

Medical Policy

Subject:	Digital Therapy Devices for Treatment of Amblyopia	Publish Date:	06/28/2024
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Description/Scope

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

Position Statement

Investigational and Not Medically Necessary:

Digital therapy devices for treatment of amblyopia are considered **investigational and not medically necessary**.

Rationale

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 in the stronger eye.

Recently developed digital therapy devices have the potential to address compliance 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.

A 2015 study by Li and colleagues reported on eight individuals with amblyopia who participated in binocular game play and no patching compared to ten individuals with amblyopia who also participated in binocular game play who did have patching after outcome. For those without patching, the mean baseline BCVA improved from 0.30 logMAR to 0.15 logMAR after 4 to 8 weeks of binocular game play. For those who received patching, the mean baseline BCVA improved from 0.43 logMAR to 0.29 logMAR after 4 to 12 weeks of binocular game play.

In 2015, Birch and colleagues reported on whether binocular visual experience with dichoptic games could effectively treat amblyopia in preschool children. There were 50 children enrolled in the study, 5 assigned to sham games and 45 assigned to binocular games. In the binocular games group, 30 children also were treated with patching at various times of the day. In the sham group, 4 children were treated with patching. After 4 weeks, those

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in the binocular group had improvement of mean visual acuity from 43 ± 0.03 logMAR (20/54 Snellen equivalent) at baseline to 0.34 ± 0.03 (20/44 Snellen equivalent). For those in the sham group, visual acuity was 0.40 ± 0.05 logMAR (20/50 Snellen equivalent) at baseline and 0.38 ± 0.06 (20/48 Snellen equivalent) at 4 weeks.

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 visual acuity (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. Limitations include lack of occlusion dose monitors, adherence data reliance on parental report (particularly for eye patch wearing), low adherence among the video game participants, and lack of monitoring of wearing the red-green glasses required to play the video game.

A Cochrane Intervention Review of binocular treatments compared to standard treatments for amblyopia cited the Holmes study described above as the only randomized controlled trial eligible for their analysis (Tailor, 2022). The authors concluded with moderate certainty that 16 weeks of this binocular treatment improved vision comparably to patching. They noted that,

due to the limited sample size and lack of long term (52 week) follow- up data, it is not yet possible to draw robust conclusions regarding the overall safety and sustained effectiveness of binocular treatment... Further research, using acknowledged methods of visual acuity and stereoacuity assessment with known reproducibility, is required to inform decisions about the implementation of binocular treatments for amblyopia in clinical practice, and should incorporate longer term follow-up to establish the effectiveness of binocular treatment.

In a 2018 randomized, double-masked trial by Gao and colleagues, the authors evaluated efficacy of a home-based digital therapy video game compared to a placebo video game to improve visual function. The study included children age 7 years and older and adults. Participants were prescribed video game play for a minimum of 1 hour per day for 6 weeks. The primary outcome was the change in VA from baseline to 6 weeks. Treatment compliance was recorded by the video game software as well as a written diary completed by study participants. There were 56 participants randomized to the active group and 59 participants who participated in a placebo video game. At the 6 week follow-up, there were 50 participants available in the active group and 57 participants in the placebo group. In the active group, there were 36 participants (64%) who met the study definition of compliance compared to 49 (83%) in the placebo group. At 6 weeks, the mean improvement of VA from baseline was 0.06 logMAR (3 letters)

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in the active group and 0.07 logMAR (3.5 letters) in the placebo group. No significant differences were found between the two groups.

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.

Birch and colleagues (2019) reported on use of binocular treatment for 27 amblyopic children with contrast-rebalanced dichoptic movies over a 2 week period. BCVA improved from 0.57 ± 0.22 at baseline to 0.42 ± 0.23 logMAR.

In a 2019 study by the Pediatric Eye Disease Investigator Group, the authors compared visual acuity for those with amblyopia treated with a binocular game plus continued spectacle correction versus spectacle correction alone. In this randomized controlled trial, participants were randomly assigned to an 8 week treatment with a dichoptic binocular game for 1 hour per day for 5 days and spectacle use if needed (n=69) or continued spectacle correction alone (n=69). At 4 weeks, after adjusting for baseline VA, mean amblyopic-eye VA letter score improved from baseline by 1.3 (95% CI: 0.1 to 2.6; equivalent to 0.026 logMAR) in the binocular treatment group and 1.7 (95% CI: 0.4 to 3.0; equivalent to 0.034 logMAR) in the spectacle only group. At 8 weeks, mean amblyopic-eye visual acuity letter score in the binocular group improvement was (2.3, 98.3% CI: 0.7 to 3.9) compared with the control group (2.4, 98.3% CI: 0.8 to 4.0).

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; $p < .001$) 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).

In a 2022 prospective, multi-center, randomized non-inferiority trial by Wygnanski-Jaffe, 103 participants with amblyopia received either digital therapy (n=51) or eye patch (n=52). Digital therapy consisted of passively watching visual content streamed separately to each eye. The system software blurred central vision in the non-

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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 visual acuity 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. While improvement was noted in the digital therapy treatment group, further studies are necessary to explore longer treatment durations and effects for those treated with digital therapy.

As a follow-up to the above 2022 Wagnanski-Jaffe study, in 2024, Wagnanski-Jaffe and colleagues 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 didn't 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% 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 which introduces the potential for bias and reduces the generalizability of the findings.

