Visual Information Processing Evaluation and Orthoptic and Vision Therapy

Policy Number: SRST2026T0072GG
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Instructions for Use

Table of Contents **Page**

Related Policies
None

Coverage Rationale

See Benefit Considerations

Remote, online, and/or digital therapy for Amblyopia is unproven and not medically necessary due to insufficient evidence of efficacy.

Definitions

Amblyopia: Amblyopia is a decreased vision in one or both eyes due to abnormal vision development in infancy and childhood. In the first few years of life, the brain must learn to see or interpret the images provided by the eyes. In Amblyopia, the brain receives a poor image from one eye and thus does not learn to see well. Vision loss occurs in this case because nerve pathways between the brain and the eye are not properly stimulated. Amblyopia is often referred to as lazy eye. [American Association for Pediatric Ophthalmology and Strabismus (AAPOS) 2019]

Vision Therapy: Optometrists define Vision Therapy as an attempt to develop or improve visual skills and abilities; improve visual comfort, ease, and efficiency; and change visual processing or interpretation of visual information. An optometric Vision Therapy program consists of supervised in-office and at home reinforcement exercises performed over weeks to months. In addition to exercises, lenses (“training glasses”), prisms, filters, patches, electronic targets, or balance boards may be used. (AAPOS, 2020)

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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

CPT Code	Description
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

Benefit Considerations

Certain UnitedHealthcare plans exclude benefits for Vision Therapy (orthoptic training). Refer to the member specific benefit plan document for details.

Clinical Evidence

Remote, Online, and/or Digital Therapies or Vision Therapy (VT) for Amblyopia

Only limited quality clinical evidence was found to support the superiority of remote, online, or digital orthoptic or VT for amblyopia over conventional treatments. Existing studies are limited by single-arm design, insufficiently long follow-up for a chronic condition, and a large dropout rate.

Ming et al. (2025) conducted a systematic review and meta-analysis on perceptual learning and video game training for adults with monocular amblyopia to analyze the effectiveness of perceptual learning and video game training. To carry out the review, data on interventions, sample size, and log MAR visual acuity (VA) were extracted and analyzed. The review resulted in the identification of 6439 studies with 22 meeting the inclusion criteria. The analysis showed a statistically significant standardized mean difference (SMD) of -0.68 in the experimental group (EG) compared with controls, indicating an improvement in VA ($p < 0.05$). Subgroup analyses indicated that perceptual learning and video game training also resulted in visual improvement ($p < 0.05$). In addition, the results indicated a significant improvement in VA with dichoptic training or monocular training, reaching VA improvement ($p < 0.05$). The authors concluded that targeted visual training facilities neural plasticity reduces interocular suppression, and reinforces neural pathways associated with visual processing. This review is limited by the limitation of the included studies and the heterogeneity in device used. Future research that focuses on refining training protocols to enhance both monocular and binocular visual function most effectively is necessary.

In 2023, Hayes conducted an evolving evidence review on Luminopia One (Luminopia Inc.) for treating amblyopia in children. The review found minimal support from clinical studies, no/unclear support from systematic reviews, and weak support from guidelines for Luminopia One for treating amblyopia in children aged 4 to 7 years of age. Although Luminopia One may improve VA in children aged 4 to 7 years with amblyopia and be more appealing than patching and atropine which could lead to better treatment adherence, future studies are necessary to compare with the current standards of care, and post treatment VA. Additionally, the technology requires internet access and devices, which may be costly and can lead to possible treatment disparities. This review was updated in 2025 resulting in no newly published studies that may meet the inclusion criteria set out in the 2023 report.

In a 2024 Hayes evolving evidence review on RevitalVision perceptual learning vision training program (Talshir Medical Technologies LTD) for treating amblyopia minimal support was found from clinical studies, no/unclear support of systematic reviews, and no/unclear support from practice guidelines. The review's insights suggest RevitalVision as a treatment option for individuals with amblyopia who have not achieved optimal vision with conventional measures. This software-based training program may interest adults with significant amblyopia, as conventional treatments are usually not effective. The literature reveals no safety concerns. Although findings show consistent improvement in technical measures of vision measures, they do not evaluate impact on social or academic function or quality of life. The available studies are few and are limited by weak study designs, lack of follow-up beyond treatment completion, lack of statistical comparisons with standard care, and/or unknown generalizability to typical amblyopia populations. At this point, additional evidence from ongoing trials is not forthcoming. This Hayes evidence review was updated in 2025. The review of full-text clinical studies suggested minimal support for the technology. No/unclear support was uncovered through systematic reviews and clinical practice guidelines, and position statements.

In an ECRI clinical evidence assessment published in 2024, the CureSight System (NovaSight, Inc.) was explored for treating amblyopia. The publication concluded that CureSight is safe and may work as well as patching to improve VA at up to one-year follow-up for children with amblyopia, based on evidence from two RCTs and one pre-post study. However, the available studies are small, and added studies are necessary to support firm conclusions about how well CureSight works compared with patching. The existing studies report comparative outcomes at only short-term follow-up. Longer-term studies (e.g., ≥ three years) are needed to consider CureSight's permanent benefit and amblyopia recurrence. One ongoing trial is not likely to address evidence gaps due to the small sample size and single-arm design but will provide outcomes for individuals ages two through 20.

