



MEDICAL POLICY STATEMENT

Ohio Medicaid

Policy Name & Number	Date Effective
Digital Therapy Devices for Treatment of Amblyopia-OH MCD-MM-1841	12/01/2025
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination. According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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A. Subject

Digital Therapy Devices for Treatment of Amblyopia

B. Background

Amblyopia (ie, "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 $\leq 20/30$ with the best optical correction.

According to the American Academy of Ophthalmology 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 AAOS 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 American Academy of Ophthalmology (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." Research with this technology is ongoing, which will be used to delineate use of binocular therapy for treatment of amblyopia. Another randomized prospective clinical trial studied a digital therapeutic using a desk-based computer platform, red-blue anaglyph glasses and an eye tracker found at 16 weeks the therapeutic (2.8 lines of improvement to be non-inferior to patching 2 hours per day).

C. Definitions

- **Amblyopia** – Also known as "lazy eye," is 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 (traditional health and wellness apps) by the following unique characteristics (Digital Therapeutics Alliance, 2021).
 - **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

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.

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		
Date Effective	12/01/2025	
Date Archived		

H. References

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Approved by ODM on 09/02/2025