| 9.03.03 O          | rthoptic Training for the | Treatment of Vision or Le | arning Disabilities |
|--------------------|---------------------------|---------------------------|---------------------|
| Original Policy Do | ate: October 9, 1996      | Effective Date:           | May 1, 2023         |
| Section:           | 9.0 Other                 | Page:                     | Page 1 of 17        |

# **Policy Statement**

- I. Office-based vergence/accommodative therapy may be considered **medically necessary** when **both** of the following criteria are met:
  - A. Individuals with symptomatic convergence insufficiency
  - B. Symptoms have failed to improve following a minimum of 12 weeks of home-based therapy which may include **any** of the following:
    - 1. Jump-to-near convergence exercises
    - 2. Maintaining convergence for 30 to 40 seconds
    - 3. Push-up exercises using an accommodative target
    - 4. Push-up exercises with additional base-out prisms
    - 5. Recession from a target
    - 6. Stereogram convergence exercises
- II. Orthoptic eye exercises are considered **investigational** for the treatment of learning disabilities.
- III. Orthoptic eye exercises are considered **investigational** for all other conditions, including but not limited to the following:
  - A. Slow reading
  - B. Visual disorders other than convergence insufficiency

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

# **Policy Guidelines**

This policy addresses office-based orthoptic training. It does not address standard vision therapy with lenses, prisms, filters, or occlusion (i.e., for treatment of amblyopia or acquired esotropia prior to surgical intervention).

Up to 12 sessions of office-based vergence/accommodative therapy, typically performed once a week, has been shown to improve symptomatic convergence insufficiency in children aged 9 to 17 years. If patients remain symptomatic after 12 weeks of orthoptic training, alternative interventions should be considered.

A diagnosis of convergence insufficiency is based on asthenopic symptoms (sensations of visual or ocular discomfort) at near point combined with difficulty sustaining convergence.

Convergence insufficiency and stereoacuity are documented by all of the following:

- Appreciation by the patient of at least 500 seconds of arc on stereoacuity testing
- Exodeviation at near vision at least 4 prism diopters greater than at far vision
- Insufficient positive fusional vergence at near (positive fusional vergence [PFV] <15 prism diopters blur or break) on PFV testing using a prism bar
- Near point of convergence (NPC) break of more than 6 cm

# Description

Orthoptic training refers to techniques designed to correct accommodative and convergence insufficiency (or convergence dysfunction). Regimens may include push-up exercises using an accommodative target of letters, numbers, or pictures; push-up exercises with additional base-out prisms; jump-to-near convergence exercises; stereogram convergence exercises; and/or recession from a target. In addition to its use to treat convergence insufficiency, orthoptic training has been investigated for treating attention deficit disorders, dyslexia, and dysphasia.

# **Related Policies**

N/A

# **Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

# **Regulatory Status**

N/A

# Rationale

# **Background**

#### **Treatment**

Orthoptic training refers to techniques designed to correct accommodative and convergence insufficiency (or convergence dysfunction), which may include push-up exercises using an accommodative target of letters, numbers, or pictures; push-up exercises with additional base-out prisms; jump-to-near convergence exercises; stereogram convergence exercises; and recession from a target.<sup>1</sup>, A related but distinct training technique is behavioral or perceptual vision therapy, in which eye movement and eye-hand coordination training techniques are used to improve learning efficiency by optimizing visual processing skills.

In addition to its use in the treatment of accommodative and convergence dysfunction, orthoptic training is being investigated for the treatment of attention deficit disorders, dyslexia, dysphasia, and reading disorders.

#### Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

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To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice. The following is a summary of the key literature to date.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

# Orthoptic Training for Convergence Insufficiency Clinical Context and Therapy Purpose

Convergence insufficiency is a binocular vision disorder associated with defects in the eyes' ability to turn inward toward each other (e.g., when looking at near objects). The diagnosis of convergence insufficiency is made when patients have a remote near point of convergence or difficulty in sustaining convergence in conjunction with sensations of visual or ocular discomfort at near vision. Symptoms of this common condition may include eyestrain, headaches, blurred vision, diplopia, sleepiness, difficulty concentrating, movement of print, and loss of comprehension after short periods of reading or performing close activities. Prism reading glasses, home therapy with pencil push-ups, and office-based vision therapy and orthoptics have been evaluated for the treatment of convergence insufficiency.

The purpose of orthoptic training in individuals who have convergence insufficiency is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of orthoptic training in patients who have convergence insufficiency improve net health outcomes?

The following PICO was used to select literature to inform this review.

#### **Populations**

The relevant population of interest is individuals with convergence insufficiency.

#### Interventions

The treatment being considered is in-office orthoptic training. Orthoptic training refers to techniques designed to correct accommodative and convergence insufficiency (or convergence dysfunction).

# Comparators

The comparator of interest is standard management of convergence insufficiency with at-home vision training exercises.

#### **Outcomes**

The general outcomes of interest are symptoms and functional outcomes.

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Timing of intervention is approximately 12 weeks of in-office training, followed by 6 months of athome training. Follow-up at 1 year or more is preferable.

### Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

# Review of Evidence Systematic Reviews

At least 2 systematic reviews have addressed the role of orthoptic training for convergence insufficiency. A systematic review by Rawston et al (2005) assessing the applicability and efficacy of eye exercises found that small controlled trials and a large number of cases supported their use in the treatment of convergence insufficiency. 2-Scheiman et al (2020) conducted a systematic review and network meta-analysis of RCTs that evaluated nonsurgical treatments for convergence insufficiency.<sup>3,</sup> Six trials in children (n=968) were analyzed. When treatment success was defined as a composite of normal clinical convergence parameters and a prespecified magnitude of improvement, office-based vergence/accommodative (orthoptic) training with home reinforcement was more likely to lead to a successful outcome than home-based computer training (risk ratio, 1.96; 95% confidence interval [CI], 1.32 to 2.94) and home-based pencil/target push-up training (risk ratio, 2.86; 95% CI, 1.82 to 4.35). An analysis that defined treatment success as a composite of both improved convergence parameters and improved symptoms found that office-based training with home reinforcement was more effective than home-based computer training (risk ratio, 4.65; 95% CI, 1.23 to 17.54) or home-based pencil push-up training (risk ratio, 4.41; 95% CI, 1.26 to 15.38); however, these findings were based on low-certainty evidence. Six RCTs in adults were included, but none compared office-based and home-based orthoptic training. Three trials in adults compared officebased training to placebo; results were limited and the authors concluded that the benefit of orthoptic training in adults was less clear overall than in children.

### **Randomized Controlled Trials**

In 2008, the Convergence Insufficiency Treatment Trial Study Group reported on an RCT of 221 children with symptomatic convergence insufficiency. <sup>4,</sup> Symptoms were evaluated by the Convergency Insufficiency Symptom Survey, a 15-item survey with a final score ranging from 0 (least symptomatic) to 60 (most symptomatic). Scores of less than 16 were considered "asymptomatic," and a decrease of 10 or more points was considered "improved." On blinded evaluation after 12 weeks of treatment (99% completion rate), 73% of patients treated with office-based therapy were considered to be successful or improved on the composite outcome of Convergency Insufficiency Symptom Survey, near point convergency, and positive fusional vergency, as defined above, compared with 43%, 33%, and 35% of those treated with home pencil push-ups, home computer exercise, or placebo, respectively. At 1-year follow-up, 88% of the 32 children who were asymptomatic at the completion of the 12-week office-based treatment program remained successful or improved; 67% of the home-based pencil push-up group remained successful or improved.<sup>5,</sup> A limitation of this RCT is that near point exercises generally consisted of multiple therapies, making it difficult to correlate outcomes with specific modalities.

Following the publication of the main results of the Convergence Insufficiency Treatment Trial, a number of reanalyses were performed. The effectiveness of these forms of vision therapy (pencil push-ups, home computer exercises, office-based vision therapy) in improving accommodative amplitude in 164 (74%) of the 221 children who had coexisting accommodative dysfunction with

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convergence insufficiency was reported by the Convergence Insufficiency Treatment Trial Study Group in 2011.<sup>6,</sup> Of the 164 children with accommodative dysfunction, 63 (29%) had a decreased amplitude of accommodation, 43 (19%) had decreased accommodative facility (latency and speed of the accommodative response), and 58 (26%) had both. After 12 weeks of treatment, increases in amplitude of accommodation were significantly greater in the 3 active groups (range, 5.8–9.9 diopters) compared with office-based placebo therapy (2.2 diopters). The percentage of children who no longer showed decreased amplitude of accommodation was 91.4% for office-based therapy, 79.3% for home computer therapy, 74.1% for home pencil push-ups, and 35.7% for placebo treatment. Accommodative facility improved by 9.4 cycles per minute for office-based therapy, 7.0 cycles per minute for home computer-based therapy, 5.0 cycles per minute for home pencil push-ups, and 5.5 cycles per minute for office-based placebo therapy; only the office-based therapy showed significantly greater improvement than office-based placebo therapy. One year after completion of therapy, recurrence of decreased accommodative amplitude was found in 5 (11%) of 44 children and in 4 (12.5%) of 32 children who did not undergo subsequent treatment.

The effect of successful treatment for convergence insufficiency on parents' perception of academic behavior in the 218 children who completed this trial was also reported by the Convergence Insufficiency Treatment Trial group (2012).<sup>7</sup> Participants were classified as successful (n=42), improved (n=60), or nonresponder (n=116) after 12 weeks of treatment. This study used the Academic Behavior Survey, a 6-item questionnaire (scoring range, 0-24 points) developed by the Convergence Insufficiency Treatment Trial Study Group to quantify parents' perceptions of the frequency of adverse behaviors exhibited by children when reading or performing school work (5 questions) and overall parental concern about the child's academic performance (1 question). Mean Academic Behavior Survey score at baseline was 12.85 points, which improved by 4.0, 2.9, and 1.3 points in children classified as successful, improved, and nonresponder, respectively. Improvements in Academic Behavior Survey scores correlated with reductions in symptom level (r=0.29), but not changes in measures of convergence. Although the Academic Behavior Survey has not been validated outside of this study, the effect sizes in the successful and improved groups were 0.9 and 0.7, representing a clinically meaningful change.