Tsani et al. (2024) explored the use of binocular digital therapy for amblyopia when compared to standard treatments or placebo therapy. The review comprised of randomized controlled trials (RCTs), including individuals with unilateral amblyopia who received binocular therapy or standard amblyopia or placebo treatment for more than two weeks and who had VA assessment pre- and post-treatment. The results of this exploration included 20 RCTs with 1769 individuals incorporated into the review. Two main types were identified: presentation of low-contrast images in the fellow eye, including stimuli presented only in the amblyopic eye and the second type combines the approach with complementary dichoptic deficits in the images presented to both eyes to encourage their simultaneous use. The authors concluded that binocular amblyopia treatment has shown promising results in addressing unilateral anisometropic, strabismic or mixed type of amblyopia. Nevertheless, further RCTs are essential to prove the exact dosage, type, and duration of binocular therapy as a standard component of amblyopia care. The following publications, discussed in more detail below, were reviewed as part of this systematic review: Manh et al., 2018; Pang et al. 2021; Roy et al. 2023; Herbison et al. 2016; Elhusseniny et al. 2021; Jost et al. 2022; Wygnanski-Jaffe et al. 2023; Kadhum et al. 2024.

Through an RCT, Kadhum et al. 2024 sought to compare the efficacy and effectiveness of supervised dichoptic action-videogame play to occlusion therapy in children with amblyopia. The trial, conducted after 16 weeks of refractive adaptation, involved participants who were randomized to gaming one hour a week and supervised or electronically monitored occlusion two hours a day. The primary outcome measured was VA change from baseline to 24 weeks. The results of the trial showed a median VA improvement by 0.30 logMAR (IQR 0.20-0.40) after gaming, 0.20 logMAR (0.00-0.30) after occlusion ($p = 0.823$). Treatment effectiveness was 1.25 logMAR/100 h (range 0.42-2.08) with gaming, 0.08 (-0.19-0.68) with occlusion ($p < 0.001$). The authors concluded that dichoptic gaming presents a promising and practical alternative for older children with refractive amblyopia after glasses adaptation. Treatment efficiency with gaming under continuous supervision was 15 times greater than with occlusion at home, offering a hopeful prospect for the future of amblyopia treatment. The findings are, however, limited by the large dropout rate and feasibility of researcher-supervised weekly gaming. (Included in the 2024 systematic review by Tsani et al.)

In 2024, Wygnanski-Jaffe and associates set out to report the long-term outcomes of a noninferiority RCTs with a binocular eye-tracking-based home treatment (CureSight; Novasight, Ltd.) for those with amblyopia through a prospective, multicenter, nonrandomized, long-term follow-up observational study of an RCT. At 12 weeks post-treatment of the intervention group, improvement in amblyopic eye VA was retained vs. baseline (0.27 ±0.14 logMAR, $p < .0001$), with no change vs the end-of-treatment visit ($p > .05$). At one year there was a partial reduction in the amblyopic eye VA gain of 0.085 ±0.1 logMAR related to end-of-treatment ($p = .001$), but the residual gain of 0.20 ±0.14 logMAR compared to baseline was statistically significant ($p < .0001$). Gains in stereoacuity and binocular VA were maintained vs baseline at both 12-weeks and 1-year post-treatment ($p < .0001$), with no change vs end-of-treatment ($p > .05$). Amblyopia recurrence (a worsening of ≥ 2 logMAR levels compared with end-of-treatment) occurred in 2/38 people at 12-weeks post-treatment (5.3%), and in 5/27 people at 1-year post-treatment (20.4%). The authors concluded that VA and stereopsis gains after binocular treatment with CureSight were retained for one year without further treatment. The findings are, however, limited by lack of comparison groups.

In the 2023 prospective, multicenter, randomized, masked, controlled, noninferiority pivotal clinical trial conducted by Wygnanski-Jaffe and colleagues, the authors compared visual outcomes after the use of binocular eye-tracking based home treatment (CureSight; NovaSight Ltd) with patching. Children aged four to less than nine years with anisometropic, small-angle strabismic, or mixed-mechanism amblyopia (n = 103) were randomized 1:1 to a group getting either CureSight or patching treatment. In the CureSight group, the participants utilized the device for 90 minutes/day, five days/week for 16 weeks (120 hours), while the patching group received two hours of patching seven days a week for 224 hours. The primary outcomes measured were the improvement in the amblyopic eye VA, modeled with a repeated measures analysis of covariance, stereo acuity, binocular VA, and treatment adherence rates, which were evaluated by a 1-sample Wilcoxon test in each group and a 2-sample Wilcoxon test that compared the two groups. The safety results were calculated by the frequency and severity of the study-related adverse events (AE). The trial resulted in the CureSight group VA improvement found to be noninferior to the patching group improvement [0.28 ±0.13 logMAR ($p < 0.0001$) and 0.23 ±0.14 logMAR ($p < 0.0001$), respectively; 90% confidence interval (CI) of difference, -0.008 to 0.076]. Stereoacuity improvement of 0.40 log arcseconds ($p < 0.0001$) and improved binocular VA (0.13 logMAR; $p < 0.0001$) were observed

in the binocular treatment group, with similar improvements in the patching group in stereoacuity (0.40 log arcseconds; p < 0.0001) and binocular VA (0.09 logMAR; p < 0.0001), with no significant difference between improvements in the two groups in either stereoacuity (difference, 0; 95% CI, -0.27 to -0.27; p = 0.76) or binocular VA (difference, 0.041; 95% CI, -0.002 to 0.085; p = 0.07). The binocular treatment group had a significantly higher adherence than the patching group (91% vs. 83%; 95% CI, -4.0% to 21%; p = 0.011). No severe AEs were found. The limitations of the study include most individuals having anisometropic amblyopia, lack of generalizability between strabismic and mixed amblyopia populations, and lack of evaluation on the impact of dosing for the rapidity of visual improvement, durability, and effect of subgroups for treatment effectiveness. The authors concluded that the binocular treatment was well tolerated after a 16-week trial period and showed higher regimen adherence rates and parent preferences, though non-inferior to patching for children with amblyopia. Improvements were seen in stereopsis and binocular VA. (Included in the 2024 systematic review by Tsani et al.)

