerized systems such as virtual reality headsets or 3-dimensional glasses; typically, high-contrast images are presented to the amblyopic eye and low-contrast images are presented to the fellow eye. This is a proposed way to help the eyes work together.

According to the AAO (2024), “Although data from early nonrandomized studies were promising, results from three randomized trials of early software applications failed to demonstrate that game play prescribed 1 hour per day was as good as patching prescribed 2 hours per day or better than placebo game play.” Digital therapy research is ongoing and will be used to delineate use of binocular therapy for treatment of amblyopia.

C. Definitions

- **Amblyopia** – A developmental disorder of the central nervous system that results from the abnormal processing of visual images, leading to reduced visual acuity (VA) in one or both eyes due to abnormal vision development in infancy and childhood**.**
- **Convergence Insufficiency** – Inability to maintain binocular function (keeping the two eyes working together) while working at a near distance. Typically, one eye will turn outward (intermittent exotropia) when focusing on a word or object at near distance.

- **Occlusion Therapy** – Also called “patching,” is the mainstay of amblyopia treatment. Patching the unaffected, or good eye, provides monocular stimulation to the amblyopic eye, promoting visual development. Occlusion therapy is prescribed to improve vision and, as a rule, does not eliminate strabismus.
- **Orthoptic Vision Therapy** – Eye exercises usually weekly over many months done in the optometrist office.
- **Pharmacologic Penalization Therapy** – Therapy using eye drops, typically atropine, to blur the vision in the better-seeing eye, thus encouraging the use of the weaker, amblyopic eye.
- **Prescription Digital Therapeutics (PDTs)** – Software-based therapeutic interventions for the prevention, management, or treatment of medical illnesses or diseases that have been evaluated for safety and efficacy. PDTs are authorized by the US Food and Drug Administration to treat diseases through an approved label and are differentiated from other digital health technologies (such as traditional health and wellness apps).
- **Strabismus** – Misalignment of the eyes. Strabismus is commonly described by the direction of the eye misalignment such as esotropia, exotropia, and hypertropia.

D. Policy

I. CareSource considers the following services medically necessary:
   A. occlusion therapy or pharmacologic penalization therapy for treating amblyopia
   B. orthoptic therapy or vision therapy for treating convergence insufficiency
   C. prism adaptation therapy for treating esotropia

II. According to Centers for Medicare & Medicaid Services: “Early and Periodic Screening, Diagnostic and Treatment services (EPSDT) does not require coverage of treatments, services, or items that are experimental or investigational.” However, requested treatments for children will be reviewed individually to determine the best course of treatment.

III. Unproven and Not Medically Necessary
   A. orthotic vision therapy for treating other conditions not listed above are considered unproven and not medically necessary
   B. prescription digital therapeutics for amblyopia

E. Conditions of Coverage

NA

F. Related Policies/Rules

Experimental or Investigational Item or Service

G. Review/Revision History

	DATE	ACTION
Date Issued	07/30/2025	New policy. Approved at Committee.
Date Revised	07/29/2026	Review: revised background, updated references. Approved at Committee.
Date Effective	11/01/2026	
Date Archived		

H. References

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Approved by ODM on 08/12/2026