In 2012, the Convergence Insufficiency Treatment Trial Study Group reported on a post hoc analysis of this RCT evaluating the effect of convergence insufficiency treatment on specific types of symptoms.<sup>8,</sup> Outcomes were measures on the Convergency Insufficiency Symptom Survey, which has 2 subscales: a performance-related subscale consisting of 6 symptoms related to visual efficiency when reading or performing near work (e.g., loss of place with reading) and an eye-related subscale consisting of 9 symptoms specific to visual function or asthenopic-type complaints (e.g., eye pain). Those with a "treatment response" (improvement of at least 8 points) on the overall Convergency Insufficiency Symptom Survey score demonstrated improvements in both the performance-related subscale and the eye-related subscale (mean, 1.1 points). Further research is needed to determine whether the treatment-related improvement in performance-related symptoms seen with orthoptics training translates into improvements in reading performance and attention.

In 2019, results of the Convergence Insufficiency Treatment Trial - Attention & Reading Trial (CITT-ART) were published.<sup>9,</sup> Children with convergence insufficiency were randomized to 16 weeks of weekly office-based vergence/accommodative therapy or office-based placebo therapy. Both groups performed home exercises 15 minutes per day, 5 days per week. The study outcomes for convergence ability and symptoms were the same as the outcomes in the Convergence Insufficiency Treatment Trial. After 16 weeks, mean Convergence Insufficiency Symptom Survey scores had decreased from baseline by -11.8 (95% CI, -13.4 to -10.3) and -10.4 (95% CI, -12.4 to -8.4) in the therapy and placebo groups, respectively, which was statistically similar between groups. There was no difference in the proportion of patients in each group that achieved normal or improved symptoms. Significantly more patients in the therapy group versus the placebo group met the criteria for normal or improved near point of convergence (p<0.001) and positive fusional vergence (p<0.001). Several composite outcomes for treatment success found significant improvements with therapy versus

placebo. Interpretation of the symptom comparisons in this trial may be limited by the clinically relevant improvement in symptoms in the placebo group. Results for accommodation were published separately by Chen et al (2020). Among the 288 children in the CITT-ART study with decreased accommodative amplitude or facility, normal amplitude (69% vs. 32%; p<0.0001) and facility (85% vs. 49%; p<0.0001) were achieved by significantly more patients in the therapy group compared to the placebo group, respectively. In a separate publication, results for improvement in reading comprehension were not significantly different between the therapy and placebo groups. Reading comprehension subtest scores of the Wechsler Individual Achievement Test, Third Edition (WIAT-III) increased by 3.68 points in the therapy group and 3.8 points in the placebo group (difference -0.12; 95% CI, -1.89 to 1.66). All other reading outcome measures were also similar between groups.

Singh et al (2021) published results of an RCT in 176 children and young adults (aged 9 to 30 years, mean 19 years) with symptomatic convergence insufficiency. Patients were randomized to 6 weeks of office-based orthoptic therapy (3 times per week) or home-based pencil push-up exercises (15 minutes per day). At study end, there was no difference between groups in near point of convergence or Convergence Insufficiency Symptom Survey scores, but there was a significantly greater improvement in positive fusional vergence with office-based therapy compared to home-based exercises (p<0.001). Limitations of this study include lack of blinding, a wide range of patient ages, short duration compared to other studies, 20% to 30% loss to follow-up leading to a lack of power, and the study was conducted at a single center in India.

Alvarez et al (2020) conducted the Convergence Insufficiency Neuro-mechanism in Adult Population Study, a small RCT (N=50) that compared 6 weeks of twice weekly office-based vergence/ accommodation therapy and office-based placebo therapy in young adults (aged 18 to 35 years) with symptomatic convergence insufficiency.  $^{13}$ , All patients performed home-based computer exercises 10 minutes per day, 3 days per week. Outcomes included change in near point of convergence, positive fusional vergence, and Convergence Insufficiency Symptom Survey scores. Both near point of convergence (p<0.01) and positive fusional vergence (p<0.001) were significantly improved with office-based therapy compared to placebo, but there was no difference between groups in symptom scores (2.3 points; 95% CI, -8.3 to 4.6; p=0.6).

Tables 1 and 2 summarize the key RCTs in patients with convergence insufficiency.

