Prescription Digital Therapeutics for Amblyopia

Clinical Policy ID: CCP.1556

Recent review date: 5/2026

Next review date: 9/2027

Policy contains: Amblyopia; binocular; CureSight; dichoptic; Luminopia; prescription digital therapeutic.

First Choice Next has developed clinical policies to assist with making coverage determinations. First Choice Next's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered, on a case by case basis, by First Choice Next when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. First Choice Next's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. First Choice Next's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, First Choice Next will update its clinical policies as necessary. First Choice Next's clinical policies are not guarantees of payment.

Coverage policy

The following prescription digital therapeutics for amblyopia (dichoptic binocular treatment) are investigational/not clinically proven and, therefore, not medically necessary:

- CureSight™ CS100 (NovaSight Ltd., Walnut, California)
- Luminopia® (Luminopia, Inc., Cambridge, Massachusetts)

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Refractive correction
- Occlusion (e.g., monocular patching or pharmacologic cycloplegic treatment)

- Bangerter filters
- Oculomotor exercises
- Polarized glasses
- Surgical repair of the pathology causing visual alterations (e.g., cataract surgery, strabismus repair, or retinal detachment repair)

Background

Amblyopia, commonly known as a “lazy eye,” is a vision disorder characterized by alterations in cortical visual pathway development during early childhood. Amblyopia is the most common cause of decreased vision in a single eye, affecting approximately 2% to 4% of children. Amblyopia creates disruption and eventual breakdown in binocular vision affecting visual acuity, pattern recognition, and low sensitivity to motion and contrast. This condition most often occurs unilaterally but may occur bilaterally, especially in cases involving bilateral cataracts or high refractive error (Blair, 2024).

Causes of amblyopia include media opacities, cataracts, strabismus, or anisometropic refractive errors that can shape asymmetric visual development. Left untreated, amblyopia can lead to permanent vision loss in the affected eye, even if the underlying ocular pathology is later resolved. Initial goals of treatment involve correcting the underlying cause of visual deprivation, refractive correction, and stimulation of the amblyopic eye using monocular patching or blurring (e.g., atropine 1%). Treatment may involve surgical repair of the pathology causing visual alterations (e.g., cataract surgery, strabismus repair, or retinal detachment repair). Non-surgical options include Bangerter Filters, oculomotor exercises, polarized glasses, and binocular dichoptic (reduced contrast) therapy (Blair, 2024).

Binocular dichoptic therapy involves presenting different images to each eye and posing a visual task that can only be completed by combining information from both eyes. The primary objective of this approach is to restore binocular fusion and stereopsis (depth perception and three-dimensional structure), with the expected secondary outcome of improved visual acuity in the amblyopic eye. A dichoptic approach is thought to overcome the limitations of traditional monocular approaches, such as patching, associated with poor patient compliance. Monocular approaches may improve visual acuity but do not prevent residual or recurrent amblyopia, ocular motor problems, fine motor issues, and contrast sensitivity abnormalities in many individuals (Yabanoğlu, 2025).

The U.S. Food and Drug Administration (2026) has issued 510(k) clearance for two Class II digital therapy devices for amblyopia to be commercially marketed in the United States. Dichoptic binocular treatment occurs while the child wears the device to watch any streamed content for a prescribed dosage and duration. As passive approaches, both devices offer long-format versions of popular animated films or television programs presented in a dichoptic format. They are intended for both previously treated and untreated patients to be used as an adjunct to full-time refractive correction in an at-home environment.

CureSight consists of an eye-tracker, red-blue anaglyph glasses, and tablet software. CureSight is indicated for the improvement in visual acuity and stereo acuity in patients ages 4 to less than 9 years with amblyopia associated with anisometropia and/or with mild strabismus. CureSight treatment is prescribed for a minimum of 90 minutes per day, five days a week, for a duration determined by the eye care professional. Eye care providers and the clinical team at the CureSight Monitoring Center receive feedback via a dedicated web portal, including real-time remote compliance monitoring (NovaSight, 2025).

