VISUAL INFORMATION PROCESSING EVALUATION AND ORTHOPTIC AND VISION THERAPY

Guideline Number: MMG137.I

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COVERAGE RATIONALE

The following are proven and medically necessary:

- Occlusion Therapy or Pharmacologic Penalization Therapy for treating Amblyopia
- Orthoptic Therapy or Vision Therapy for treating Convergence Insufficiency
- Prism Adaptation Therapy for treating Esotropia

The following are unproven and not medically necessary due to insufficient evidence of efficacy:

- Orthoptic Therapy or Vision Therapy for treating all other indications not listed above
- Virtual perception therapy for treating any type of learning disability or language disorder
- Vision Restoration Therapy (VRT) for treating visual field deficits following stroke or neurotrauma
- Visual information processing to diagnose reading or learning disabilities

DEFINITIONS

Amblyopia: the reduction of best-corrected visual acuity (BCVA) of one or both eyes that cannot be attributed exclusively to a structural abnormality of the eye. Amblyopia develops during childhood and results in the interruption of normal cortical visual pathway development. It is clinically defined as a difference in BCVA of 2 or more lines of acuity between the eyes (American Academy of Ophthalmology [AAO], 2015). Amblyopia is often referred to as “lazy eye (American Association for Pediatric Ophthalmology and Strabismus [AAPOS], 2017).

Convergence Insufficiency: inability to maintain binocular function (keeping the two eyes working together) while working at a near distance. Typically, one eye will turn outward (intermittent Exotropia) when focusing on a word or object at near distance (AAPOS, 2017).

Estropia: A type of Strabismus in which one or both eyes turn inward. It can be intermittent or constant (AAPOS, 2016).

Exotropia: a form of Strabismus in which one or both of the eyes turn outward. It is the opposite of crossed eyes, or Esotropia. Exotropia may occur from time to time (intermittent exotropia) or may be constant, and is found in every age group (AAPOS, 2015).

Occlusion Therapy: patching of the dominant eye; used for treating Amblyopia (American Optometric Association [AOA], 2004).
Orthoptic Therapy: eye exercises to improve binocular function (AAPOS, 2016). Also referred to as vision therapy. The profession of orthoptics includes the evaluation and treatment of disorders of the visual system, particularly involving binocular vision and eye movement (American Associated of Certified Orthoptists [AACO], 2018).

Pharmacologic Penalization Therapy: The instillation of pharmacologic drops (e.g., atropine) to blur the eyesight of the better-seeing eye (PEDIG, 2015).

Prism Adaptation Therapy: the use of clear, triangular shaped objects that bend light to permit alignment of the visual axes, simulating the absence of Strabismus. It is also proposed as a way to more accurately determine the angle of deviation or the target angle for Strabismus surgery (AAO, 2018).

Strabismus: misalignment of the eyes. Strabismus is most commonly described by the direction of the eye misalignment such as Esotropia, Exotropia, and hypertropia (AAPOS, 2018).

Vision Restoration Therapy (VRT): a computer-based program used in the diagnosis and improvement of visual functions in patients with impaired vision that may result from trauma, stroke, inflammation, surgical removal of brain tumor(s), or brain surgery (NovaVision, 2018).

Vision Therapy: a nonsurgical program of visual activities to improve visual acuity (VA) and binocularity. Also termed “orthoptics,” or eye exercises. This therapy may include computer programs, prisms, filters, metronomes, vergence activities, accommodation activities, antisuppression activities, and eye-hand coordination exercises (AAO, 2017).

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 guideline 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.

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DESCRIPTION OF SERVICES

For purposes of this policy, Orthoptic or Vision Therapy does not include the use of refractive treatment including refractive lenses.

Vision Therapy is also referred to as eye exercise therapy, visual therapy, visual training, vision training, Orthoptic Therapy, orthoptics, orthoptic vision therapy, or optometric vision therapy. Vision Therapy encompasses a wide range of optometric treatment modalities, with the therapeutic goal of correcting or improving specific dysfunctions of the vision system.

The Vision Therapy program is based on the results of a comprehensive eye examination or consultation, and takes into consideration the results of standardized tests, the needs of the patient, and the patient’s signs and symptoms. The use of lenses, prisms, filters, occluders, specialized instruments, and computer programs is an integral part of Vision Therapy. The length of the therapy program varies depending on the severity of the diagnosed conditions, typically ranging from several months to longer periods of time. Activities paralleling in-office techniques are typically taught to the patient to be practiced at home, thereby reinforcing the developing visual skills.

Vision Therapy is used for eye movement and fixation training to eliminate or improve conditions such as lazy eye (Amblyopia), crossed eyes (Strabismus), focusing, eye-teaming, and tracking disorders.

Visual perceptual therapy is a psychoeducational intervention intended to correct visual-motor or perceptual-cognitive deficiencies that are claimed to contribute to delay in speech and language development in preschool children.

Visual information processing evaluation (VIPE) identifies problems with processing of information for enhanced school and/or social development. Visual processing refers to a group of skills used for interpreting and understanding visual information. The evaluation may include testing for visual spatial orientation skills, visual analysis skills, including auditory-visual integration, visual-motor integration skills and rapid naming.
Orthoptics is an allied health profession within the ophthalmic field pertaining to the evaluation and treatment of patients with disorders of the visual system with an emphasis on binocular vision and eye movements (AACO, 2018).

**CLINICAL EVIDENCE**

**Therapies for Amblyopia**

Manh et al. (2018) conducted a randomized controlled trial (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 measure was change in amblyopic eye VA from baseline to 16 weeks. Mean amblyopic eye VA improved from baseline by 3.5 letters (2-sided 95% confidence interval [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 patient 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.