Table 1. Summary of Key Randomized Controlled Trial Characteristics

| Study; Trial   | Countries | Sites | Dates         | Participants   | Interventions   |  |
|--|-----------|-------|---------------|--|---|--|
|  |           |       |               |  | Active  | Comparator   |
| Convergence<br>Insufficiency<br>Treatment Trial<br>Study Group<br>(2008) <sup>4,</sup> | US        | 9     | 2005-<br>2006 | Children aged 9 to 17 years, exodeviation at or near at least 4∆ greater than at distance, insufficient positive fusional convergence, receded near point of convergence of ≥6 cm break, best corrected visual acuity of 20/25 in both eyes at distance and near, Convergence Insufficiency Symptom Survey score ≥16, not previously treated with pencil push-up or vergence orthoptic therapy | Office-based<br>vergence<br>therapy with<br>home<br>reinforcement;<br>weekly visits and<br>15 minutes/day,<br>5 days/week for<br>12 weeks; n=60 | Home-based pencil push-up therapy; 15 minutes/day, 5 days/week for 12 weeks; n=54  Home-based computer vergence therapy with pencil push-ups; 20 minutes/day, 5 days/week for 12 weeks; n=53  Office-based placebo therapy with home reinforcement; weekly visits and 15 minutes/day, 5 days/week for 12 weeks; n=54 |

| Study; Trial  | Countries | Sites | Dates | Participants                              | Interventions     |                         |
|---------------|-----------|-------|-------|---|-------------------|-------------------------|
| CITT-ART      | US        | 9     | 2014- | Children aged 9 to 14                     | Office-based      | Office-based placebo    |
| Investigator  |           |       | 2017  | years with exodeviation at                | vergence          | therapy with home       |
| Group (2019); |           |       |       | or near at least 4 $\vartriangle$ greater | therapy with      | reinforcement;          |
| CITT-ART9,    |           |       |       | than at distance,                         | home              | weekly visits and 15    |
|               |           |       |       | insufficient positive                     | reinforcement;    | minutes/day, 5          |
|               |           |       |       | fusional convergence,                     | weekly visits and | days/week for 16 weeks; |
|               |           |       |       | receded near point of                     | 15 minutes/day,   | n=104                   |
|               |           |       |       | convergence of ≥6 cm                      | 5 days/week for   |                         |
|               |           |       |       | break, best corrected                     | 16 weeks; n=206   |                         |
|               |           |       |       | visual acuity of 20/25 in                 |                   |                         |
|               |           |       |       | both eyes at distance and                 |                   |                         |
|               |           |       |       | near, Convergence                         |                   |                         |
|               |           |       |       | Insufficiency Symptom                     |                   |                         |
|               |           |       |       | Survey score ≥16, not                     |                   |                         |
|               |           |       |       | previously treated with                   |                   |                         |
|               |           |       |       | office-based or home-                     |                   |                         |
|               |           |       |       | based vergence therapy                    |                   |                         |

CITT-ART: Convergence Insufficiency Treatment Trial - Attention & Reading Trial; RCT: randomized controlled trial.

Table 2. Summary of Key Randomized Controlled Trial Results

| Study  | Change in Convergence<br>Insufficiency Survey<br>Symptom score <sup>a</sup><br>(mean, 95% CI)                                       | Symptoms resolved or improved at end of study <sup>b</sup>  | Convergence<br>ability normal or<br>improved at end<br>of study <sup>c</sup>                       |
|--|---|---|--|
| Convergence Insufficiency<br>Treatment Trial Study Group<br>(2008) <sup>4,</sup> | N=221   | N=218   | N=218  |
| Office-based vergence therapy  | -14.8 (-17.2 to -12.4)  | 72.9%   | 72.9-95.0%   |
| Home-based pencil push-up therapy  | -7.1 (-9.6 to -4.5)   | 47.1%   | 56.6-77.4%   |
| Home-based computer vergence therapy with pencil push-ups                        | -6.0 (-8.6 to -3.4)   | 38.5%   | 59.6-77.0%   |
| Office-based placebo therapy   | -7.8 (-10.4 to -5.3)  | 42.6%   | 44.5-59.3%   |
| Mean difference (95% CI); p-value  | Office-based vergence<br>therapy vs. home-based<br>pencil push-ups:<br>7.9 (4.4 to 11.4); p<0.001                                   | Office-based vergence<br>therapy vs. home-based<br>pencil push-ups:<br>p=0.008                                      | Office-based<br>vergence therapy<br>vs. home-based<br>pencil push-ups:<br>p<0.05                   |
|  | Office-based vergence<br>therapy vs. home-based<br>computer vergence therapy<br>with pencil push-ups:<br>8.4 (4.9 to 11.9); p<0.001 | Office-based vergence<br>therapy vs. home-based<br>computer vergence<br>therapy with pencil<br>push-ups:<br>p=0.006 | Office-based vergence therapy vs. home-based computer vergence therapy with pencil pushups: p<0.05 |
| CITT-ART Investigator Group<br>(2019); CITT-ART <sup>9,</sup>                    | N=311   | N=311   | N=311  |
| Office-based vergence therapy  | -11.8   | 61.8%   | 92.4-95.5%   |
| Office-based placebo therapy   | -10.4   | 58.7%   | 50.0-67.3%   |
| Mean difference (95% CI); p-value  | 1.5 (-3.8 to 0.8); p=0.21   | p=NS  | p<0.001  |

CI: confidence interval; CITT-ART: Convergence Insufficiency Treatment Trial - Attention & Reading Trial; NS: not significant.

