Treatment Intervention Advisory Committee Review and Determination

Date: July 12, 2019

To: Wisconsin Department of Health Services

From: Wisconsin Department of Health Services Treatment Intervention Advisory Committee: Shannon Stuart, Ph.D. (chairperson)

RE: Determination of LearningRX as a proven and effective treatment for children and adults

☐ This is an initial review

☒ This is a re-review. Previously reviewed (rated) on July 25, 2014 (4) and July 31, 2015 (4), October 28, 2016 (4).

☒ No new research located; determination from October 28, 2016 (4) stands (details below)

Section One: Overview and Determination

Please find below a statement of our determination as to whether or not the committee views LearningRX as a proven and effective treatment. In subsequent sections you will find documentation of our review process including a description of the proposed treatment, a synopsis of review findings, the treatment review evidence checklist, and a listing of the literature considered. In reviewing treatments presented to us by the Department of Health Services, we implement a review process that carefully and fully considers all available information regarding a proposed treatment. Our determination is limited to a statement regarding how established a treatment is with regards to quality research. The committee does not make decisions regarding funding.

Description of proposed treatment

The LearningRx franchise is a network of over 85 "brain training" centers throughout the United States. Brain training (also referred to as cognitive training or cognitive remediation) is grounded in the concept of "neuroplasticity," which refers to the brain's ability to change or adapt. LearningRx is a brain-training program consisting of tasks specifically designed to strengthen underlying cognitive skills that are essential for reading and learning (e.g., auditory and visual processing; memory; attention). The training tasks are sequentially organized to move from simple to progressively more challenging exercises. The highly structured Learning Rx training is delivered during one-on-one sessions by certified LearningRx trainers (with the option for parents to provide a portion of the training at home). An important component of the training is the use of immediate reinforcement, consistent feedback, and repetition/drill to enhance the student's learning and mastery.

LearningRx includes two primary training programs; each program may be implemented entirely by certified LearningRx trainers, or through a combination of training sessions delivered by LearningRx trainers (50% of training) and by parents (50% of training).

(a) ThinkRx training (6 hours per week; 12 weeks) includes sequentially leveled tasks that focus on cognitive skills such as auditory processing, visual processing, and working memory. Because the pace

and progression through training tasks is regulated by each student's attainment of mastery, the number of tasks completed during sessions may differ from student to student. Whereas all cognitive skills are addressed, ThinkRx training is tailored to meet individual needs and to strengthen each student's deficient areas.

(b) ReadRx training (5 hours per week; 24 weeks) includes the ThinkRx procedures (above) as well as additional tasks focusing on auditory processing, basic decoding skills, fluency, comprehension, spelling, and writing.

Individuals who participate in the LearningRx program are evaluated at pre-training and post-training using the Woodcock-Johnson Tests of Cognitive Abilities (WJ-COG) and Woodcock Johnson Tests of Achievement (WJ-ACH).

Synopsis of current review (July 2019)
Committee members completing current review of research base: Tia Schultz and Shannon Stuart

Please refer to the reference list (Section Four) which details the reviewed research.

Reviewers found two studies that had been published since the last review. However, neither of the studies evaulated the intervention with individuals with developmental disabilities/ASD. The two studies are included in the reference list, but were not reviewed because they do not meet screen criteria for a full review.

Therefore, it is the decision of the committee that LearningRx retain a Level 4 - Insufficient Evidence (Experimental Treatment).

Committee's Determination: After reviewing the research and applying the criteria from the Treatment Review Evidence Checklist, it is the decision of the committee that LearningRX retain an efficacy rating of Level 4 - Insufficient Evidence (Experimental Treatment).

Review history
(October 2016- Shannon Stuart and Tia Schultz)
1.No new peer-reviewed research was found in the time period since the last review.

2. There are results from a survey prepared by Learning Rx and published on the Learning Rx website, "Client Outcomes and Research Results." Learning Rx developed a study that placed participants into three groups: 77 students who completed 60 hours of ThinkRxcognitive training; 69 students who completed 120 hours of ReadRx cognitive training, and a control group of 80 students who didn't undergo any training. They then surveyed parents of 226 school-age children who had been previously identified as having oppositional behavior and academic difficulties. Learning Rx reports that Both treatment groups saw a reduction in academic difficulty; the control group saw an increase in academic

difficulty;both treatment groups improved on ratings of oppositional behavior; the control group's ratings of oppositional behavior worsened.

There are severe limitations to the validity of the conclusions that LearningRx made due to (a) lack of randomization, (b) inherent self-selection bias in the treatment versus control groups, the number of participants are 206, however the number of parents surveyed is 226. The publication linked on the Learning Rx website seems in violation of the U.S. District Court for the District of Colorado decision that finds Learning Rx in violation of making unsubstantiated claims about the performance, benefits, or efficacy of their programs. See below.