A 2015 RCT conducted by PEDIG on a total of 73 children 3 to < 8 years of age with stable residual amblyopia concluded that the benefits to augmenting atropine therapy with a plano lens on the affected eye were small and not statistically significant. A larger study would be helpful for a better estimate of treatment effect.

Repka et al. (2014) reported VA of patients at 15 years of age who were younger than 7 years when enrolled in a treatment trial for moderate amblyopia. In a multicenter clinical trial, 419 children with amblyopia (VA, 20/40 to 20/100) were randomly assigned to patching (minimum of 6 h/d) or pharmacologic penalization with atropine sulfate eyedrops, 1% (1 drop daily), for 6 months. Treatment after 6 months was at the discretion of the investigator. Two years after enrollment, an unselected subgroup of 188 children were enrolled into long-term follow-up. At 15 years of age, most children treated for moderate amblyopia when younger than 7 years have good VA, although mild residual amblyopia is common. The authors found the outcome to be similar regardless of initial treatment with atropine or patching. Better VA at the 15-year examination was achieved in those who were younger than 5 years at the time of entry into the RCT (mean logMAR, 0.09) compared with those aged 5 to 6 years (mean logMAR, 0.18; P < .001). When we compared subgroups based on original treatment with atropine or patching, no significant differences were observed in VA of amblyopic and fellow eyes at 15 years of age (P = .44 and P = .43, respectively). The authors concluded that the results indicate that improvement occurring with amblyopia treatment is maintained until at least 15 years of age.

In a prospective, multicenter RCT, the Pediatric Eye Disease Investigator Group (PEDIG) evaluated the effectiveness of increasing prescribed daily patching from 2 to 6 hours in children with stable residual amblyopia. The study group consisted of 169 children aged 3 to <8 years (mean, 5.9 years) with stable residual amblyopia (20/32–20/160) who had received 2 hours of daily patching for at least 12 weeks. The main outcome measure was BCVA in the amblyopic eye after 10 weeks. Ten weeks after randomization, amblyopic eye VA had improved an average of 1.2 lines in the 6-hour group and 0.5 line in the 2-hour group (difference in mean VA adjusted for a = .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 patient 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.

In a RCT, Rutstein et al. (2010a) evaluated whether VA improvement with Bangerter filters is similar to improvement with patching as initial therapy for children with moderate amblyopia. The study enrolled 186 children, 3 to <10 years old, with moderate amblyopia. Children were randomly assigned to receive either daily patching or to use a Bangerter filter on the spectacle lens in front of the fellow eye. Study visits were scheduled at 6, 12, 18, and 24 weeks. At 24 weeks, amblyopic eye improvement averaged 1.9 lines in the Bangerter group and 2.3 lines in the patching group. The authors concluded that because the average difference in VA improvement between Bangerter filters and patching was less than half a line and there was lower burden of treatment on the child and family, Bangerter filter treatment is a reasonable option to consider for initial treatment of moderate amblyopia. The authors indicated that although the mean difference between groups was only 0.38 line, the end of the confidence interval on the difference was 0.76 line, and thus, treatment with Bangerter filters did not quite meet the prespecified definition of non-inferiority to patching when initiating therapy for moderate amblyopia. However, the authors also did not find that patching was statistically superior to Bangerter filters. Therefore, the authors could not conclude that the Bangerter filter treatment effect is
similar to that seen with patching (based on our predefined definition of non-inferiority), but they also could not conclude that patching is definitely better.

In a prospective, RCT, Agervi et al. (2010) compared spectacles plus patching 8 hours or more daily 6 days a week with spectacles plus patching 8 hours or more on alternate days to treat amblyopia in 40 children 4 to 5 years of age. The main outcome measure was median change in BCVA of the amblyopic eye after 1 year. The median change in BCVA of the amblyopic eye did not differ significantly between the 2 groups. Binocular function improved in both groups with no significant differences between the groups at 1 year. The investigators concluded that the magnitude of change in the BCVA 1 year after spectacles plus prescribed alternate-day patching was not significantly different than that after spectacles plus prescribed daily patching to treat amblyopia in children 4 to 5 years old. The effect of patching was not separate from that of optical correction with a period of refractive adaptation. Thus, the improvement in VA is a combined effect of spectacle wear and occlusion therapy.

A 2009 multicenter RCT by PEDIG compared weekend atropine sulfate use augmented by a plano lens for the sound eye (optical penalization/study group) with weekend atropine use alone (pharmacologic penalization/control group) for moderate amblyopia in 180 children aged 3 years to younger than 7 years. Primary outcome measured was masked assessment of amblyopic eye VA using the Amblyopia Treatment Study HOTV testing protocol at 18 weeks. The researchers concluded that optical penalization was not substantially better than pharmacologic penalization in this patient population.

A large RCT supported by the National Eye Institute (NEI) involved 419 children. The participants were assigned to either patching or penalization with atropine drops as treatment for amblyopia. VA improved in both groups (79% in the patching group and 74% in the atropine group). Both treatments were well tolerated, but the parents of the atropine treated group reported a slightly higher degree of acceptability (PEDIG, 2002).