<sup>&</sup>lt;sup>a</sup> Based on the Convergence Insufficiency Symptom Survey, a 15-item survey with scores ranging from 0 (least symptomatic) to 60 (most symptomatic). A score of <16 is considered asymptomatic, and a decrease of  $\geq$ 10 points is considered improved.

<sup>&</sup>lt;sup>b</sup> Asymptomatic (Convergence Insufficiency Symptom Score <16) or improved (change in Convergence

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Insufficiency Symptom Score ≥10 points).

c Based on near point convergency and positive fusional vergency. A "normal" near point convergency was defined as <6 cm, and an improved near point convergency was defined as an improvement (decrease) of >4 cm from baseline to follow-up. To be classified as having normal positive fusional vergency, a patient had to pass Sheard's criteria (i.e., positive fusional vergency blur, or if no blur, then a break value at least twice the near phoria magnitude) and have a positive fusional vergency blur/break of >15 prism diopters. Improvement in positive fusional vergency was defined as an increase of ≥10 prism diopters from baseline to follow-up.

Tables 3 and 4 display notable limitations identified in each study.

Table 3. Study Relevance Limitations

| Study                          | Population <sup>a</sup> | Intervention <sup>b</sup> | Comparator <sup>c</sup> | Outcomes <sup>d</sup> Duration of Follow-up <sup>e</sup> |
|--------------------------------|-------------------------|---------------------------|-------------------------|--|
| Convergence                    |                         |                           |                         | 3 - harms  |
| Insufficiency                  |                         |                           |                         | briefly  |
| Treatment Trial                |                         |                           |                         | described  |
| Study Group                    |                         |                           |                         | in text  |
| (2008) <sup>4,</sup>           |                         |                           |                         |  |
| CITT-ART                       | 3 - patients with       |                           | 2 - placebo             |  |
| Investigator Group             | learning or             |                           | involved some           |  |
| (2019); CITT-ART <sup>9,</sup> | developmental           |                           | eye exercises and       |  |
|                                | disabilities were       |                           | may have had a          |  |
|                                | not excluded            |                           | therapeutic effect      |  |

CITT-ART: Convergence Insufficiency Treatment Trial - Attention & Reading Trial

The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

- <sup>a</sup> Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
- <sup>b</sup> Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
- <sup>c</sup>Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
- <sup>d</sup> Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

Table 4. Study Design and Conduct Limitations

| Study   | Allocation <sup>a</sup> Blinding <sup>b</sup> | Selective<br>Reporting | Data<br>Completeness | Power <sup>e</sup> Statistical <sup>f</sup> |
|---|---|------------------------|----------------------|---|
| Convergence Insufficiency                                     | 1 - office vs.                                | reporting              | Completeness         |   |
| Treatment Trial Study Group                                   | home  |                        |                      |   |
| (2008) <sup>4,</sup>  | therapy                                       |                        |                      |   |
| CITT-ART Investigator Group<br>(2019); CITT-ART <sup>9,</sup> |   |                        |                      |   |

CITT-ART: Convergence Insufficiency Treatment Trial - Attention & Reading Trial

The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

- <sup>a</sup> Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
- <sup>b</sup> Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
- <sup>c</sup>Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
- <sup>d</sup> Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
- <sup>e</sup> Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
- f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2.

<sup>&</sup>lt;sup>e</sup> Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

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Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

# **Nonrandomized Comparative Studies**

Shin et al (2011) reported on a nonrandomized comparative study of office-based vision therapy. <sup>14,</sup> Fifty-seven children with symptomatic convergence insufficiency or combined convergence insufficiency and accommodative insufficiency were divided into a treatment and a sham control group, matched by age and sex. Vision therapy was performed in the school clinic 2 times a week with instructions for home exercises to be performed for 15 to 25 minutes a day during the week. After 12 weeks of office-based vision therapy, the mean College of Optometrists in Vision Development-Quality of Life questionnaire score decreased from 27.07 to 10.40, and near point convergency improved from 8.67 to 3.20 in the children with convergence insufficiency. Mean positive fusional vergency improved from 13.93 to 26.80. Sixty-seven percent of the children were considered to have been cured, and 82% were improved. There were no significant changes between baseline and 12-week follow-up for the control group. Of the 20 children in the treatment group who completed a 1-year follow-up, 3 (15%) showed recurrence.

Dusek et al (2011) reported on a nonrandomized comparative study of 134 children with convergence insufficiency who had been referred to a tertiary care center in Austria for reading difficulties.<sup>15,</sup> Thirty-two participants refused all treatment offered (control group); the remaining children were given base-in prism reading glasses (n=51) or computerized home vision therapy (n=51) based on preference. Parents were instructed to ensure that their child carried out the procedure correctly; compliance was verified weekly. All participants were examined for total reading time, reading error score, the amplitude of accommodation, and binocular accommodative facility at baseline and after 4 weeks. Prismatic reading glasses were not worn during testing. Significant improvements were found in the prism glasses and computer exercise groups for total reading time, reading error score, the amplitude of accommodation, binocular accommodative facility, and vergence facility. For example, reading speed improved by 21 seconds in the reading glasses group, by 12 seconds in the computer exercise group, and by 4 seconds in the control group. Mean amplitude of accommodation improved by 1.4 diopters in the reading glasses group, by 1.0 diopters in the computer exercise group, and by 0.3 diopters in the control group. The only significant improvement for the control group was vergence facility. Although this nonrandomized study had the potential for selection and performance bias, the results suggested that base-in prism reading glasses might be an effective treatment for convergence insufficiency and associated reading problems in children.

