Clinical UM Guideline

Subject:	Dichoptic Digital Therapy for Amblyopia		
Guideline #:	CG-MED-102	**Publish Date:**	04/16/2025
Status:	New	**Last Review Date:**	02/20/2025

Description

This document addresses dichoptic digital treatment devices for amblyopia. These devices incorporate dichoptic (viewing a separate and independent field through each eye) presentations to improve visual acuity (VA) of individuals with amblyopia.

Clinical Indications

Medically Necessary:

Initial Use

An initial 12-month trial of dichoptic digital therapy is considered **medically necessary** when the following criteria are met:

1. Individual is age 4 through 9 years (at least 4 years 0 days and less than 10 years old); **and**
2. The individual has anisometropic, small-angle (10 prism diopters or less) strabismic amblyopia or mixed-mechanism amblyopia; **and**
3. There is failure to respond to a 6-month trial of patching or atropine (or contraindication/allergy/intolerance to atropine); **and**
4. The individual has passed a dedicated 10 minute in-clinic performance ability test to assure suitable eye tracking performance (validity of eye tracking data > 90% and successful calibration process); **and**
5. Myopia, if present, is not greater than -6.00 D. spherical equivalent in either eye; **and**
6. There is no history of light induced seizures; **and**
7. There are no conditions documented that prevent the individual from completing a continuous 45-90 minutes of treatment per day while sitting in front of a near screen; such as children who don't like or cannot watch TV or movies for more than 60 minutes every day according to the parent's report.

Continued Use

Each additional 12-month interval of dichoptic digital therapy is considered **medically necessary** when:

1. The clinical records document adherence to therapy; **and**
2. The amblyopic visual acuity demonstrates continued improvement (note: when amblyopic visual acuity does not improve over two successive measurements at least 3 months apart, this requirement is not met).

Not Medically Necessary:

Dichoptic digital therapy is considered **not medically necessary** when the criteria above are not met.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

0687T	Treatment of amblyopia using an online digital program; device supply, educational set-up, and initial session [e.g., RevitalVision]
0688T	Treatment of amblyopia using an online digital program; assessment of patient performance and program data by physician or other qualified health care professional, with report, per calendar month [e.g., RevitalVision]
0704T	Remote treatment of amblyopia using an eye tracking device; device supply with initial set-up and patient education on use of equipment [e.g., CureSight]
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 [e.g., CureSight]
0706T	Remote treatment of amblyopia using an eye tracking device; interpretation and report by physician or other qualified health care professional, per calendar month [e.g., CureSight]

HCPCS

A9292	Prescription digital visual therapy, software-only, FDA cleared, per course of treatment [e.g., Luminopia]

ICD-10 Diagnosis

H53.001-H53.009	Unspecified amblyopia
H53.021-H53.029	Refractive amblyopia
H53.031-H53.039	Strabismic amblyopia

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met or for all other diagnoses not listed.

Discussion/General Information

Current amblyopia treatment involves re-training the brain to force it to use the weaker eye. This can be accomplished by wearing an eye patch over the stronger eye or the use of eye drops (atropine) in the stronger eye.

Recently developed digital therapy devices have the potential to address issues that may occur with patching or drops. These digital therapy devices use noninvasive, computerized systems such as 3-dimensional glasses or virtual reality headsets. Participants watch videos on a tablet-like device in which eye-tracking technology blurs images in the center of vision for the stronger eye, while the weaker eye sees clear content. This is proposed as a way to help the eyes learn to work together.

Several digital devices have received 510(k) clearance from the United States Food and Drug Administration for treatment of amblyopia including the RevitalVision System (Talshir Medical Technologies LTD, Modi'in, Israel); Luminopia One, (Luminopia, Cambridge, MA); and CureSight (NovaSight, Airport City, Israel).