In a meta-analysis of part-time (PTO) versus full-time occlusion therapy (FTO) for treatment of amblyopia, Yazdani et al. (2017) included six studies [3 RCTs and 3 non-RCTs]. Pooled standardized difference in the mean changes in the VA was 0.337 [lower and upper limits: 0.009, 0.683] higher in the FTO as compared to the PTO group; however, this difference was not statistically significant (P ¼ 0.056, Cochrane Q value ¼ 20.4 (P ¼ 0.001), I2 ¼ 75.49%). Egger’s regression intercept was 5.46 (P ¼ 0.04). The pooled standardized difference in means of VA changes was 1.097 [lower and upper limits: 0.68, 1.513] higher in the FTO arm (P < 0.001), and 0.7 [lower and upper limits: 0.315, 1.085] higher in the PTO arm (P < 0.001) compared to PTO less than two hours. The authors concluded that this meta-analysis showed no statistically significant difference between PTO and FTO in treatment of amblyopia. However, their results suggest that the minimum effective PTO duration, to observe maximal improvement in VA is six hours per day.

In a Cochrane review, Taylor and Elliott (2014) evaluated the most effective treatment for strabismic amblyopia. The review found that occlusion, while wearing necessary refractive correction, appears to be more effective than refractive correction alone in the treatment of strabismic amblyopia.

**Prism Adaptation Therapy for Esotropia**

The NEI sponsored the Prism Adaptation Study (PAS), a multicenter RCT to determine the overall effect of prism adaptation (PA). The study randomized 333 eligible patients who were at least 3 years of age, had no previous eye surgery, and had acquired deviations of 12 to 40 prism diopters. All patients had 20/40 or better VA in each eye, and amblyopic patients underwent occlusion therapy before entry. Two levels of randomization were used. Sixty percent of the patients (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 8 prism diopters of esotropia or exotropia. Success rates 6 months after surgery were highest in PA responders who underwent augmented surgery and lowest in patients who did not undergo PA (89% versus 72%). The estimated overall rate of success for patients who went through the PA process was significantly better than the success rate of patients 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 patients with acquired esotropia (PAS Research Group, 1990).
In a retrospective review, Quigley et al. (2017) evaluated the PAT response and postoperative outcomes in a cohort of children with accommodative esotropia who underwent bilateral medial rectus recession. The authors reported that 36% of patients showed a requirement for increase of prism dosage to retain orthotropia during PAT; these patients did better than those whose deviation was stable, with postoperative rate of motor success (defined as ≥10Δ esotropia) of 100% versus 56%. PAT may be a useful positive prognostic test, and it also identifies a substantial patient population who may avoid undercorrection, the prism builders. The authors suggest that additional randomized studies are required to demonstrate definitive benefit of PAT.

In a prospective interventional case series, Akbari et al. evaluated the surgical outcomes in patients with acquired nonaccommodative esotropia treated with bilateral medial rectus muscle recession based on a short prism adaptation test (PAT) to determine the subgroup of patients most responsive to PAT. Patients were classified as either prism responders (if the angle of deviation increased >10 Δ compared to the entry angle) or prism nonresponders. Of the 28 subjects enrolled, 14 (50%) were prism responders and 14 (50%) were classified as prism nonresponders. After 6 months, 100% of prism responders and 92.9% of nonresponders were aligned within 8 Δ of orthotropia at distance and near fixation. None of the patients with an entry angle of >30 Δ were prism responders. The researchers concluded that a short PAT with an endpoint of motor stability in patients with acquired nonaccommodative esotropia was associated with a good surgical outcome and a low rate of over- and undercorrection. PAT may be unnecessary for patients with an angle of deviation of >30 Δ (2018).

**Therapies for Convergence Insufficiency (CI)**

In a systematic review of the literature on orthoptic therapy for CI, Rucker and Phillips (2018) reported that convergence exercises reduce symptoms and improve signs of CI in otherwise healthy patients. However, the most efficacious convergence tasks and the optimal duration and frequency of these tasks, remain unknown. The authors did not identify RCTs that show treatment consisting of repetitive ocular motor tasks improves learning disabilities, reading, dyslexia, or ADHD.

Scheiman et al. (2011a) systematically assessed and synthesized evidence from RCTs on the effectiveness of nonsurgical interventions for CI. The review included six trials (three in children, three in adults) with a total of 475 participants. The authors concluded that for children, office-based vision therapy is more effective than home-based convergence exercises (i.e., pencil push-ups) or home-based computer vision therapy. The evidence of the effectiveness of nonsurgical treatments of CI in adults was considered less consistent.

Cacho Martinez et al. (2009) conducted a systematic review of reports published from 1986 to 2007 to analyze the scientific evidence available on the nonsurgical treatment of accommodative and non-strabismic binocular dysfunctions, identifying the types of treatment used and their efficacy. Of the 565 articles identified, 16 met the inclusion criteria and only 3 were clinical trials. All analyzed treatment of CI. According to the authors, results of clinical trials support the conclusion that vision therapy improves symptoms and signs for CI. The authors stated that the evidence indicates that pencil push-up treatment is not as effective as vision therapy and that prism glasses are no more effective than placebo glasses. They also stated that for the other non-strabismic binocular conditions and accommodative disorders, there is a lack of published RCTs that support the evidence for the efficacy of each treatment.

The NEI sponsored the CI Treatment Trial (CITT) study, a RCT comparing the effectiveness of different treatment options for the condition in 221 children (age 9 to 17 years). Three types of vision therapy were compared with a placebo therapy intervention. Vision therapy included: (1) office-based vision therapy with at-home exercises; (2) home-based pencil push-ups with additional computer vision therapy (HBCVAT+); and (3) home-based pencil push-up (HBPP) therapy alone. The placebo therapy group was given placebo vision activities that simulated office-based therapy. The study found that after 12 weeks of treatment, nearly 75% of children who received office-based vision therapy with at-home reinforcement achieved normal vision or had significantly fewer symptoms of CI. In comparison, only 43% of patients who completed home-based therapy alone showed similar results, as did 33% of patients who used HBCVAT+ and 35% of patients who underwent office-based placebo therapy (Convergence Insufficiency Treatment Trial Study Group, 2008).