Lee et al (2014) reported on results from a small nonrandomized, controlled trial of vision therapy in children with vergence insufficiency and symptomatic ADHD. 16, Of 1,123 children (age range, 8-13 years) who were screened for ADHD, 81 were identified as having symptomatic ADHD; of those, 16 were identified as having accommodative dysfunction on binocular function testing. Eight subjects received vision therapy, and the remainder acted as a control group; eligibility criteria for vision therapy included: high exophoria at near vision (36 prism diopters), exophoria at near vision at least 4 prism diopters greater than at distant vision, a receded near point of convergence break (36 cm), or insufficient positive fusional vergency at near vision, failing Sheard's criterion (positive fusional vergency less than twice the near phorias), or a minimum positive fusional vergency of 15 prism diopters or less base-out blur or break. Vision therapy included progressive home- and office-based convergence and accommodative exercises over 12 weeks. At the 12-week follow-up, intervention group subjects demonstrated improvements in near point convergency (11.50 to 4.38 cm; p<0.05), breakpoint of near positive fusional vergency (11.88 to 32.38 cm; p<0.01), recovery point of near positive fusional vergency (6.38 to 19.75 cm; p<0.01), and near exophoria (12.00 to 7.81 cm; p<0.05). ADHD symptoms, as measured by the parent-reported Korea-ADHD Rating Scale, improved from 23.25 at baseline to 17.13 (p<0.05) after vision therapy. Only within-group comparisons were reported. Control group subjects did not demonstrate improvements in vision metrics or Korea-ADHD Rating Scale scores.

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In a small randomized comparative study, Momeni-Moghaddam et al (2015) compared the effectiveness of pencil push-up therapy with office-based vision therapy in 60 individuals who had convergence insufficiency (mean age, 21.3 years). Subjects received either pencil push-up therapy or office-based therapy without home intervention and underwent reevaluation at 4 and 8 weeks after the start of treatment. With a single exception, the 2 groups did not differ significantly regarding the near point convergency, phoria, and positive fusional vergency. After 4 and 8 weeks of follow-up, positive fusional vergency was significantly more improved in the pencil push-up therapy group (p=0.001). Study authors suggested that pencil push-up therapy and office-based vision therapy were largely comparable for treatment of convergence insufficiency.

### **Noncomparative Studies**

Borsting et al (2016) published the results of a single-arm multicenter study, the Convergence Insufficiency Treatment Trial Reading Study. 18, Investigators evaluated parent-reported behavioral and emotional problems at baseline among children with symptomatic convergence insufficiency and after 16 weeks of office-based vergence accommodative therapy. The intervention was consistent with that administered in the Convergence Insufficiency Treatment Trial. Parent-reported ADHD symptoms were assessed with the Conners 3 ADHD Index and behavioral and emotional symptoms with the 120-item Child Behavior Checklist. Of the 53 children enrolled, 48 consented to office-based therapy and 44 completed therapy and provided posttreatment data. After completion of therapy, there were significant within-subject improvements in Convergency Insufficiency Symptom Survey scores and Conners 3 ADHD Index scores ( $\alpha$ =0.58, significantly different from zero). Subjects also demonstrated statistically significant improvements in the Child Behavior Checklist competency-related subscale related to school performance but not to social- or activities-related performance. On Child Behavior Checklist's symptom-related subscales, there were statistically significant improvements in the anxious/depressed, somatic complaints, and internalizing problems subscales. This study provided some evidence that ADHD-like and emotional and behavior problems may improve among children with symptomatic convergence insufficiency after office-based vision therapies. However, the study's small size and lack of a control group preclude drawing definitive conclusions about the efficacy of this treatment.

# Section Summary: Orthoptic Training for Convergence Insufficiency

At least 2 systematic reviews support the efficacy of orthoptic training for convergence insufficiency, especially in children. The most direct evidence on office-based orthoptic training comes from a 2008 RCT that demonstrated that office-based vision training improves symptoms of convergence insufficiency in a greater percentage of patients than a home-based vision exercise program. Subgroup analyses of this RCT demonstrated improvements in accommodative vision, parental perception of academic behavior, and specific convergence insufficiency-related symptoms. However, in this trial, as in others, the home-based regimen did not include the full range of home-based therapies, which may have biased results in favor of the orthoptic training. Another RCT published in 2019 did not find a difference in symptoms of convergence insufficiency between office-based orthoptic training plus home exercises and office-based placebo therapy plus home exercises, possibly due to notable improvements in symptoms in the placebo group.