In 2023, Roy et al. performed a prospective, randomized, interventional study to evaluate smartphone-based dichoptic video games versus occlusion therapy for children with anisometropic amblyopia. Children aged 5 to 15 with anisometropic amblyopia were included in the study (n = 55) and randomized into two groups: the video game group (n = 27) and the patching group (n = 28). The video game group played a dichoptic video game with adjusted contrast for two hours a day, and the patching group received occlusion therapy of the non-amblyopic eye for six hours a day. The outcomes measured were the BCVA, near vision, contrast sensitivity (CS), and near and distance stereoacuity at baseline, at one, two, and three months. The study's results showed that the mean distance BCVA improved from 0.74 ±0.19 and 0.70 ±0.18 logMAR in the video game and patching groups, respectively, at baseline to 0.53 ±0.19 and 0.49 ±0.19 logMAR, at three months (p < .001 for both). The mean near vision was 0.82 ±0.19 and 0.81 ±0.17 logMAR in the video game and patching groups, respectively, at baseline and improved to 0.60 ±0.16 and 0.63 ±0.17 logMAR at three months (p < .001 for both). There was no sizable difference in distance and near vision among the two groups at baseline and the last follow-up visit. CS was 1.41 ±0.20 and 1.38 ±0.20 in the video game and patching groups, respectively, at baseline and 1.74 ±0.18 and 1.61 ±0.21 at three months (p < .001 for both). At the final follow-up visit, CS was better in the video game group compared to the patching group (p = .01). Near stereoacuity notably progressed only in the video game group (p = .006); in contrast, distance stereoacuity did not improve in either group. The limitations of the study include the small sample size and lack of long-term follow-up. The authors concluded that dichoptic video game therapy showed better outcomes in terms of improved CS and near stereoacuity and comparable results for distance and near vision compared to patching for children with anisometropic amblyopia. The accessibility of exciting games is necessary to support children's interests. (Included in the 2024 systematic review by Tsani et al.)

In a systematic review and meta-analysis, Shao and colleagues (2023) sought to uncover how VR technology varies from conventional patching therapy's efficacy. The meta-analysis consists of eight studies and ten trials with 459 participants. The results of the review and analysis showed that overall, VR technology treatment considerably improved VA by 0.07 logMAR [95% confidence interval (CI), -0.11 to -0.02; p < 0.001; I2 = 94.4%] versus traditional patching therapy. In addition, subgroup analyses also exposed that treatment with VR technology was more efficient when the child was younger than seven years old or when the intervention was no more than twenty hours. The studies limitations include a high degree of heterogeneity, lack of analysis on the effect of VR technology on stereo acuity, and the meta-analysis only included studies published in English. Furthermore, most included studies were of short duration (2-12 weeks), and it is unclear whether the observed benefit would be sustained after the initial interest of the child. The authors concluded that VR technology treatment substantially improved VA for children seven years of age or younger with amblyopia.

In An RCT by Liang et al. (2023), the authors assessed the effectiveness of binocular vision training (BVT) and Fresnel press-on prism (FPP) for children with esotropia combined with amblyopia. Registered for the trial were children aged 3-9 years with esotropia and amblyopia (n = 101). Two random groups were formed, the combined group (n = 48) and the prism group (n = 53). The children in the prism group received FPP treatment, while those in the combined group received a combination of therapy, BVT, and FPP. The primary outcomes measured were the VA, binocular function, and strabismic therapeutic effects. The results demonstrated a sizable improvement in both groups for VA versus before treatment (p = 0.0079). The binocular-monocular function, plus synoptophore visual function and the Titmus stereopsis, in both groups, was significantly better compared with those before treatment (p < 0.05), and it was more substantial in the combined group versus the prism group (p < 0.05). The cure rate of strabismus was 87.50% (42/48) and 30.19% (16/53) in the combined group and the prism group, respectively, and there was a significant difference between groups (p = 0.0036). The cure time decreased with the lower degree of esotropia. The study is limited by the small sample size. Larger, multi-center, and multi-disciplinary, high-quality research should be performed for further investigation. The authors concluded that BVT combined with FPP can efficiently promote the healing of BVin children with esotropia combined with amblyopia, and some children can attain a complete cure for strabismus.

In a 2023 systematic review and meta-analysis, Yeh et al. investigated the efficacy of the Cambridge Stimulator with grating element stimulation of VA, grating acuity (GA), and CS for individuals with amblyopia. The search uncovered 1221

studies, with 24 of those studies encompassing 900 individuals included in the review. The results of the review suggested that the outcome measure of all visual indexes (VA: Hedges' g of -0.43, 95% CI = -0.81 to -0.05, I2 = 86%, p = 0.02; GA: Hedges' g of 3.79, 95% CI = 1.05 to 6.54, I2 = 98%, p = 0.01; CS: Hedges' g of 0.64, 95% CI = 0.19 to 1.09, I2 = 41%, p = 0.00) significantly favored in the grating group. The limitations of the study include high risk of bias and the lack of varying methodologies in the study designs. The authors concluded that grating stimulation may positively benefit visual functions for individuals with amblyopia.

In a retrospective interventional comparative study, 36 children with unilateral amblyopia were enrolled to determine the efficacy of VT for unilateral refractive amblyopia in children aged 7-10. For the study, the participants were divided into a case group and a control group. The case group received VT, optical correction, and part-time patching of the weaker eye, and the control group received optical correction and part-time patching of the weaker eye. Outcomes of VA were measured at baseline, three months, six months, nine-month visits, and three months after completion of treatment. The case group consisted of 19 individuals and 17 individuals in the control group. The study showed a mean improvement in the case group from 0.39 ±0.24 logMAR at baseline to 0.10 ±0.23 logMAR after treatment. The results for the control group demonstrated an improvement from 0.64 ±0.30 logMAR at baseline to 0.52 ±0.27 logMAR after treatment. All participants underwent follow-up examinations within six to 12 months, with no regression of VA seen in the case group three months after completion of therapy. Individuals in the case group who received VT demonstrated improved VA versus those who received optical correction and patching. A limitation of the study is the retrospective design which restricts the ability to control and randomize the participants into case and control groups. The authors concluded from the study that for children aged 7-10 with unilateral refractive amblyopia, VT combined with conventional treatment such as optical correction and part-time patching are more effective than traditional treatment alone. Furthermore, the therapy provided more significant vision gain and a shorter duration of treatment when compared to conventional treatment. (Hsieh et al., 2022)