Shin et al. (2011) conducted a prospective controlled trial comparing office-based vision therapy with no vision therapy treatment. The study included 57 children aged 9-13 years who were diagnosed with symptomatic CI (n = 27) or combined symptomatic CI and accommodation insufficiency (AI) (n = 30). They were independently divided into a treatment and a control group, matched by age and gender. Office-based vision therapy significantly improved symptoms and clinical signs including near point of convergence (NPC), positive fusional vergence, mean accommodative amplitude, and mean accommodative facility relative to no treatment in children with CI and AI. Of the patients with concurrent CI and AI who received vision therapy, 77% were considered improved and 61% were considered cured. Of the 11 patients who completed the 1-year follow-up, symptom scores had deteriorated to
abnormal levels in 2 children and 1 child also showed regression of the NPC. The authors concluded that this study supports the use of vision therapy as a successful method of treating CI and CI combined with AI.

In a RCT, Scheiman et al. (2011b) assessed the effectiveness of various types of vision therapy for improving accommodative amplitude or accommodative facility in 221 children with deficiencies in these measures at baseline. All types of vision therapy (i.e., office-based vision therapy, HBCVAT+, and HBPP) were superior to office-based placebo vision treatment for improving mean accommodative amplitude. With regard to accommodative facility, only the office-based vision therapy group exhibited a significantly greater improvement than the placebo group. This study did not report the results of symptoms or other clinical signs. One year after completion of therapy, reoccurrence of decreased accommodative amplitude was present in only 12.5% and accommodative facility in only 11%. The authors concluded that vision therapy/orthoptics is effective in improving accommodative amplitude and accommodative facility in school-aged children with symptomatic CI and accommodative dysfunction.

**Vision Therapy for Convergence Excess or Nystagmus**
No well-designed clinical trials evaluating the use of vision therapy for convergence excess or nystagmus were identified.

**Vision Therapy for Divergence Excess or Insufficiency**
No well-designed clinical trials evaluating the use of vision therapy for divergence excess or divergence insufficiency were identified.

**Orthoptic or Vision Therapy for Exotropia**
Shin et al. (2017) conducted a retrospective review to determine the effect of preoperative PTOtherapy on long-term surgical success in early-onset exotropia in 51 consecutive patients. The mean duration of preoperative occlusion therapy was 10.2 ± 5.4 months (range, 6 to 28 months). The mean follow-up duration after surgery for exotropia was 78.0 ± 28.1 months (range, 36 to 135 months). Overall, the final success rate of surgery for early-onset exotropia was 66.7%. Five patients (9.8%) showed persisting consecutive esotropia and eventually underwent surgical correction for these consecutive esotropia at a mean age of 18.8 months (range, 8 to 40 months) after the primary surgery for exotropia. A higher long-term success and lower recurrence rate was found in patients who were deemed as compliant (≥50%) than in the group of patients who were deemed to be non-compliant (<50%).

Joyce et al. (2015) conducted a systematic review of RCTs, quasi-experimental and cohort studies with a comparison group examining interventions for divergence excess, simulated divergence excess or basic type exotropia in children, up to and including 18 years of age, followed for at least 6 months. Eleven studies satisfied the eligibility criteria. Seven examined the comparative effectiveness of two surgical procedures; four compared surgery with other interventions, including botulinum toxin A therapy, orthoptic exercises, occlusion, binocular vision training and watchful waiting. The evidence retrieved was of limited extent and quality with differences across studies in terms of outcome assessment and most appropriate time-point for measuring long-term outcomes. There were mixed outcomes when comparing unilateral recession/resection (R&R) with bilateral lateral rectus recession (BLR) on improving angle of deviation, which makes it difficult to recommend either surgical option with confidence. While nonsurgical interventions appear less effective in terms of improving angle of deviation, they are rarely associated with adverse outcomes. The authors concluded that given the limited evidence base, better designed studies are required to address the question of the most effective management for treatment of childhood exotropia. Importantly, consensus is required on what constitutes a successful outcome as well as agreement on how this should be measured.

PEDIG conducted a RCT to compare part-time patching with observation for previously untreated intermittent exotropia (IXT) in children 12-35 months old (n=201). Participants were randomly assigned to either observation (no treatment for 6 months) or patching prescribed for 3 hours daily for 5 months, followed by 1 month of no patching. The authors reported deterioration (defined as constant exotropia measuring at least 10Δ at distance and near or receipt of non-protocol treatment for IXT) over 6 months was uncommon, with or without patching treatment. There was insufficient evidence for the authors to recommend part-time patching for the treatment of IXT in children in this age group (Mohney et al., 2015).