Wygnanski-Jaffe (2023) published a prospective, multi-center, randomized non-inferiority trial of 103 participants with amblyopia who received either digital therapy (n=51) or eye patch (n=52). Inclusion criteria consisted of children with amblyopia associated with strabismus, anisometropia, or both (untreated or previously treated [prior treatment had to have been discontinued with no treatment for a minimum of 8 weeks prior to screening]), age 4 to less than 9 years of age, VA of 20/32 to 20/100 inclusive in the amblyopic eye, a dominant eye VA 20/40 or better in those aged 4 or 20/32 or better in age 5 or older. Digital therapy (CureSight) consisted of passively watching visual content streamed separately to each eye. The system software blurred central vision in the non-amblyopic eye to encourage use of the amblyopic eye. Those who received the digital therapy used the treatment for 90 minutes per day, 5 days per week for 16 weeks. The eye patch group wore their patch for 2 hours per day, 7 days per week. The primary outcome was mean improvement of VA from baseline at 16 weeks (a non-inferiority of no more than 0.10 logMAR). Assessments were performed at 4, 8, 12, and 16 weeks. The baseline mean amblyopic eye VA in the digital treatment group was 0.37 ± 0.15 logMAR and 0.37 ± 0.14 logMAR in the eye patch group. At 16 weeks, the mean change from baseline was 0.26 logMAR in the digital therapy treatment group and 0.23 logMAR in the eye patch group (standard error 0.02). The authors considered digital therapy to be non-inferior to eye patching. There were no serious adverse events reported.

As a follow-up to the above 2023 Wygnanski-Jaffe study, in 2024, Wygnanski-Jaffe and colleagues (2024b) evaluated long-term outcomes of a binocular eye-tracking home-based treatment for individuals with amblyopia. This observational study followed those in the treatment arm who reached the 16-week end of treatment and did not receive any additional treatment. There were 27 participants tested at the 1-year visit. There was a partial reduction in the amblyopic eye VA gain of 0.06 ± 0.11 logMAR with a residual gain of 0.20 ± 0.14 logMAR compared to baseline. Median improvement in stereoacuity was maintained at 52 weeks post-treatment with no significant change. The mean binocular VA decreased by about 2 chart letters and there was a residual gain of 0.09 ± 0.09 logMAR compared to baseline. At 52 weeks, amblyopia recurrence occurred in 5 participants (20.4%; 95% confidence interval [CI]: 9.6%-40.4%). While improvements were noted at the 1-year follow-up visit, limitations of the study include the observational design and lack of a control group. Also of note is that only a subset (27 of 43) of individuals enrolled in the original study were evaluated, which introduces the potential for bias and reduces the generalizability of the findings.

Increasing the 2023 Wygnanski-Jaffe pooled sample size, in 2024 Wygnanski-Jaffe and colleagues (2024a) reported the results of a prospective, masked, multicenter randomized controlled trial which compared binocular treatment (n=75) to patching (n=74) in the treatment of amblyopia. Participants were randomized in a 1:1 fashion using a permuted block design. Those in the binocular treatment group were assigned to use the CureSight device for 90 minutes per day, 5 days per week for 16 weeks. Those in the patching group were asked to wear an adhesive patch over the fellow eye for 2 hours per day, 7 days per week for 16 weeks. Primary outcome was the mean VA improvement from baseline in the amblyopic eye to week 16. At baseline, in the modified intention-to-treat population, the mean ± standard deviation (SD) amblyopic eye VA was 0.4 ± .16 logMAR in the binocular treatment group and 0.38 ± 0.13 logMAR in the patching group. At 16 weeks, mean ± SD improvement from baseline was 0.27 ± 0.14 logMAR in the binocular treatment group ($p<0001$) and 0.22 ± 0.13 logMAR in the patching group ($p<0001$). The authors conclude the binocular treatment was found to be noninferior to patching following a 16-week trial.

A 2020 single-arm, single center, open-label study by Xiao and colleagues reported the efficacy of Luminopia One for the treatment of amblyopia. Inclusion criteria was diagnosis of unilateral amblyopia associated with strabismus, anisometropia, or both, age 4-7 years old, having sufficient refractive correction at baseline (within 0.75D spherical equivalent of latest cycloplegic refraction) and to have moderate amblyopia, defined as amblyopic eye best corrected visual acuity (BCVA) between 20/40 and 20/200 at baseline. Primary endpoint was the change in amblyopic eye BCVA from baseline to 12 weeks. Of the 10 participants included, 9 of those had prior amblyopia therapy. The 10 participants were prescribed the device to be worn at home for 1 hour per day, 7 days per week, for 12 consecutive weeks. Adherence to treatment was automatically recorded by the device. BCVA was tested at each follow-up visit and improved by 0.29 logMAR from baseline to the 12-week visit. There were 6/10 children who had resolution of their amblyopia with final interocular difference in VA was <0.3 logMAR. The mean adherence was 78%. There were no adverse events reported.