3. The Federal Trade Commission (FTC) published a press release on May 18, 2016 saying that the developers and marketers of LearningRx "brain training" agreed to stop claiming that their programs were clinically proven to permanently improve serious health conditions like ADHD, autism, dementia, Alzheimer's disease, strokes, and concussions and that the training substantially improved school grades, college admission test scores, career earnings, and job and athletic performance. Further, The developers and marketers of the LearningRx "brain training" agreed to pay $200,000 under a settlement with the FTC. According to the FTC's complaint, LearningRx Franchise Corp. and its CEO, Dr. Ken Gibson, deceptively claimed that their programs were clinically proven to permanently improve serious health conditions like ADHD, autism, dementia, Alzheimer's disease, strokes, and concussions and that the training substantially improved school grades and college admission test scores, career earnings, and job and athletic performance. They also allegedly claimed that LearningRx brain training is 10 times more cost-effective than tutoring. According to the FTC, the defendants promoted LearningRx through LearningRx.com and affiliated websites, as well as through a blog, Facebook and Twitter posts, print and radio ads, and direct mail pieces. They also allegedly used Google search ads to target consumers searching for terms such as "cure for ADD," "autism cure," "Asperger cure," and "severe traumatic brain injury cure." The defendants, based in Colorado Springs, Colorado, offered LearningRx training through more than 80 LearningRx centers that it franchised in 25 states.

The proposed order settling the FTC's charges prohibits the defendants from claiming that their programs improve performance at work or in athletics, or improve the cognitive function of individuals with age-related or other health conditions, unless the claims are not misleading and substantiated by human clinical testing. The order further prohibits the defendants from making unsubstantiated claims about the performance, benefits, or efficacy of their programs, including claims about improvement in school grades or scores on standardized academic tests, performance on everyday tasks, increased income, or superiority to academic tutoring. Finally, the order prohibits the defendants from misrepresenting the existence or results of any tests or studies, and from providing others with the means to make the prohibited claims.

The order imposes a $4,000,000 judgment against the company, which will be suspended upon the payment of $200,000 as disgorgement of ill-gotten gains.
The Commission vote authorizing the staff to file the complaint and proposed stipulated final judgment and order was 3-0. The complaint and order were filed in the U.S. District Court for the District of Colorado. NOTE: The Commission files a complaint when it has "reason to believe" that the law has been or is being violated and it appears to the Commission that a proceeding is in the public interest. Stipulated final orders have the force of law when approved and signed by the District Court judge.

https://www.ftc.gov/news-events/press-releases/2016/05/marketers-one-one-brain-training-programs-settle-ftc-charges
Therefore, it is the decision of the committee that LearningRX retain a Level 4 - Insufficient Evidence (Experimental Treatment).

(July 2015 - Jeff Tiger and Shannon Stuart)
No additional research has been published since the previous review. Therefore, it is the decision of the committee that LearningRX retain a Level 4 - Insufficient Evidence (Experimental Treatment).

(July 2014 - Maribeth Gettinger and Shannon Stuart)
Six documents were reviewed. Of these, three are dissertations, two are unpublished reports of data analyses, and one is a 2011 report prepared by Learning Rx (based on 2009 data). All documents are available through the LearningRx website.

LearningRx has several thousand students who complete the program at training centers nationwide each year, which produces extensive data (pre- to post-training) on measures of cognitive functioning (primarily, WJ-COG and WJ-ACH). The unpublished reports and dissertations (listed below) have used these archival data (provided by LearningRx) and reported statistically significant changes in test scores (from pretest to posttest).

Two studies cited in the reference list (Carpenter, 2009; Pfister, 2012) utilized a control group. For each study, however, the "control group" was comprised of children who completed pretesting, but whose parents opted not to enroll their child in the LearningRx program. As such, there are severe limitations to the validity of the conclusions that LearningRx students made greater cognitive gains than did control students due to (a) lack of randomization, and (b) inherent self-selection bias in the treatment versus control groups.

The committee's conclusions regarding LearningRx include:

- The committee has been unable to identify any scientific studies of the effectiveness of the LearningRx program for children with ASD published in peer-reviewed journals.

- Based on the LearningRx report of 2009 training results, a small percentage of children who participated in LearningRx were diagnosed with ASD (approximately 5%). Moreover, the reported gains on the primary outcome measures (Woodcock-Johnson Tests of Cognitive Abilities and Woodcock-Johnson Tests of Achievement) are not disaggregated by disability status in the LearningRx report. As such, it is not possible to document outcomes for individuals with ASD and/or other developmental disabilities.

- To date, there have been no studies (published or unpublished) conducted independent of the involvement of the LearningRx franchise (i.e., training and assessment are conducted through LearningRx centers).

In sum, it is the decision of the committee that Learning Rx has insufficient evidence and, at this time, is assigned a Level 4 rating.