In a retrospective comparative study, individuals aged 7-10 years were enrolled to determine the effects of VT on bilateral amblyopia unresponsive to conventional treatment. The control group consisted of 16 cases with age and VA -matched bilateral amblyopes; 15 cases were included in the treatment group. The study showed no improvement in either group for VA for more than three months with part-time patching and full refraction correction. Of 22 eyes, 68.7% showed no improvement in the control group versus the treatment group, which exhibited better VA in every eye. The treatment group revealed significant improvement in BCVA, with an average gain of 0.32 ±0.15 logMAR vs. 0.003 ±0.19 logMAR in the control group. The benefits of treatment are most significant in the first three months of treatment and continue until the endpoint. Results of stereoacuity showed improvements from 190.00 ±163.34 to 85.00 ±61.24 arc seconds (a 55.26% improvement). The l limitations of the study are the retrospective design, which restricts the ability to randomize participants, small sample size, and lack of complete stereoacuity data. The authors conclude that a VT program comprising orthoptic therapy, perceptual learning, and dichoptic training successfully increases VA and stereoacuity in 7–10-year-old individuals with bilateral amblyopia that is unresponsive to conventional treatment. (Huang et al., 2022)

In 2022, Jost et al. conducted an RCT to evaluate the effectiveness of dichoptic movies versus patching for treating amblyopia in children aged three to seven. After inclusion and exclusion criteria were met, 65 children were considered eligible, and enrolled in the trial, and 60 participants completed the study through the four-week visit. Children were randomized to a movie group and a patching group. During the first two weeks, the movie group watched 5.7 ±0.7 movies, and the patching group averaged 30.0 ±11.0 hours of patching. At the two-week primary outcome visit, the movie and patching groups had similar improvement in amblyopic eye BCVA (0.07 vs. 0.06 logMAR). Treatment with movie and patching significantly improved VA (0.07 ±0.05 logMAR and 0.06 ±0.05 logMAR, respectively). VA continued to advance in the movie group after the two-week primary outcome visit, with enhancements of 0.13 ±0.11 logMAR by four weeks and 0.15 ±0.10 logMAR by six weeks. The patching group exhibited comparable improvements after crossing over to movies at two weeks. By week eight, the patching group who crossed over at two weeks gained 0.18 ±0.07 logMAR. The choice to remain in the movie treatment past the four weeks visit for up to six weeks of the movie treatment was chosen by 35 (58%) participants. After six weeks of watching contrast re-balanced dichoptic movies (six-week visit for the movie group and eight weeks visit for the patching group), 26% of children had ≤ 0.1 logMAR interocular difference in VA. The authors concluded that the at-home binocular movie treatment effectively improves amblyopic eye BCVA. Additional improvements were seen with up to six weeks of treatment, making repeated binocular visual experience with contract re-balanced dichoptic movies an additional treatment option for amblyopia. Limitations of the study include short treatment duration, the difference in VA tests, and lack of objective adherence monitoring. (Included in the Shao et al. 2023, and Tsani et al. systematic reviews.)

Xiao et al. (2022) evaluated the safety and efficacy of a dichoptic digital therapeutic for amblyopia. This phase three RCTs consisted of 105 children aged four to seven with amblyopia and enrolled at 21 academic and community sites in the United States. Individuals were randomized to the treatment or comparison group in a 1:1 ratio and stratified by site. The treatment group consisted of 51 participants and 54 in the comparison group. Individuals in the comparison group

continued to wear glasses on a full-time basis while the treatment group used the therapeutic at home for one hour a day, six days a week, and wore glasses full-time. To determine efficacy, the change in amblyopic eye VA from baseline to 12 weeks was measured by masked examiners. The authors evaluated the frequency and severity of study-related AEs (anticipated and unanticipated) to determine the therapy's safety. The intention-to-treat population was utilized to develop a primary analysis. In the treatment group at 12 weeks, amblyopic eye VA improved by 1.8 lines (95% CI, 1.4-2.3 lines; n = 45); and in the comparison group, there was an improvement of 0.8 lines (95% CI, 0.4-1.3 lines; n = 45). The difference between groups was significant 1.0 line (0.10 logMAR; 96.14% CI, 0.33-1.63 lines; p = 0.0011). Individuals sustained high adherence to the therapeutic throughout the study, and adherence was associated with overall satisfaction. No serious AEs were reported, and the study was stopped early per protocol due to success. Limitations include the lack of comparison between patching and atropine penalization, short follow-up time, and risk of bias. The authors support the value of the therapeutic in clinical practice as an effective treatment. Additional independent studies with longer follow-up and sham interventions are warranted to confirm the long-term value of this approach over or in addition to standard treatments. (Included in the Shao et al. 2023, and Tsani et al. systematic reviews.)

In 2021, Roda et al. conducted a systematic review and meta-analysis of RCTs to summarize the available evidence to determine if binocular treatment is more effective than patching in children with amblyopia. VA and stereopsis were assessed as primary outcome measures. Out of five RCTs, no significant difference in VA between individuals treated with binocular treatment and patching was demonstrated at -0.12 (95% CI: -0.45-0.20; p = 0.464). Additionally, no significant difference in stereopsis was found between individuals treated with binocular treatment versus patching -0.07 (95% CI: -0.61-0.48; p = 0.809). Limitations to the study include the high heterogeneity in effect estimation, inconsistency between studies, and the lack of consideration regarding cost and availability of treatment. The authors concluded that this meta-analysis uncovered no substantial evidence that supports the efficacy of binocular therapy as an alternative to traditional patching. Although binocular treatment can be considered a good complementary therapy in particular cases, it cannot fully replace conventional treatment. The following publications, discussed in more detail below, were reviewed as part of this systematic review: Manh et al., 2018; Rajavi et al., 2019.