The 2022 Xiao study reported the results of a phase 3 randomized controlled trial in which 105 participants with amblyopia were treated either with a digital therapeutic device (Luminopia One) or wore glasses. The digital devices in this study employed dichoptically transmitted streaming images of popular television shows. Differences in contrast and masking between the eyes required the use of both eyes to fully understand the content. The digital therapy group used their device at home for 1 hour per day, 6 days per week and wore glasses. Those in the comparison group wore refraction-correcting glasses full-time. The primary outcome was the change in VA from baseline to 12 weeks after treatment. There were 51 participants randomized to digital treatment and 54 participants randomized to the comparison group. At 12 weeks following treatment, those in the digital treatment group had improved VA by 1.8 lines while those in the glasses-only group had VA improvement by 0.8 lines. There were no serious adverse events reported. The study was stopped after 12 weeks as a success according to protocol. There were no comparisons with this digital therapy to the current standard treatment for amblyopia such as patching or atropine.

Another randomized clinical trial compared VA changes in participants with amblyopia who were treated with binocular vision video game or spectacle correction. In 2022 Manny and colleagues reported on children aged 4 to

6 years who received 8 weeks treatment with either a video game (n=92) or spectacle correction (n=90). Before the study, those who wore spectacles were required to have had a minimum of 16 weeks of wear. Primary outcome was change in VA from baseline to 4 weeks and to 8 weeks. Participants in the spectacle group were prescribed to wear them during all waking hours. Those in the video game group were prescribed play for 1 hour per day, 5 days per week. At the 4-week visit, there were 85 participants (92%) in the video game group and 84 participants (93%) in the spectacle group available for analysis. Parents reported adherence of greater than 75% for 74 spectacle group participants (95%) and 66 (78%) video game participants. At 8 weeks, 75% adherence was reported for78 (95%) in the spectacle-wearing group and 69 participants (78%) in the video game group. At 4 weeks, mean VA improved 1.1 logMAR lines in the video game group and 0.6 logMAR lines in the group who wore spectacles. At 8 weeks, the mean VA improvement for the video game group was 1.3 and 1.0 in the spectacle group.

In a 2022 randomized trial, Jost and colleagues compared the results of treatment using dichoptic movies versus patching as a treatment for amblyopia. There were 65 participants randomized to either binocular treatment (consisting of three movies per week) or patching for 14 hours per week. Primary outcome was change in BCVA after 2 weeks. At the 2-week visit, BCVA had improved in the movie group (0.07 ± 0.02 logMAR; $p<0.001$) and patching group (0.06 ± 0.01 logMAR; $p<0.001$). For the first 2 weeks, the participants randomized to the movie group watched 5.7 ± 0.7 movies (approximately 8.6 h; 95% adherence) and those in the patching group averaged 30.0 ± 11.0 h of patching (107% adherence).

A 2016 randomized trial by Holmes and colleagues studied whether treatment of amblyopia using a binocular video game was noninferior than treatment with eye patching. The primary outcome measure was the change in VA from baseline to 16 weeks. The eye patch group (n=195) was prescribed to wear the patch 2 hours per day, 7 days per week. The binocular video game group (n=190) was prescribed play for 1 hour per day, 7 days per week. Compliance was measured by parental recording of the number of hours the participant played the game or wore the patch. The video game device recorded the duration of game play, contrast, and performance. There were 172 participants (92.5%) in the eye patch group who completed more than 75% of the prescribed treatments in the 16-week treatment period. In the video game group, there were 176 participants (66.7%) available for evaluation at the 16-week visit from the video game group. Only 39 participants of these 176 participants (22.2%) completed more than 75% of their prescribed treatments, as measured by the video game log file data. The mean amblyopic VA improved from 1.08 lines at baseline in the video game group and by 1.32 lines in the eye patch group. There were no significant between-group differences found for changes in amblyopic eye VA.