# Orthoptic Training for Learning Disabilities Clinical Context and Therapy Purpose

Some learning disabilities, particularly those in which reading is impaired, have been associated with deficits in eye movements and/or visual tracking. For example, many dyslexic persons may have an unstable binocular vision and report that letters appear to move around, causing visual confusion.

The purpose of orthoptic training in individuals who have learning disabilities is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of orthoptic training in patients who have learning disabilities improve net health outcomes?

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The following PICO was used to select literature to inform this review.

#### **Populations**

The relevant population of interest is individuals with learning disabilities, including attention deficit disorders, dyslexia, dysphasia, and reading disorders. Diagnosis of learning disabilities should be conducted by a qualified, licensed professional. Attention deficit disorder can be diagnosed by professionals qualified and licensed to do so, as well as by psychiatrists and physicians, although only medical doctors can prescribe medication.

#### Interventions

The treatment being considered is office-based orthoptic training for learning disabilities.

#### Comparators

The comparator of interest is standard management of learning disabilities. The practices currently being used to treat learning disabilities vary depending on the type of disability, but they could include receiving special services at school such as individualized education programs and accommodations.

#### **Outcomes**

The general outcome of interest is functional outcomes.

The limited available literature showed that approximately 12 sessions over 5 weeks are needed to assess results. Longer-term follow-up was not indicated.<sup>19,</sup>

#### **Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

### **Review of Evidence**

#### Systematic Review

A 2005 systematic review evaluating the applicability and efficacy of eye exercises found no clear scientific evidence to support the use of eye exercises for other disorders (e.g., learning disabilities, dyslexia), except convergence insufficiency.<sup>2,</sup>

#### **Randomized Controlled Trials**

Two studies focused on the use of tinted lenses and eye patching as a technique to steady binocular vision for dyslexia. Stein et al (2000) reported on results of a randomized trial in which 143 dyslexic children were instructed to wear yellow-tinted glasses with or without the left lens occluded.<sup>20,</sup> Children were instructed to wear these glasses when reading or writing. Significantly more children given occluded glasses gained stable binocular vision in the first 3 months (59%) compared with children given unoccluded glasses (36%). Christenson et al (2001), however, found no difference in reading ability of children with dyslexia and abnormal binocular vision tested with and without occluded, blue-tinted lenses.<sup>21,</sup>

### Nonrandomized Comparative Studies

Ramsay et al (2014) reported on results from a non-RCT assessing a computerized vergence training program in 13- to 14-year-old patients with dyslexia.<sup>19,</sup> Twelve subjects with dyslexia were treated

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with the computerized vergence training program, receiving an average of 11.75 sessions over 5 weeks; 12 control students included were not treated. All subjects underwent vision testing and were not diagnosed with convergence insufficiency. The computerized training program involved the generation of a computerized stereogram, which appears in 3 dimensions with convergent vision. For the intervention groups, reading speed improved from 87.83 to 95.58 words read per minute from baseline to follow-up (p<0.006); reading speed was unchanged from baseline to follow-up for the control group (85.00 words per minute at baseline to 89.37 words per minute at follow-up; p<0.123). Mean improvement in reading speed from baseline to follow-up did not differ significantly between groups (p<0.123).

Several studies have reported that poor reading in children with dyslexia or attention deficits may be related to impairments in accommodation or convergence, suggesting the need for an ophthalmologic and orthoptic evaluation.<sup>22,23,24,</sup>

### Section Summary: Orthoptic Training for Learning Disabilities

Peer-reviewed studies have not directly demonstrated improvements in reading or learning outcomes with orthoptic training. At least 2 earlier studies that addressed other types of vision therapies reported mixed improvements in reading.

# Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

# Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 4 physician specialty societies (5 reviewers) and 3 academic medical centers while this policy was under review in 2011. Although input supported the use of office-based orthoptic training when home-based therapy had failed, some reviewers indicated that home-based therapy would typically include more exercises than pencil push-ups. Recommended were push-up exercises using an accommodative target, push-up exercises with additional base-out prisms, jump-to-near convergence exercises, stereogram convergence exercises, recession from a target, and maintaining convergence for 30 to 40 seconds.

#### **Practice Guidelines and Position Statements**

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

#### American Academy of Pediatrics et al

In 2009 (reaffirmed in 2014<sup>25</sup>), the American Academy of Pediatrics, American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus, and the American Association of Certified Orthoptists issued a joint policy statement on pediatric learning disabilities, dyslexia, and vision. For vision therapy, the statement concluded:

"Currently, there is no adequate scientific evidence to support the view that subtle eye or visual problems cause learning disabilities. Furthermore, the evidence does not support the concept that vision therapy or tinted lenses or filters are effective, directly or indirectly, in the treatment of learning disabilities. Thus, the claim that vision therapy improves visual efficiency cannot be

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substantiated. Diagnostic and treatment approaches that lack scientific evidence of efficacy are not endorsed or recommended."

In 2011, these same 4 associations also published a joint technical report on learning disabilities, dyslexia, and vision.<sup>1,</sup> This report concluded: "There is inadequate scientific evidence to support the view that subtle eye or visual problems cause or increase the severity of learning disabilities.... 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."