In 2022, Xiao and colleagues reported the results of a phase 3 randomized controlled trial in which 105 participants with amblyopia were treated either with a digital therapeutic device 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 visual acuity by 1.8 lines while those in the glasses-only group had visual acuity 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. This study did not compare this digital therapy with eye patching, the current standard treatment for amblyopia. Further studies are needed to understand how this treatment compares to patching and to determine the treatment's long-term effects.

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

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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 for 78 (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. Additional study is needed to compare this treatment to eye patching and to understand the long-term effectiveness of this treatment.

A 2022 retrospective review by Abdal and colleagues reported on 161 participants with refractive amblyopia who received digital treatment. Digital treatment was provided by dichoptic training in a game format. Participants wore goggles that presented scenes most visible to the dominant eye. A crucial stimulus for game play was only presented to the non-dominant eye. Participants used the therapy 30 minutes per day, 5 times a week, for 6 weeks. The primary outcome was the mean change in best-corrected visual acuity after 6 weeks of treatment. Following treatment, best-corrected visual acuity in the non-dominant eye mean change was 0.39 logMAR. Best-corrected visual acuity in the dominant eye had a mean change of 0.08 logMAR following treatment. Limitations include lack of control or comparison group and a 6 week treatment period. Further study is needed to validate these results.

A 2024 American Academy of Ophthalmology (AAO) Preferred Practice Pattern for amblyopia states:
Binocular (Dichoptic) Digital Therapy

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}

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

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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.”

While the AAO has included digital therapeutics as a suitable option for amblyopia treatment, additional credible scientific evidence in the form of randomized controlled trials with long-term follow-up are needed to draw reasonable conclusions concerning the effect of digital therapy on net health outcomes for individuals with amblyopia. These trials should compare digital therapeutics to established alternatives such as eye patching, pharmacological treatment, optical treatment, and Bangerter (translucent) filters to demonstrate that long-term results and recurrence rates after cessation are as beneficial when used in clinical practice outside of investigational settings.

Background/Overview

Amblyopia occurs when there is abnormal development of the visual system in early life. Normal development of the visual cortex requires interpretation of clearly focused images from both eyes. When a developing child's two eyes do not transmit the same image to the brain, the brain will suppress the image from one eye to prevent diplopia or unclear perception. Causes 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. Amblyopia typically affects one eye but can also be a bilateral condition. 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.

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Treatment is continued until visual acuity is normal or is no longer improving on multiple observations taken several months apart.

Holmes and colleagues (2004) in the Pediatric Eye Disease Investigator Group (PEDIG) reported on the risk of amblyopia recurrence one year after cessation of amblyopia treatment. Out of 145 children whose vision had improved at least 3 logMAR levels during 3 months of patching or atropine drops, 35 (24%) had a recurrence of amblyopia at their 1-year follow up. Recurrence rates were similar for the patching and atropine groups. Recurrence was more common among children who had been treated with moderately intense patching (6-8 hours per day) and whose treatment was abruptly stopped (11 of 26 children, 42%). The recurrence rate was lower for children whose moderately intense patching was reduced to 1-2 hours per day prior to stopping therapy (3 of 22 children, 14%).

In 2014, Repka and others in the PEDIG reported long-term outcomes of a randomized clinical trial that compared amblyopia treatment with patching to treatment with atropine drops. The trial was started in 1999. It included 419 children under the age of 7 with moderate amblyopia (20/40 to 20/100) due to strabismus, anisometropia, or both. Participants were randomly assigned to patching or to atropine drops. Patching was worn every day for durations between 6 hours and full-time. Atropine treatments were instilled every day. Both study groups received their assigned treatment for at least 6 months and for up to 2 years at the treating provider's discretion. A masked outcome assessment was conducted 2 years after randomization. After that time, 188 children continued in a long-term followup study with further evaluations at 10 and 15 years of age. There were 147 participants who remained in the study through their 15-year-old follow up visit. Their average visual acuity in the amblyopic eye was 0.14 logMAR. This roughly equates to 20/25 acuity. Visual acuity was 20/25 or better for 59.9%, and 20/20 or better for 33.3%, of the amblyopic eyes. Vision at age 15 was better for children who began treatment for amblyopia before the age of 5 (mean logMAR 0.009) than for those starting treatment at the age of 5 or 6 (mean logMAR 0.18). There were no significant vision differences between the group who had been treated with patching and the group who had received atropine drops. Selection bias may have influenced this study's results. Children who had better vision improvements after their initial treatment were more likely to return for follow-up when they were 15.

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).

Definitions

Amblyopia: A type of poor vision that develops when there is a breakdown in how the brain and the eye work together, and the brain can't recognize the sight from one eye.

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

logMAR: the Logarithm of the Minimum Angle of Resolution 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

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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.

Coding

The following codes for treatments and procedures applicable to this document 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 are Investigational and Not Medically Necessary:

For the following procedure codes; or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

0687T	Treatment of amblyopia using an online digital program; device supply, educational set-up, and initial session
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
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

HCPCS

A9292	Prescription digital visual therapy, software-only, FDA cleared, per course of treatment
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ICD-10 Diagnosis

All diagnoses

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Medical Policy

Digital Therapy Devices for Treatment of Amblyopia

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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.

Document History

Status	Date	Action
	08/21/2024	Revised Rationale and References sections.
Reviewed	05/09/2024	MPTAC review. Revised Rationale and References sections.
	09/27/2023	Updated Coding section with 10/01/2023 HCPCS changes; added A9292.
Reviewed	05/11/2023	MPTAC review. Updated Rationale, Background/Overview, and References sections.
New	02/16/2023	MPTAC review. Initial document development.

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