Gnanaraj and Richardson (2005) conducted a systematic review to clarify the effects of various surgical and nonsurgical treatments for management decisions in distance IXT. No RCTs were found that met selection criteria. The authors found that the current literature consists mainly of retrospective reviews and these are difficult to compare and analyze due to variations in definition, intervention criteria, and outcome measures. Data from individual studies on suggested intervention criteria were found to be variable, although there was some consistency in suggesting that small-angle deviations (less than 20 prism dipters) may be improved by nonsurgical treatments such as exercising fusion, eliminating suppression, or inducing accommodation using minus lenses. According to the authors, the efficacy of these treatments remains debatable.
Hatt and Gnanaraj (2013) analyzed the effects of various surgical and non-surgical treatments in randomized trials of people with IXT, to report intervention criteria and determine the significance of factors such as age with respect to outcome. The authors searched for RCTs of any surgical or non-surgical treatment for IST. One randomized trial was eligible for inclusion in the review. This trial showed that unilateral surgery was more effective than bilateral surgery for correcting basic IXT. According to the authors, measures of severity and criteria for intervention were poorly validated for all identified studies. The authors concluded that there is a need for improved measures of severity, a better understanding of the natural history and carefully planned clinical trials to improve the evidence base for the management of this condition.

Buck et al. (2012) investigated the current patterns of management and outcomes of distance IXT in an observational cohort study which recruited 460 children aged < 12 years of age with previously untreated distance exotropia. Data collected included angle, near stereoaucity, VA, control of distance exotropia measured with the Newcastle Control Score (NCS), and treatment. The main outcome measures were change in clinical outcomes in treated and untreated distance exotropia, 2 years from enrolment (or, where applicable, 6 months after surgery). At follow-up, data were available for 371 children (81% of the original cohort). Of these, 53% (195) had no treatment; 17% (63) had treatment for reduced VA only (pure refractive error and amblyopia); 13% (50) had no-surgical treatment for control (spectacle lenses, occlusion, prisms, exercises) and 17% (63) had surgery. Only 0.5% (2/371) children developed constant exotropia. The surgically treated group was the only group with clinically significant improvements in angle or NCS, but rates of overcorrection are high. Non-surgical treatment of intermittent distance exotropia had less significant impact on angle of deviation or scores on the NCS.

**Orthoptic or Vision Therapy for Stroke and Traumatic Brain Injury**

Hunt et al. (2016) conducted a systematic review of evidence regarding the use of oculomotor-based vision assessment to identify and monitor recovery from mild traumatic brain injury (mTBI). Their objectives were to (1) identify changes in oculomotor-based vision following mTBI; (2) distinguish methods of assessment; (3) appraise the level and quality of evidence; and, if warranted, (4) determine clinical recommendations for assessment. Articles were included if study populations were clearly identified as having mTBI and used an assessment of oculomotor-based vision. 20 articles met their inclusion criteria. Exploratory findings suggest that measurements of saccades, smooth pursuit, and vergence are useful in detecting changes associated with mTBI. The authors noted that the strength of this evidence is not yet sufficient to warrant clinical recommendations. Research using rigorous methods is required to develop reliable, valid, and clinically useful assessment protocols.

An overlap of investigators and, presumably, overlap of study participants were found for several studies evaluating vision therapy after traumatic brain injury. Three RCTs by the same primary author appeared to be reporting data for different endpoints on the same study group (Thiagarajan and Ciuffreda, 2014; Thiagarajan et al., 2014; Thiagarajan and Ciuffreda, 2013). These trials showed improvement with the use of vision therapy but evaluated only 12 patients.

vanWyk et al. (2014) evaluated the effect of saccadic eye movement training with visual scanning exercises (VSEs) integrated with task-specific activities on unilateral spatial neglect (USN) poststroke. A matched-pair RCT was conducted. Subjects were matched according to their functional activity level and allocated to either a control (n = 12) or an experimental group (n = 12). All patients received task-specific activities for a 4-week intervention period. The experimental group received saccadic eye movement training with VSE integrated with task specific activities as an "add on" intervention. Assessments were conducted weekly over the intervention period. Statistically significant differences were noted on the King-Devick Test (P = .021), Star Cancellation Test (P = .016), and Barthel Index (P = .004). The authors concluded that intensive saccadic eye movement training with VSE integrated with task-specific activities has a significant effect on USN in patients poststroke. Long-term follow-up and further studies with larger patient populations are needed to verify these results.

Mizuno et al. (2011) conducted a multicenter, double-masked, RCT to evaluate the effects of a 2-week PAT on USN. A total of 38 USN patients with right-brain damage were divided into prism (n = 20) and control (n = 18) groups. Patients were divided into mild and severe USN groups according to Behavioral Inattention Test (BIT) parameters (mild ≥ 55 and severe<55). The prism group performed repetitive pointing with prism glasses that induce rightward optical shift twice daily, 5 days per week, for 2 weeks, whereas the control group performed similar pointing training with neutral glasses. The Functional Independence Measure (FIM) improved more significantly in the prism group. In mild USN patients, there was significantly greater improvement of BIT and FIM in the prism group. The authors concluded that PA therapy can significantly improve activities of daily living in patients with subacute stroke. These findings require confirmation in a larger study.

In a systematic review of interdisciplinary literature, Klinke et al. (2015) identified rehabilitation interventions that can be integrated into ward-based nursing for patients with hemispatial neglect following stroke in the right brain hemisphere. Using 41 original studies, 11 interventions were identified. The selected studies were graded according to the strength of their evidence (Levels 1-5); the proposed interventions were given recommendation grades (Grades A-D). The interventions included right half-field eye patching (Grade D), smooth pursuit eye-movement training...
(Grade B) and visual scanning training (Grade D). The authors noted that there was general low level of evidence and the diversity of interventions which made it difficult to endorse specific priorities and combinations for implementation.