Elhusseiny et al. (2021) conducted a pilot, prospective, randomized, double-masked, crossover clinical trial at a single center site using (n = 20) children and young adult participants. The participants had unilateral anisometropic and/or strabismic amblyopia with amblyopia treatment failure. Eleven participants underwent eight weeks of binocular treatment using a VR headset that contained a therapeutic software application. The sham-crossover group (n = 9) underwent four weeks of sham treatment followed by four weeks of binocular treatment. Both groups underwent one hour of treatment per day. Participants and clinicians were masked to prescribed treatment. The devices were loaned to the participants and devices used were Apple iPhone 6 Plus smartphone, preloaded with the prototype therapeutic software, and a Zeiss VR One Plus VR headset that delivered the visual input to each eye dichotically. Outcomes in the full-treatment group (n = 11), the mean amblyopic eye logMAR VA at 16 weeks was 0.49 ±0.26, compared with 0.47 ±0.20 at baseline. Compared to the sham-crossover group, it was 0.51 ±0.18 at 16 weeks, compared with 0.53 ±0.21 at baseline. Stereoacuity (log arcsec) was significantly improved, from 7.3 – 2 at baseline to 6.6 – 2.3 at 8 weeks ($p < 0.001$) and 6.7 – 2.6 at 16 weeks ($p < 0.001$). No significant AEs (diplopia, asthenopia, or worsening strabismus) were noted in either group. The authors concluded that virtual reality-based prototype binocular amblyopia therapy did not significantly improve VA. Stereoacuity did improve compared to baseline measurements when all participants were combined. The study is limited by its small sample size and short follow-up. The authors report that they did not achieve the target sample size due to participant attrition. (Included in the Shao et al. 2023, and the Tsani et al. 2024 systematic reviews.)

Birch et al. (2020) conducted an RCT with (n = 48) children diagnosed with amblyopia. The children were randomly divided into two groups. Group one (n = 24) received binocular amblyopia game treatment for one hour a day, five days a week. Group two (n = 24) received patching treatment for two hours per day, seven days a week. The outcomes measured were changes in the amblyopic eye best-corrected VA at the two-week visit. Baseline factors examined were age at enrollment, VA, stereoacuity, and suppression. At baseline, the mean amblyopic eye best-corrected VA ±standard deviation (SD) was 0.49 ±0.16 logMAR (~20/63 ±1.6 lines), range = 0.3-0.8 logMAR (20/40-20/125). VA was 0.3-0.6 logMAR (20/40-20/80) in 38 (79%) children and 0.7-0.8 logMAR (20/100-20/125) in 10 (21%) children. After two weeks, the measurements for group one, who received binocular amblyopia game treatments showed improvement which ranged from 0.0 to 0.4 logMAR; 21 children (87.5%, CI95% = 69%-96%) improved by 0.1 logMAR or more (2 improved 0.3-0.4 logMAR, 10 improved 0.2 logMAR, 9 improved 0.1 logMAR), and three children did not improve (12.5%, CI95% = 4%-31%). Group two, who received patching treatment, showed improvement which ranged from -0.1 to 0.2 logMAR; 12 children (50%, 95% CI = 31%-69%) improved by 0.1 logMAR or more (5 improved 0.2 logMAR, 7 improved 0.1 logMAR), and 11 children (46%, CI95% = 28%-65%) did not improve, and one child (4%, CI95% = 1%-20%) decreased by -0.1 logMAR. At the 2-week visit, 35% (95%CI: 19%-55%) of children playing the binocular game recovered normal VA for age (≤ 0.2 logMAR; 20/32 or better). Only 8% (CI95% = 2%-26%) of the children in the patching group had recovered normal VA for age at the 2-week visit. The authors concluded that after two weeks of treatment, VA improvement was significantly greater with the binocular game treatment than patching. Children with moderate amblyopia and orthotropia had more VA

improvement with binocular game play than those with severe amblyopia. Limitations of this trial include small sample size; short time duration and inability to monitor the number of hours of patching objectively. The authors relied on a calendar log completed by their parents.

Rajavi et al. (2019) conducted an RCT with 38 children diagnosed with unilateral amblyopia who received amblyopia therapy via interactive binocular treatment (I-BiT™) and others received standard patching of the dominant eye with a placebo I-BiT. Children who had BCVA less than 20/30 (0.3 logMAR) in one eye or a difference of two lines of Snellen between their two eyes were included in this study and randomly divided into the case study group (n = 19) and control group (n = 21). The case study group was recommended to play the I-BiT games using red-green glasses, 20 to 30 minutes per day for at least five days a week for one month (total hours = 6). The control group underwent two- and four-hour patching of dominant eye per a day and to play I-BiT games with no red-green glasses, 20 to 30 minutes per day for at least five days a week for one month. The authors concluded that BCVA improved significantly in both groups after one-month treatment (case: $p = 0.003$, control: $p < 0.001$). There was not a significant difference between the two groups ($p = 0.52$). Stereopsis improved in the case study group by ($p < 0.001$) and control group by ($p < 0.001$), but they did not identify large difference between the two groups pre- and post-therapy. The children engaged in playing I-BiT games for six hours total during one month in both groups. Compliance in the case study group was 87.5% and 76% in the control group. Limitations of this study include a small sample size, the short study duration, and lack of monitoring for recurrence of decreased BCVA. Additionally, some participants were excluded after randomization due to lack of compliance, which could introduce biases in the findings. (Included in the Shao et al. 2023, and the Tsani et al. 2024 systematic reviews.)