A 2018 randomized clinical trial by Manh and colleagues compared improvement of VA in participants with amblyopia following either treatment with binocular video game play or wearing an eye patch. Participants were 13-16 years old and were followed for 16 weeks after treatment. Those in the binocular video game group (n=40) were prescribed 1 hour of game play each day for 7 days each week. Those in the eye patch group (n=60) were prescribed to wear the patch 2 hours per day. Parents or participants recorded the number of hours of treatment each day. The video game device also recorded the duration of game play. There were 39 participants (98%) in the video game group and 58 participants (97%) in the eye patch group who completed the 16 weeks of treatment. Adherence after 16 weeks was assessed to be adequate in 24 video game participants (62%) and 42 eye patch participants (75%). However, in the video game group, the game device recorded only 13% of participants who completed 75%

of their prescribed treatments. At 16 weeks, mean VA in the amblyopic eye improved by 3.7 letters at baseline and by 6.3 letters in the eye patch group. While a major limitation of this study is poor treatment adherence, the authors reported more improvement in VA in the eye patch group compared to the binocular vision treatment group.

In 2023, Zhao and colleagues reported results of a randomized trial in which 48 participants with anisometropic amblyopia received either patching and digital therapy (n=25) or only patching of the contralateral eye. Participants were followed for 3 months. For compliance, those in the control group showed 14 participants (60.87%) completed the required near visual activities training on a daily basis. In the digital therapy group, 21/25 participants (84%) were found to complete the digital amblyopia training twice per day. The remaining 4 participants completed training once per day. For corrected distance VA, there was no statistically significant difference in the main effect of group (control vs. digital therapy) ($F(1,46)=0.71$, $p=0.40$).

In a 2024 systematic review by Tsani and colleagues, the authors reported on 20 randomized controlled trials which evaluated the use of binocular digital therapy compared to standard treatments or placebo. Primary outcome was BCVA. There were 12 different types of binocular treatments used to treat amblyopia. The treatment which involves presentation of low-contrast images in the fellow eye included the falling blocks game, dig rush game, Tetris game, the Chinese game, i-Bit system games, Virtual Reality One, Barron Vision software, Diplopia Game, and dichoptic action video game. The treatment with complementary dichoptic deficits in the images presented to both eyes to encourage simultaneous use included the CureSight, Luminopia, and Matlab software systems. There were 6 different types of binocular therapy which showed improvement of the amblyotic eye with noninferiority to occlusion therapy. However, only 1 study included treatment-naïve participants. There was a lack of long-term outcomes with the studies. The authors concluded that further randomized controlled trials are necessary to establish the specific type and duration of binocular therapy.

A 2024 American Academy of Ophthalmology® (AAO) Preferred Practice Pattern for amblyopia states:

> Binocular (Dichoptic) Digital Therapy
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> Binocular therapy has been used to treat amblyopia in children with no strabismus or small angle strabismus with some binocularity. Images are presented dichoptically; typically, high-contrast images are presented to the amblyopic eye and low-contrast images are presented to the fellow eye. Binocular treatment has been adapted to tablet devices and early versions used a “falling blocks” game, with red-green anaglyphic eyeglasses to allow dichoptic presentation. Although data from early nonrandomized studies were promising,[201-204] 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.[205, 206, 209]
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> A randomized trial of second generation programming comparing binocular therapy with continued glasses alone in 7- to 12-year-olds found no benefit.[210] However, a parallel trial in children 4 to 6 years of age found clinically important improvement at 4 weeks, although the benefit was not sustained at 8 weeks.[211]

> Software and hardware development has continued and has been associated with improved outcomes. A randomized clinical trial of a digital dichoptic treatment using virtual reality headsets to deliver reduced contrast images to the nonamblyopic eye with masking of portions of the image visible to each eye, while viewing web-based content, found at 12 weeks that the mean amblyopic eye VA improved by 1.8 lines in the treatment group compared with 0.8 lines in the continued glasses group (P = 0.0011).[212] A randomized trial of movie viewing on a hand-held device using contrast reduction and complementary areas of image masking found improvement similar to that achieved with 2 hours of patching after 2 weeks of treatment.[213] Research with this technology is ongoing, which will be used to delineate use of binocular therapy for treatment of amblyopia.[208] 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 (2.3 lines of improvement).* (*I +, Good, Discretionary*).