In a Cochrane review, Pollock et al. (2011) determined the effects of interventions for visual field defects after stroke. Thirteen studies (344 randomized participants, 285 of whom were participants with stroke) met the inclusion criteria for this review. However, only six of these studies compared the effect of an intervention with a placebo, control or no treatment group and were included in comparisons within this review. The authors concluded that there is insufficient evidence to reach generalized conclusions about the benefits of visual prisms (substitutive intervention) for patients with visual field defects after stroke.

In a single blinded pilot RCT, Turton et al. (2010) evaluated the feasibility of delivering PAT in a clinically valid sample and assessed its impact on self-care in 37 right hemisphere stroke patients with USN. The patients were randomized into either PA or sham treatment (using plain glasses) groups. Treatment was delivered each weekday for two weeks. Thirty four patients received treatment: 16 with prisms, 18 with sham treatment. Mean compliance was 99% and 97%, respectively. Over the treatment days only the prism treated group showed increased leftward bias in open loop pointing to targets on a touch screen. However, despite the group level changes in pointing behavior no overall effect of the treatment on self-care or BIT were found.

A National Institute for Health and Care Excellence (NICE) guidance document states that eye movement therapy can be offered to people who have persisting hemianopia after stroke and who are aware of the condition. This recommendation was based on 3 RCTs, the confidence level of results ranging from very low to moderate (2013).

**Orthoptic or Vision Therapy for Dyslexia and Other Learning Disabilities**

Hall et al. (2013) conducted a randomized, double blind trial with 73 delayed readers to compare changes in reading and spelling as well as irregular and non-word reading skills after 3 months of wearing either the Harris or the Dyslexia Research Trust (DRT) filters. Reading improved significantly after wearing either type of filter, with 40% of the children improving their reading age by 6 months or more during the 3 month trial. However, spelling ability and non-word reading improved significantly more with the DRT than with the Harris filters. The authors concluded that education and rehabilitation professionals should consider colored filters as an effective intervention for delayed readers experiencing visual stress. According to the authors, this research will help to support the use of colored filters for visual reading capacity but further more rigorous research is needed.

In a double-masked, placebo crossover RCT, Ritchie et al. (2011) tested the efficacy of Irlen colored overlays for alleviating reading difficulties thought to have been caused by Irlen syndrome, a proposed perceptual disorder with controversial diagnostic status. Sixty-one school children (aged 7-12 years) with reading difficulties were included in the study. Based on the study results, the authors concluded that Irlen colored overlays do not have any demonstrable immediate effect on reading in children with reading difficulties.

**Visual Information Processing Evaluation**

Limited clinical evidence was found to support the use of visual information processing evaluations for diagnosing learning-related or other types of visual deficits.

Goldstand et al. (2005) compared visual and visual-information processing skills between children with and without mild reading and academic problems and examine the incidence of visual deficits among them. A total of 71 seventh graders classified as proficient (n=46) and non-proficient (n=25) readers were compared with respect to scores on an accepted vision screening, on tests of visual-perception, visual-motor integration, and academic performance. Further, academic performance and visual-information processing were compared between children who failed and passed the vision screening. Visual deficits were found in 68% of the participants, and among significantly more boys than girls. Non-proficient readers had significantly poorer academic performance and vision-screening scores than the proficient readers. Participants who passed the visual screening performed significantly better in visual perception than those who failed. According to the investigators, visual function significantly distinguishes between children with and without mild academic problems, as well as on visual-perception scores. The investigators concluded that the high occurrence of visual deficits among participants warrants consideration of vision deficits among school children with academic performance difficulties. These findings require confirmation in a larger study.

**Visual Perceptual Therapy**

In a prospective study, Yalcin and Balci (2014) evaluated the efficacy of neural vision therapy, also known as perceptual vision therapy, in enhancing BCVA and contrast sensitivity function in amblyopic patients. The study enrolled 99 subjects (age 9 to 50 years) previously diagnosed with unilateral hypermetropic amblyopia. The subjects were divided into two groups, with 53 subjects (53 eyes) in the perceptual vision therapy group and 46 subjects (46 eyes) in the control group. Because the nature of the treatment demands hard work and strict compliance, the minimal number of subjects required to achieve statistically significant results were enrolled. Study phases included a
baseline screening, a series of 45 training sessions with perceptual vision therapy, and an end-of-treatment examination. BCVA and contrast sensitivity function at 1.5, 3, 6, 12, and 18 cycles per degree spatial frequencies were obtained for statistical analysis in both groups. All subjects had follow-up examinations within 4-8 months. With the exception of one subject from the study group and two subjects from the control group, all subjects had occlusion during childhood. The study was not masked. The results for the study group demonstrated a mean improvement of 2.6 logarithm of the minimum angle of resolution (logMAR) lines in VA (from 0.42 to 0.16 logMAR). Contrast sensitivity function improved at 1.5, 3, 6, 12, and 18 cycles per degree spatial frequencies. The control group did not show any significant change in VA or contrast sensitivity function. None of the treated eyes showed a drop in VA. The authors concluded that the results of the study demonstrate the efficacy of perceptual vision therapy in improving VA. According to the authors, long-term follow-up and further studies are needed to verify these results.