Manh et al. (2018) conducted an RCT to compare VA improvement of 100 participants aged 13 to < 17 years (mean 14.3 years) with amblyopia who were treated with either part-time eye patching or a binocular game on a tablet device. Participants were randomly assigned to treatment for 16 weeks of either the binocular game prescribed for 1 hour per day (n = 40) or patching of the fellow eye prescribed for 2 hours per day (n = 60). The main outcome measured was a change in amblyopic eye VA from baseline to 16 weeks. Mean amblyopic eye VA improved from baseline by 3.5 letters (2-sided 95% CI: 1.3-5.7 letters) in the binocular group and by 6.5 letters (2-sided 95% CI: 4.4-8.5 letters) in the patching group. After adjusting for baseline VA, the difference between the binocular and patching groups was -2.7 letters (95% CI: -5.7 to 0.3 letters, $p = .082$) or 0.5 lines, favoring patching. In the binocular group, treatment adherence data from the device indicated that only 13% of participants completed > 75% of prescribed treatment. In this population, eye patching was favored over the binocular group; however, it remains unclear whether the minimal response to binocular treatment was due to poor treatment adherence or lack of treatment effect. (Included in the 2024 systematic review by Tsani et al.)

In 2016, Herbison et al. conducted a three-arm RCT that was performed on children with Amblyopia. The (n = 75) children were randomized and assigned one of three treatments I-BiT game (n = 26), Non-I-BiT game (n = 25) and I-BiT digital video disc (DVD) (n = 24). The I-BiT game being used is VR technology that uses either DVD footage or computer games that present a common background for both eyes and a foreground that contains imagery of interest for the amblyopic eye only. The assigned groups received treatment for 30 minutes weekly for six weeks. The primary outcome is the difference in VA between the group treated with I-Bit game versus non-I-Bit game which I measured by using a logMAR VA test at pretreatment (baseline), and after three, six and final treatment over 10 weeks. The secondary outcomes included changes in stereoacuity (Frisby test), safety, acceptability, and compliance during treatment. The authors concluded that modest VA improved in all three arms by approximately 0.07 logMAR in the amblyopic eye at 6 weeks. There was not a significant difference between I-BiT DVD and non-I-BiT games compared with I-BiT games in terms of improvement of vision. The limitations of the trial are short treatment times, trial was hospital based during work and school hours with limited the duration and frequency of treatment sessions, a high number of participants with previous amblyopia treatment failures, and a high number of participants with strabismus created disadvantages for dichoptic stimulation. An adverse effect reported of diplopia which led to decreased VA and participant withdrawal from the trial. Further, I-BiT game multi-center and longer duration studies are needed with the amblyopic population. Lack of comparison with conventional amblyopia therapy is another limitation of this study. (Included in the Shao et al. 2023, and Tsani et al. 2024 systematic reviews.)

The National Eye Institute sponsored the Prism Adaptation Study (PAS), a multicenter RCT to determine the overall effect of PA. The study randomized 333 eligible participants who were at least 3 years of age, had no previous eye surgery, and had acquired deviations of 12 to 40 PD. All participants had 20/40 or better VA in each eye, and individuals with amblyopia underwent occlusion therapy before entry. Two levels of randomization were used. Sixty percent of the individuals (n = 199) underwent PA and 40% (n = 134) did not. Those who did not have PA underwent conventional surgery for their entry angle of deviation. Of those who responded to prisms with motor stability and sensory fusion (n = 131), half (n = 67) underwent a conventional amount of surgery, i.e., surgery for angle at entry, and half (n = 64) underwent augmented surgery based on the prism-adapted angle of deviation. A successful outcome was defined as a deviation of less than or equal to eight PD of esotropia or exotropia. Success rates 6 months after surgery were highest in PA responders who underwent augmented surgery and lowest in those who did not undergo PA (89% versus 72%). The

estimated overall rate of success for people who went through the PA process was significantly better than the success rate of participants who did not undergo PA but underwent surgery for their deviation at entry into the study (83% versus 72%). The investigators concluded that there was a beneficial overall effect of the PA process for those with acquired esotropia. (PAS Research Group, 1990)

Clinical Practice Guidelines

American Academy of Ophthalmology (AAO)

In the 2022, updated in 2024 AAO preferred practice pattern for Amblyopia, the recommendations are as follows:

- Treatment of refractive error alone can improve VA in children with anisometropic, strabismic, or combined Amblyopia. VA of children with bilateral refractive Amblyopia also can substantially improve with refractive correction alone.
- 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.
- Following treatment of Amblyopia caused by strabismus, anisometropia, or both, continued monitoring is necessary, and additional treatment, if needed, is associated with the long-term durability of the VA improvement.
- Suitable treatment options for Amblyopia include optical correction, patching, pharmacological treatment, optical treatment, Bangerter (translucent) filters, digital therapeutics, and managing the underlying cause of Amblyopia.
- Amblyopia treatment may be effective in older children and adolescents, particularly if they have not previously been treated.

(Cruz et al., 2023)

The AAO's 2021; updated 2023 Preferred Practice Pattern guidelines for pediatric ophthalmology/strabismus summary benchmarks for treating amblyopia:

- All children with amblyopia should be offered treatment regardless of age, including older children and teenagers, especially if not treated previously.
- Prognosis for attaining normal vision depends upon age of onset, cause, severity, and duration of amblyopia, history of and response to previous treatment, adherence to treatment, and concomitant conditions.
- The first goal is to correct any cause of visual deprivation; the second goal is to correct refractive errors likely to cause blur; third is to promote use of the amblyopic eye, ultimately to achieve equal VA between the two eyes.
- Choose treatment based on age; VA; adherence and response to previous treatment; and physical, social, and psychological status.
- Once maximal VA has been obtained, treatment intensity can be tapered to maintenance therapy.
- If VA in amblyopic eye is maintained as therapy is tapered, treatment may be stopped but with follow up planned because approximately one-fourth of children experience a recurrence within the first year off treatment.