The AAO Preferred Practice Pattern further indicates that "Suitable treatment options for amblyopia include optical correction, patching, pharmacological treatment, optical treatment, Bangerter (translucent) filters, and digital therapeutics, in addition to managing the underlying cause of amblyopia."

Based on the available evidence and solicited input from relevant practitioners, there is credible scientific evidence that dichoptic digital treatment improves net health outcomes in selected individuals with amblyopia. However, the evidence directly comparing this therapy to existing established alternatives remains limited. The Holmes, 2016 and Manh, 2018 studies did not find digital therapy to be more effective than patching. The Jost 2022 and Wygnanski-Jaffe 2023 studies report binocular treatment is noninferior to patching. Thus, dichoptic digital treatment should be reserved for those individuals who do not obtain adequate improvement from established recommended therapies such as patching or atropine.

According to the AAO, 2019

> Amblyopia is clinically defined as reduction of visual acuity in one or both eyes, caused by abnormal binocular interaction during the critical period of visual development, that cannot be attributed to any ocular or visual system abnormality or to refractive error. The American Academy of Ophthalmology considers amblyopia an interocular difference of 2 lines or more in a visual acuity table (without specifying any), or visual acuity worse than or equal to 20/30 with the best optical correction.

Causes of amblyopia include unequal refractive errors between the eyes (refractive amblyopia), obstructed vision (such as from a cataract) that is worse in one eye (obstructive amblyopia), or misalignment of the eyes (strabismic amblyopia). Over time, the brain relies more on the stronger eye while vision in the weaker eye gets worse. The difference between amblyopia and simple refractive error, visual obstruction, or strabismus is that, in amblyopia, the visual cortex is suppressing the images received from one or both eyes.

Amblyopia usually occurs in one eye and affects approximately 3% of the population. It is the most common cause of vision loss in children. Early treatment therapy is over 90% effective and prevents long-term vision problems.

Treatment of amblyopia begins with correction of visual refraction, obstruction, or misalignment. This is combined with treatments that encourage use of the amblyopic eye. The most commonly used methods for this are to occlude the better-seeing eye, such as with periodic patching, or by blurring vision in the better-seeing eye, such as with atropine drops. Better results are seen when therapy is started as soon as possible after diagnosing amblyopia. Treatment is continued until VA is normal or is no longer improving on multiple observations taken several months apart.

Definitions

Amblyopia: Amblyopia is clinically defined as reduction of visual acuity in one or both eyes, caused by abnormal binocular interaction during the critical period of visual development, that cannot be attributed to any ocular or visual system abnormality or to refractive error.

Dichoptic training: Training that uses simultaneous and separate stimulation of both eyes to encourage use of the non-dominant eye.

logMAR: An abbreviation for the Logarithm of the Minimum Angle of Resolution, which is measurement of visual acuity obtained by asking an individual to read a chart made up of letters of decreasing size. It is considered to be more reliable and precise than the Snellen chart for measurement of visual acuity. In the logMAR, visual acuity is reported as a single number where 0.0 is standard vision. Visual acuity decreases as the number increases and improves as the number decreases.

Mixed-mechanism amblyopia: A type of amblyopia that occurs when both strabismus (misalignment of the eyes) and anisometropia (a condition where the two eyes have significantly different refractive powers) are present.

Strabismic amblyopia: Also known as "lazy eye". A condition where one eye develops significantly poorer vision than the other due to a misalignment of the eyes (strabismus)

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CureSight
Luminopia
RevitalVision
Vivid Vision

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
New	02/20/2025	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development. Moved content of MED.00145 Digital Therapy Devices for Treatment of Amblyopia to new clinical utilization management guideline document with revised title.