**Vision Restoration Therapy (VRT)**

In a prospective, double-blind, placebo-controlled RCT, Sabel and Gudlin (2014) determined if behavioral activation of areas of residual vision using daily 1-hour VRT for glaucoma for 3 months improved detection accuracy compared with placebo. The study participants included a volunteer sample of patients with glaucoma (mean age, 61.7 years) with stable visual fields and well-controlled intraocular pressure. Study interventions included computer-based VRT for glaucoma (n = 15) or visual discrimination placebo training in the intact visual field (n = 15). After randomization, 4 patients withdrew from the trial because of mild headaches (n = 2) or lack of time to complete the schedule (n = 2). The primary end point was change in detection accuracy in high-resolution perimetry. VRT for glaucoma led to significant detection accuracy gains in high-resolution perimetry, which were not found with white-on-white or blue-on-yellow perimetry. Furthermore, the pre-post differences after VRT for glaucoma were greater compared with placebo in all perimetry tests, and these results were independent of eye movements. VRT for glaucoma (but not placebo) also led to faster reaction time. Vision-related quality of life (QOL) was unaffected, but the health-related QOL mental health domain increased in both groups. The authors concluded that visual field defects caused by glaucoma can be improved by repetitively activating residual vision through training the visual field borders and areas of residual vision, thereby increasing their detection sensitivity. According to the authors, this trial revealed evidence that visual field loss is in part reversible by behavioral, computer-based, online controlled vision training, comprising a new rehabilitation treatment option in glaucoma. These findings require confirmation in a larger study with long-term follow-up.

In a systematic review, Dundon et al. (2015) evaluated the rationale underlying treatment paradigms in VRT and summarized the available evidence with respect to treatment efficacy. The authors observed that sustained improvements require repetitive stimulation which, depending on the method, may take months. Functional magnetic resonance imaging studies have revealed effects within wider distributed networks, i.e., BOLD changes occur not only in the visual cortex, but also in extrastriate areas. In a similar vein, the notion that treatment improvements driven by VST are exclusively driven by compensatory eye movements has been challenged by some recent experimental findings. They concluded that, broadly speaking, visual rehabilitation targeting restoration of a portion of the visual field, appears to represent an optimal approach to address visual field function and size. However, VRT consists of a long-lasting training protocol, which may not suit the life circumstances of all patients.

In a Cochrane review, Pollock et al. (2011) determined the effects of interventions for people with visual field defects after stroke. Thirteen studies (344 randomized participants, 285 of whom were participants with stroke) met the inclusion criteria for this review. However, only six of these studies compared the effect of an intervention with a placebo, control or no treatment group and were included in comparisons within this review. The authors concluded that there is insufficient evidence to reach generalized conclusions about the benefits of visual restitution training (VRT) for patients with visual field defects after stroke.

Jung et al. (2008) evaluated the effects of VRT on the visual function of 10 patients with anterior ischemic optic neuropathy in a double-blind pilot RCT. All patients were evaluated before VRT and after 3 and 6 months of treatment by Early Treatment Diabetic Retinopathy Study (ETDRS) VA, contrast sensitivity, reading speed, 24-2 SITA-standard Humphrey visual field (HVF), High Resolution Perimetry (HRP) (perimetry obtained during VRT), and vision-based QOL questionnaire. Patients were randomized between two VRT strategies (5 in each group): I) VRT in which stimulation was performed in the seeing VF of the affected eye ("seeing field-VRT"); II) VRT in which stimulation was performed along the area of central fixation and in the ARV (areas of residual vision) of the affected eye ("ARV-VRT"). The results of the HRP, HVF, and clinical assessment of visual function were compared for each patient and between the two groups at each evaluation. VA qualitatively improved in the ARV-VRT group; however the change was not statistically significant. Binocular reading speed significantly improved in the ARV-VRT group. HVF foveal sensitivity increased mildly in both groups. HRP analysis showed a similar increase in stimulus accuracy in both groups (mean improvement of about 15%). All patients reported functional improvement after VRT. A small study population limits the conclusions that can be reached from this study.

Mueller et al. (2007) performed a clinical observational analysis of visual fields of 302 patients before and after being treated with computer-based VRT for a period of 6 months. The visual field defects were due to ischemia, hemorrhage,
head trauma, tumor removal or anterior ischemic optic neuropathy. Primary outcome measure was a visual field assessment with super-threshold perimetry. VRT improved patients' ability to detect super-threshold stimuli in the previously deficient area of the visual field by 17.2% and these detection gains were not significantly correlated with eye movements. Notable improvements were seen in 70.9% of the patients. Efficacy was independent of lesion age and etiology, but patients with larger areas of residual vision at baseline and patients older than 65 years benefited most. Conventional perimetry validated visual field enlargements and patient testimonials confirmed the improvement in every day visual functions. The lack of a control group limits the validity of the results of this study.

**Professional Societies**

**American Academy of Pediatrics (AAP)/ Section on Ophthalmology, Council on Children with Disabilities/ American Association of Pediatric Ophthalmology and Strabismus (AAPOS)/ American Association of Certified Orthoptists (AACO)**

According to a joint policy statement issued by the AAP, AAO, AAPOS, and AACO, diagnostic and treatment approaches for dyslexia that lack scientific evidence of efficacy such as behavioral vision therapy, eye muscle exercises, or colored filters and lenses are not endorsed or recommended. The ophthalmologist should identify and treat any significant visual defect according to standard principles of treatment. Strabismus, amblyopia, and refractive errors may require glasses, eye patching, eye drops, or eye-muscle surgery. In addition, the ophthalmologist should discuss the lack of efficacy of vision therapy and other "alternative treatments" with the parents (AAP, 2009; reaffirmed 2014).

A 2011 joint technical report by the same societies indicates that vision problems can interfere with the process of reading, but children with dyslexia or related learning disabilities have the same visual function and ocular health as children without such conditions. Currently, there is inadequate scientific evidence to support the view that subtle eye or visual problems cause or increase the severity of learning disabilities. According to the report, scientific evidence does not support the claims that visual training, muscle exercises, ocular pursuit-and-tracking exercises, behavioral/perceptual vision therapy, "training" glasses, prisms, and colored lenses and filters are effective direct or indirect treatments for learning disabilities. There is no valid evidence that children who participate in vision therapy are more responsive to educational instruction than children who do not participate (Handler and Fierson, 2011).