Luminopia and its precursor Luminopia One are software-only, digital therapy designed to be used with commercially available virtual reality headsets compatible with the software application. Luminopia is indicated

for improvement in visual acuity in patients ages 4 to less than 13 years with amblyopia associated with anisometropia and/or with mild strabismus. Treatment is for one hour a day for six days a week (Luminopia, Inc., 2026).

Findings

Guidelines

Current U.S. guidelines stress early recognition and treatment of amblyopia to prevent vision loss. Amblyopia is a treatable condition in children and adolescents but is more responsive to treatment among children younger than 7 years of age. Patching, pharmacologic cycloplegic treatment, optical treatment, and Bangerter Filters are nonsurgical treatment options in children who do not improve with refractive correction alone or who have incomplete resolution of their visual acuity deficit (American Academy of Ophthalmology, 2022; McConaghy, 2019).

The U.S. Preventive Services Task Force (2017) recommends vision screening for all children at least once between 3 and 5 years of age to detect the presence of amblyopia or its risk factors. Current evidence is insufficient to assess the balance of benefits and harms of vision screening in children younger than 3 years. The American Academy of Family Physicians recommends referral to a pediatric ophthalmologist for children 3 to 5 years of age with visual acuity less than 20/40 in either eye, or children 5 years and older with visual acuity less than 20/32 in either eye (McConaghy, 2019). There is consensus on the need to quantify significant refractive error in the presence of visual conditions such as amblyopia using cycloplegic retinoscopy for the first evaluation in preschool and school-age children (American Optometric Association, 2017).

The American Academy of Ophthalmology (2022) issued a discretionary recommendation for using binocular dichoptic digital therapy based on limited evidence from randomized controlled trials that failed to confirm the potential benefit to improve visual acuity found in earlier nonrandomized studies. The American Academy of Ophthalmology (2025) issued general recommendations for the treatment of pediatric amblyopia without mentioning any specific therapy. Choice of treatment should take into account the patient's age; visual acuity; adherence and response to previous treatment; and physical, social, and psychological status.

Evidence review

Systematic reviews and meta-analyses place binocular dichoptic treatment in the context of other nonsurgical treatments for amblyopia. Treatment outcomes were defined as changes in best-corrected visual acuity and stereopsis from baseline and treatment adherence. While binocular dichoptic therapies such as Luminopia or CureSight show preliminary improvements in efficacy and adherence, they do not consistently surpass conventional methods, particularly in older children (Chen, 2025; Martinez-Perez, 2026; Tan, 2026).

Variability in treatment effects may be due to differences in study design, patients, and treatment methods. Dichoptic interventions encompass a spectrum of devices and stimuli that differ in their mechanisms of binocular separation and visual stimulation. Pooled results of multiple dichoptic therapies from these studies should be interpreted with caution. The nature and age-appropriateness of the intervention play key roles in treatment adherence. Lack of long-term outcomes and inconsistent adherence continue to limit their clinical use as an adjunct or alternative for those who may not tolerate patching well.

The best evidence supporting the treatment efficacy of Luminopia and CureSight consists of two randomized controlled trials enrolling children with unilateral amblyopia associated with strabismus, anisometropia, or both combined. One trial compared continuous refraction correction (spectacles) without (n = 54) and with Luminopia One (n = 51) in children ages 4 to 7 years. The majority (79%) had undergone prior treatment beyond refractive correction, including patching, but no treatment exceeded one year. Luminopia One was prescribed for one hour

per day, six days per week. At 12 weeks, the Luminopia One group improved mean best-corrected visual acuity by 1.8 lines (0.18 logarithm of the Minimum Angle of Resolution, 95% confidence interval 1.4 to 2.3) compared to 0.8 lines (0.08 logarithm of the Minimum Angle of Resolution, 95% confidence interval 0.4 to 1.3) in the spectacles-only group (difference: 1.0 line; *P* = .0011). There was no significant difference in stereopsis improvement between groups. Median adherence to the prescribed regimen was high (88.2%). No serious adverse events were reported, but 19.6% in the Luminopia One group and 13.0% in the spectacles group experienced nonserious adverse events, the most common being worsening visual acuity in either eye, headaches, and new heterotropias (Xiao, 2022).