The AAO's amblyopia preferred practice pattern (Repka et al. 2017) states that timely treatment of amblyopia usually improves VA and binocularity, and it decreases the likelihood of severe visual handicap if there is loss of vision in the fellow eye later in life. The prognosis for attaining normal vision in an amblyopic eye depends on many factors, including the age of onset; the cause, severity, and duration of amblyopia; the history of and response to previous treatment; adherence to treatment recommendations; and concomitant conditions. Several strategies are used in the treatment of amblyopia:

- Treatment of refractive error alone is the initial step in care of children 0 to 17 years of age with amblyopia (moderate quality, strong recommendation).
- Patching is an appropriate choice for treatment for children who do not improve with eyeglasses alone or who experience incomplete improvement (moderate quality, strong recommendation).
- Patching as initial therapy after refractive correction should be considered for children with moderate amblyopia (20/40 to 20/80) (moderate quality for treatment of amblyopia, strong recommendation) with a prescribed dose of 2 hours of daily patching or weekend atropine (moderate quality for amount of time treatment, discretionary recommendation).
- Patching should be considered for older children and teenagers, particularly if they have not previously been treated. (moderate quality, discretionary recommendation).
- Pharmacological treatment that produces cycloplegia of the non-amblyopic eye is an appropriate choice for treatment for children who do not improve with eyeglasses alone. (moderate quality, strong recommendation).
- There is insufficient evidence to recommend VT techniques.

American Association for Pediatric Ophthalmology and Strabismus (AAPOS)

In a 2017 policy statement, the AAPOS stated that "Vision screening of young children is an effective means of detecting eye disorders such as refractive error, amblyopia (poor vision), strabismus (eye misalignment) and other medical

conditions of the eye. Early detection of these abnormalities through vision screening leads to earlier treatment and life-long benefits to these children. Some eye diseases, if not detected and treated in childhood, can lead to irreversible, life-long vision loss. A comprehensive ophthalmologic examination is medically necessary in children whose vision screening has indicated a possible abnormality of eye health and/ or vision. This medical necessity exists regardless of the ultimate presence or absence of ocular pathology. Thus, in children who have failed a vision screening and who are not found to have amblyopia, strabismus, or other medical condition on examination, the examination following a failed vision screening is still considered medically necessary and not considered routine eye care."

American Association for Pediatric Ophthalmology and Strabismus (AAPOS)/ American Academy of Ophthalmology (AAO)

In 2022, the AAPOS and AAO created a joint statement on vision screening for infants and children. The recommendations for community and school screening programs state that in community and school-based screening programs, screeners should have specific training in vision screening techniques and protocols as recommended by the Academy and AAPOS. Children who do not pass these screenings should be referred to for an additional ocular assessment performed by the primary care provider or an eye care provider with training and experience in treating children.

In the primary care setting, the Academy and AAPOS recommend that an ocular assessment be performed whenever questions arise about the health of the visual system of a child of any age. In addition, even without specific signs or symptoms, they recommend that infants and children be routinely screened for vision problems and that any child who does not pass one or more of these screening tests have an ophthalmological examination.

- Photo screening and handheld autorefraction may be electively performed in children 12 months to 3 years of age, allowing earlier detection of conditions that may lead to amblyopia. Photo screening and handheld automated refraction are recommended as an alternative to VA screening with vision charts (typically used for children 3 through 5 years of age) and in children who are unable or unwilling to cooperate with routine acuity screening with vision charts (but are not superior to vision chart testing for children able to participate). Using vision charts to assess amblyopia in children 3 to 5 years of age remains a viable practice.
- Children with possible or diagnosed learning disabilities, such as dyslexia, should undergo a comprehensive eye examination to identify and treat any undiagnosed vision impairment. Such children should be referred for appropriate medical, psychological, and educational evaluations and treatment of any learning disability. There is inadequate scientific evidence to suggest that "defective eye teaming" and "accommodative disorders" are common causes of educational impairment. Hence, routine screening for these conditions is not recommended. (2022)

In a joint policy statement, the AAPOS and the AAO state that amblyopia is a medical condition and requires treatment. Amblyopia is typically a preventable and treatable form of vision loss caused by developmental abnormalities of the brain's vision centers. Unless amblyopia is treated promptly during childhood, permanent structural changes occur in the brain, resulting in decreased visual function; recovery of vision in this instance is rarely achieved.

Current methods of preschool vision screening can identify risk factors (primarily high levels of refractive error and anisometropia) that, if untreated, increase the likelihood of amblyopia developing. Therefore, these amblyopia risk factors should also be considered medical conditions.

Optical correction such as eyeglasses and contacts may be medically indicated as a part of amblyopia treatment in addition to other modalities, such as patching and/or pharmacologic treatment. (AAPOS, AAO; 2002, revised and reaffirmed 2017)

American Optometric Association (AOA)

In their guideline on care of the patient with accommodative and vergence dysfunction, the AOA states that improvement in both accommodative and vergence adaptation systems is the basis of the success of VT. According to the guideline, data is lacking for the efficacy of home-based VT by itself. Home-based VT may be less effective than office-based therapy, as there is no therapist available to provide motivation or correct inappropriate procedures. Therefore, preferred clinical management involves office-based VT in combination with home therapy. They note that therapy combining diplopia awareness with operant-conditioning techniques to reinforce alignment in the absence of visual cues has been advocated for divergence excess, and that VT is usually successful in patients with divergence insufficiency. (Cooper et al., 2010)

The AOA (2009) issued a clinical care publication on the definition of optometric VT. The document states that research has demonstrated VT can be an effective treatment option for:

- Ocular motility dysfunctions (eye movement disorders)