**American Academy of Ophthalmology (AAO)**

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).
- There is insufficient evidence to recommend vision therapy techniques

Additional strategies for treatment of amblyopia, such as pharmacologic therapy, are also addressed in this preferred practice pattern.

In a separate policy statement, the AAO (2013) maintains that children with possible or diagnosed learning disabilities, such as dyslexia, should undergo a comprehensive eye examination so that any undiagnosed vision impairment can be identified and treated. Such children should be referred for appropriate medical, psychological, and educational evaluations and treatment of any learning disability. The organization states that there is insufficient evidence to conclude that "defective eye teaming" and "accommodative disorders" can be underlying causes of educational impairment.

The AAO esotropia and exotropia preferred practice pattern (Wallace et al., 2018) states the potential benefits of treatment for esotropia include promoting binocular vision and normal visual function in each eye. If binocularity is achieved, the number of surgical procedures over a lifetime may be reduced. Treatment should be considered for all forms of esotropia, and binocular alignment should be established as soon as possible, especially in young children, to maximize binocular potential to prevent or facilitate treatment of amblyopia and to restore normal appearance.
The following are included in the list of current treatment practices for esotropia:
- Correction of refractive errors
- Bifocal eyeglasses
- Prism therapy
- Amblyopia treatment

The AAO includes the following in its list of current treatment practices for exotropia:
- Correction of refractive errors
- Stimulating accommodative convergence (overcorrection of myopia or undercorrection of hyperopia)
- Patching (antisuppression) therapy
- Amblyopia treatment
- Prism therapy
- Convergence exercises for convergence insufficiency exotropia

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

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)**

The AOA (2009) issued a clinical care publication on the definition of optometric vision therapy. The document states that research has demonstrated vision therapy 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

According to the AOA’s revised guideline on the care of the patient with strabismus: esotropia and exotropia, vision therapy is successful in the treatment of many forms of strabismus. The AOA states that vision therapy or orthoptics involves active training procedures to improve the patient’s fixation ability and oculomotor control, to help eliminate amblyopia, to improve sensory and motor fusion, and to increase facility and the range of accommodation and vergence responses. They note that the prognosis is most favorable for patients with intermittent strabismus, especially intermittent exotropia, who have sensorimotor fusion at some point in space and those with recently developed strabismus (Rutstein et al., 2010b).

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 vision therapy. According to the guideline, data is lacking for the efficacy of home-based vision therapy by itself. Home-based vision therapy 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 vision therapy in combination with home therapy. They note that therapy combining diplopia awareness with operant-conditioning technique to reinforce alignment in the absence of visual cues has been advocated for divergence excess, and that vision therapy is usually successful in patients with divergence insufficiency (Cooper et al., 2010).

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 8 years of age in whom up to 50 percent noncompliance is common. They also note that active vision therapy 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 vision therapy is remediation of these deficiencies, with subsequent equalization of monocular skills and, finally, integration of the amblyopic eye into binocular functioning. Untreated amblyopic patients are at a greater risk for loss of vision in the better eye (Rouse et al., revised 2004).

The AOA clinical practice guideline on care of the patient with learning related vision problems describes these as deficits in two broad visual system components: visual efficiency and visual information processing.

- Visual efficiency comprises the basic visual physiological processes of VA (and refractive error), accommodation, vergence, and ocular motility.
- Visual information processing involves higher brain functions including the non-motor aspects of visual perception and cognition, and their integration with motor, auditory, language, and attention systems. Learning related vision problems are the manifestation of deficits in visual efficiency and visual information processing.
- Visual efficiency problems include uncorrected refractive error, dysfunction of accommodation and vergence control systems and the interaction of these systems, and ocular motility. Accommodative and vergence dysfunctions can be primary deficits or can occur secondary to uncorrected refractive error. Isolated visual efficiency deficits are relatively uncommon; most patients present with multiple deficits.

This guideline also notes that correction of refractive error and treatment of visual efficiency dysfunctions can result in improved visual information processing. The treatment of vision information processing deficits usually requires vision therapy, which can begin during the later stages of visual efficiency therapy. This is dependent on associated conditions such as accommodative and vergence dysfunction (Garzia et al., 2008).

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 a number of different product codes. Some of these devices may be exempt from the 510(k) clearance process. For information on a specific device or manufacturer see the following web site: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed July 30, 2019)

NovaVision™, an attention task performance recorder, received FDA 510(k) approval on April 22, 2003. NovaVision™ presents visual stimuli on a computer screen, for the diagnosis and improvement of visual functions in patients 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 in patients with amblyopia. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf2/K023623.pdf. (Accessed July 30, 2019)

REFERENCES


Visual Information Processing Evaluation and Orthoptic and Vision Therapy
UnitedHealthcare West Medical Management Guideline
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GUIDELINE HISTORY/REVISION INFORMATION

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**Coverage Rationale**

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<td>• Added language to indicate Pharmacologic Penalization Therapy is proven and medically necessary for treating Amblyopia</td>
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**Definitions**

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**Supporting Information**

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This Medical Management Guideline provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard benefit plan. In the event of a conflict, the member specific benefit plan document governs. Before using this guideline, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Management Guideline is provided for informational purposes. It does not constitute medical advice.

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