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### **Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

# Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 5.

Table 5. Summary of Key Trials

| NCT No.    | Trial Name  | Planned<br>Enrollmen | Completion<br>t Date |
|------------|---|----------------------|----------------------|
| Ongoing    |   |                      |                      |
| NCT0390811 | 2 Interventions for Convergence Insufficiency in Concussed Children (ICONICC) | 264                  | March 2025           |

NCT: national clinical trial.

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# **Documentation for Clinical Review**

# Please provide the following documentation:

- History and physical and/or consultation notes including:
  - o Reason for therapy and proposed duration/number of sessions
  - o Documentation of any current symptoms

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- o Documentation of convergence insufficiency and stereoacuity
- o Prior treatment (type and duration; home or office)

### Post Service (in addition to the above, please include the following):

• Quantifiable measurements/percentage of improvement

# Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

| Туре  | Code  | Description   |
|-------|-------|---|
|       | 92065 | Orthoptic training; performed by a physician or other qualified health  |
| CPT®  | 92003 | care professional <i>(Code revision effective 1/1/2023)</i>             |
| CPI   | 92066 | Orthoptic training; under supervision of a physician or other qualified |
|       | 92000 | health care professional <i>(Code effective 1/1/2023)</i>               |
| HCPCS | V2799 | Vision item or service, miscellaneous                                   |

# **Policy History**

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

| Effective Date | Action   |
|----------------|--|
| 10/09/1996     | New Policy Adoption  |
| 06/01/2001     | Policy Review  |
| 00/01/2001     | Policy Statement Unchanged   |
| 12/18/2009     | Policy revision without position change  |
| 07/01/2011     | Policy title change from Orthoptics for Learning Disabilities with position change |
| 04/30/2015     | Policy title change from Orthoptic Training  |
| 04/30/2013     | Policy revision without position change  |
| 05/01/2016     | Policy revision without position change  |
| 05/07/2017     | Policy revision without position change  |
| 05/01/2018     | Policy revision without position change  |
| 05/01/2019     | Policy revision without position change  |
| 05/01/2020     | Annual review. No change to policy statement. Literature review updated.           |
| 05/01/2021     | Annual review. No change to policy statement. Literature review updated.           |
| 02/01/2022     | Coding update.   |
| 05/01/2022     | Annual review. Policy statement, guidelines and literature review updated.         |
| 03/01/2023     | Coding update.   |
| 05/01/2023     | Annual review. Policy statement and literature review updated.                     |

# **Definitions of Decision Determinations**

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental**: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation**: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

# Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at <a href="https://www.blueshieldca.com/provider">www.blueshieldca.com/provider</a>.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: <u>MedPolicy@blueshieldca.com</u>

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

# Appendix A

| POLICY STATEMENT  |   |  |  |  |
|---|---|--|--|--|
| BEFORE  | AFTER   |  |  |  |
| Red font: Verbiage removed  | Blue font: Verbiage Changes/Additions   |  |  |  |
| Orthoptic Training for the Treatment of Vision or Learning Disabilities 9.03.03   | Orthoptic Training for the Treatment of Vision or Learning Disabilities 9.03.03   |  |  |  |
| Policy Statement:  I. Office-based vergence/accommodative therapy may be considered medically necessary when both of the following criteria are met:  A. Patients diagnosed with symptomatic convergence insufficiency  B. Symptoms have failed to improve following a minimum of 12 weeks of home-based therapy which may include any of the | Policy Statement:  I. Office-based vergence/accommodative therapy may be considered medically necessary when both of the following criteria are met:  A. Individuals with symptomatic convergence insufficiency  B. Symptoms have failed to improve following a minimum of 12 weeks of home-based therapy which may include any of the following: |  |  |  |
| following:  1. Jump-to-near convergence exercises  2. Maintaining convergence for 30 to 40 seconds  3. Push-up exercises using an accommodative target  4. Push-up exercises with additional base-out prisms  5. Recession from a target  6. Stereogram convergence exercises   | <ol> <li>Jump-to-near convergence exercises</li> <li>Maintaining convergence for 30 to 40 seconds</li> <li>Push-up exercises using an accommodative target</li> <li>Push-up exercises with additional base-out prisms</li> <li>Recession from a target</li> <li>Stereogram convergence exercises</li> </ol>                                       |  |  |  |
| II. Orthoptic eye exercises are considered <b>investigational</b> for the treatment of learning disabilities.   | II. Orthoptic eye exercises are considered <b>investigational</b> for the treatment of learning disabilities.   |  |  |  |
| <ul> <li>III. Orthoptic eye exercises are investigational for all other conditions, including but not limited to the following:</li> <li>A. Slow reading</li> <li>B. Visual disorders other than convergence insufficiency</li> </ul>   | <ul> <li>III. Orthoptic eye exercises are considered investigational for all other conditions, including but not limited to the following:         <ul> <li>A. Slow reading</li> <li>B. Visual disorders other than convergence insufficiency</li> </ul> </li> </ul>  |  |  |  |