- Non-strabismic binocular disorders (inefficient eye teaming)
- Strabismus (misalignment of the eyes)
- Amblyopia (poorly developed vision)
- Accommodative disorders (focusing problems)
- Visual information processing disorders, including visual-motor integration and integration with other sensory modalities
- Visual sequelae of acquired brain injury

In their clinical guideline on the care of the patient with amblyopia, the AOA states that the rationale for using occlusion is that occluding the better eye stimulates the amblyopic eye, decreasing inhibition by the better eye. Occlusion enables the amblyopic eye to enhance neural input to the visual cortex. It is also important in eliminating eccentric fixation. However, noncompliance with occlusion represents a significant factor in occlusion failures, especially in patients over eight years of age in whom up to 50 percent noncompliance is common. They also note that active VT for amblyopia is designed to remediate deficiencies in four specific areas: eye movements and fixation, spatial perception, accommodative efficiency, and binocular function. The goal of VT is remediation of these deficiencies, with subsequent equalization of monocular skills and, finally, integration of the amblyopic eye into binocular functioning. Untreated individuals with amblyopia are at a greater risk for loss of vision in the better eye. (Rouse et al., 1994; revised 2004)

National Institute for Health and Care Excellence (NICE)

In the 2023 NICE guidelines on stroke rehabilitation in adults the recommendations on vision are as follows:

- Offer people who are in hospital after stroke a specialist orthoptist assessment as soon as possible. If this cannot be done before discharge, offer the person an urgent outpatient appointment.
- Offer eye movement therapy to people who have persisting hemianopia (blindness in one half of the visual field of one or both eyes) after stroke.

United States Preventative Services Task Force (USPSTF)

The USPSTF (2017) recommends the primary treatment for amblyopia as the correction of any underlying refractive error with the use of corrective lenses, occlusion therapy (eye patching, atropine eye drops, or Bangerter occlusion foils), or a combination of treatments.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Vision therapy is a procedure and, as such, is not subject to FDA regulation. Devices used in vision training programs may be classified under several different product codes. Some of these devices may be exempt from the 510(k)-clearance process. For information on a specific device or manufacturer refer to the following website: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed May 23, 2025)

NovaSight announced that the FDA has cleared CureSight, a digital therapy device for amblyopia (lazy eye). CureSight is an eye-tracking-based system that improves visual and stereo acuity by training the visual system to use both eyes simultaneously. The ground-breaking clearance was based on visual outcomes data from a multicenter, RCT in which 103 participants aged 4 to < 9 were randomized to CureSight or eye patching—the current gold standard-of-care treatment. Decision date 2022 Sep 29. For more information, refer to the following website: https://www.accessdata.fda.gov/cdrh_docs/pdf22/K221375.pdf. (Accessed May 23, 2025)

NovaVision™, an attention task performance recorder, consists of two software programs, one for healthcare professionals for precise diagnosing of visual deficiencies, develop specific therapies and analyze results of therapy. The other software is intended for individuals in their homes to train and improve impaired visual functions. It is intended for the diagnosis and improvement of visual functions for those with impaired vision that may result from trauma, stroke, inflammation, surgical removal of brain tumors or brain surgery, and may also be used to improve visual function for those with amblyopia. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf2/K023623.pdf. (Accessed May 23, 2025)

Luminopia One, Luminopia Inc. was granted De Novo classification (DEN210005) on February 26, 2021. According to the FDA website, Luminopia is a software-only digital therapeutic designed to be used with commercially available Head-Mounted Displays (HMDs), which are compatible with the software application. Luminopia One is indicated for improvement in VA for individuals with amblyopia, aged 4-7, associated with anisometropia and/or mild strabismus, having received treatment instructions (frequency and duration) as prescribed by a trained eye-care professional.

Luminopia One is intended for both previously treated and untreated people. Luminopia One is intended to be used as an adjunct to full-time refractive correction, such as glasses, which should also be worn under the HMD during Luminopia One therapy. Luminopia One is intended for prescription use only in an at-home environment. Additional information is available at: https://www.accessdata.fda.gov/cdrh_docs/pdf21/DEN210005.pdf. (Accessed May 23, 2025).

The RevitalVision technology 510K: K012530 was originally FDA cleared in 2001 (originally branded as the NeuroVision AA-1 system) for treating amblyopia in patients aged ≥ 9 years. Additional information is available at: https://www.accessdata.fda.gov/cdrh_docs/pdf/K012530.pdf. (Accessed May 23, 2025)

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Policy History/Revision Information

Date	Summary of Changes

04/01/2026	**Coverage Rationale**
	• Removed list of proven and medically necessary indications:
	  ○ Occlusion therapy or pharmacologic penalization therapy for treating Amblyopia
	  ○ Orthoptic therapy or Vision Therapy for treating convergence insufficiency
	  ○ Prism adaptation therapy for treating esotropia
	• Revised list of unproven and not medically necessary indications; removed:
	  ○ Orthoptic therapy or Vision Therapy for treating all other indications not listed [as proven and medically necessary]
	  ○ Virtual perception therapy for treating any type of learning disability or language disorder
	  ○ Vision restoration therapy for treating visual field deficits following stroke or neurotrauma
	  ○ Visual information processing evaluation to diagnose reading or other learning disabilities

Date	Summary of Changes

	Definitions
	• Removed definition of:
	  ○ Convergence Insufficiency
	  ○ Esotropia
	  ○ Exotropia
	  ○ Occlusion Therapy
	  ○ Orthoptic Therapy
	  ○ Pharmacologic Penalization Therapy
	  ○ Prism Adaptation Therapy
	  ○ Strabismus
	  ○ Vision Restoration Therapy (VRT)
	Applicable Codes
	• Removed CPT codes 92065, 92066, and 92499
	Supporting Information
	• Updated *Clinical Evidence* and *References* sections to reflect the most current information
	• Removed *Description of Services* section
	• Archived previous policy version 2026T0072FF

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