The other randomized controlled trial compared CureSight (n = 75) to patching (n = 74) in children ages 4 to less than 9 years. CureSight was applied for 90 minutes per day, five days per week. Patching was applied for two hours per day, seven days per week. At week 16, the mean improvement in amblyopic eye visual acuity from baseline in the CureSight group was noninferior to the patching group (0.034 logarithm of the Minimum Angle of Resolution, 95% confidence interval -0.009 to 0.076). These results were not affected by age group, the type of amblyopia, previous amblyopia treatment, or baseline visual acuity levels. There were no significant differences in stereopsis outcomes between groups. Median treatment adherence was significantly higher in the CureSight group than in the patching group (94.0% vs. 83.9%; *P* = .0038) (Wygnanski-Jaffe, 2023, 2025). Gains in visual acuity and stereopsis from baseline were maintained at 12 weeks (n = 38) and one year (n = 27) following CureSight treatment, although amblyopia recurred in 5.3% of participants at 12 weeks post-treatment and in 20.4% at one year post-treatment (Wygnanski-Jaffe, 2024).

Tan's network meta-analysis determined the relative effectiveness of binocular and dichoptic digital interventions for amblyopia based on the change in logarithm of the Minimum Angle of Resolution best-corrected visual acuity. The authors examined randomized controlled trials of 18 nonsurgical treatment regimens. Compared to spectacle use, combined full-time patching plus video games ranked as the most effective intervention (mean = 0.27, 95% confidence interval 0.06 to 0.48), followed by combined atropine with patching therapy as the second-best (mean = 0.25, 95% confidence interval 0.06 to 0.45). Other treatments, including Luminopia and CureSight, showed no statistically significant differences when compared either directly or indirectly to spectacle use (Tan, 2026).

In another systematic review of 66 randomized controlled trials and meta-analysis of 36 trials, atropine and occlusion were equivalent first-line treatments, based on low- to moderate-certainty evidence. Adjunctive and multimodal approaches, including Luminopia and CureSight, may offer modest additional improvement in best-corrected visual acuity and adherence in some patients when adherence, tolerability, and engagement are prioritized. The authors observed no consistent benefit in stereopsis outcomes to which moderate heterogeneity across studies in study design and populations may have contributed. The authors cautioned that statistically significant effects may not translate into a clinically significant change, where a change of approximately 0.1 logarithm of the Minimum Angle of Resolution (equivalent to one line of visual acuity) is commonly considered the minimum threshold for a clinically meaningful improvement in amblyopia (Martinez-Perez, 2026).

Adherence plays a critical role in achieving optimal visual outcomes in amblyopia. A Cochrane review was unable to draw conclusions about the effect of digital interventions or different approaches to patching on adherence, visual acuity, or stereoacuity, citing low certainty evidence and no outcomes reported beyond three months (Chen, 2025). Asensio-Jurado (2026) identified factors that may influence treatment adherence using home-based digital amblyopia interventions from 27 comparative studies. Treatment adherence was higher among movie-based interventions than video games (pooled adherence rate 85.1% versus 68.0%, *P* = .038). This difference could be explained in part by lower median age of participants (*P* = .023) and shorter treatment duration (*P* = .005). Higher adherence was associated with greater improvement in visual acuity (*P* < .001) but not in stereopsis (*P* = .095).

References

On 4/10/2026, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were: “amblyopia/therapy” (MeSH), “amblyopia,” “dichoptic,” “binocular,” “Luminopia,” and “CureSight.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

Initial review date: 5/2026 and clinical policy effective date: 6/2026

Related codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1556. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

Code	Code description
A9292	Prescription digital visual therapy, software-only, FDA cleared, per course of treatment
0704T	Remote treatment of amblyopia using an eye tracking device; device supply with initial set-up and patient education on use of equipment
0705T	Remote treatment of amblyopia using an eye tracking device; surveillance center technical support including data transmission with analysis, with a minimum of 18 training hours, each 30 days
0706T	Remote treatment of amblyopia using an eye tracking device; interpretation and report by physician or other qualified health care professional, per calendar month