Section Two: Rationale for Focus on Research Specific to Comprehensive Treatment Packages (CTP) or Models

In the professional literature, there are two classifications of interventions for individuals with Autism Spectrum Disorder (National Research Council, 2001; Odom et al., 2003; Rogers & Vismara, 2008):

(a) **Focused intervention techniques** are individual practices or strategies (such as positive reinforcement) designed to produce a specific behavioral or developmental outcome, and

(b) **Comprehensive treatment models** are "packages" or programs that consist of a set of practices or multiple techniques designed to achieve a broader learning or developmental impact.

To determine whether a treatment package is proven and effective, the Treatment Intervention Advisory Committee (TIAC) will adopt the following perspective as recommended by Odom et al. (2010):

The individual, focused intervention techniques that make up a comprehensive treatment model may be evidence-based. The research supporting the effectiveness of separate, individual components, however, does *not* constitute an evaluation of the comprehensive treatment model or "package." The TIAC will consider and review only research that has evaluated the efficacy of implementing the comprehensive treatment *as a package*. Such packages are most often identifiable in the literature by a consistently used name or label.

National Research Council. (2001). *Educating children with autism.* Washington, DC: National Academy Press.

Odom, S. L., Brown, W. H., Frey, T., Karusu, N., Smith-Carter, L., & Strain, P. (2003) Evidence-based practices for young children with autism: Evidence from single-subject research design. *Focus on Autism and Other Developmental Disabilities, 18,* 176-181.

Odom, S. L., Boyd, B. A., Hall, L. J., & Hume, K. (2010). Evaluation of comprehensive treatment models for individuals with Autism Spectrum Disorders. *Journal of Autism and Developmental Disorders, 40,* 425-436.

Rogers, S., & Vismara, L. (2008). Evidence-based comprehensive treatments for early autism. *Journal of Clinical Child and Adolescent Psychology, 37,* 8-38.

Section Three: TIAC Treatment Review Evidence Checklist

Name of Treatment: LearningRX

Level 1- Well Established or Strong Evidence (DHS 107 - Proven & Effective Treatment)

- ☐ Other authoritative bodies that have conducted extensive literature reviews of related treatments (e.g., National Standards Project, National Professional Development Center) have approved of or rated the treatment package as having a strong evidence base; authorities are in agreement about the level of evidence.
- ☐ There exist ample high quality studies that demonstrate experimental control and favorable outcomes of treatment package.
  - ☐ Minimum of two group studies or five single subject studies or a combination of the two.
  - ☐ Studies were conducted across at least two independent research groups.
  - ☐ Studies were published in peer reviewed journals.
- ☐ There is a published procedures manual for the treatment, or treatment implementation is clearly defined (i.e., replicable) within the studies.
- ☐ Participants (i.e., N) are clearly identified as individuals with autism spectrum disorders or developmental disabilities.

Notes: At this level, include ages of participants and disabilities identified in body of research

Level 2 – Established or Moderate Evidence (DHS 107 - Proven & Effective Treatment)

- ☐ Other authoritative bodies that have conducted extensive literature reviews of related treatments (e.g., National Standards Project, NPDC) have approved of or rated the treatment package as having at least a minimal evidence base; authorities may not be in agreement about the level of evidence.
- ☐ There exist at least two high quality studies that demonstrate experimental control and favorable outcomes of treatment package.
  - ☐ Minimum of one group study or two single subject studies or a combination of the two.
  - ☐ Studies were conducted by someone other than the creator/provider of the treatment.
  - ☐ Studies were published in peer reviewed journals.
- ☐ Participants (i.e., N) are clearly identified as individuals with autism spectrum disorders or developmental disabilities.

Notes: at this level, include ages of participants and disabilities identified in body of research

Level 3 – Emerging Evidence (DHS 107 – Promising as a Proven & Effective Treatment)

☐ Other authoritative bodies that have conducted extensive literature reviews of related treatments (e.g., National Standards Project, NPDC) have recognized the treatment package as having an emerging evidence base; authorities may not be in agreement about the level of evidence.
☐ There exists at least one high quality study that demonstrates experimental control and favorable outcomes of treatment package.
  ☐ May be one group study or single subject study.
  ☐ Study was conducted by someone other than the creator/provider of the treatment.
  ☐ Study was published in peer reviewed journal.
☐ Participants (i.e., N) are clearly identified as individuals with autism spectrum disorders or developmental disabilities.

Notes: At this level, include ages of participants and disabilities identified in body of research

Level 4 – Insufficient Evidence (Experimental Treatment)

☐ Other authoritative bodies that have conducted extensive literature reviews of related treatments (e.g., National Standards Project, NPDC) have not recognized the treatment package as having an emerging evidence base; authorities are in agreement about the level of evidence.
☒ There is not at least one high quality study that demonstrates experimental control and favorable outcomes of treatment package.
  ☒ Study was conducted by the creator/provider of the treatment.
  ☒ Study was not published in a peer reviewed journal.
☐ Participants (i.e., N) are not clearly identified as individuals with autism spectrum disorders or developmental disabilities.

Notes:

Level 5 – Untested (Experimental Treatment) &/or Potentially Harmful

☐ Other authoritative bodies that have conducted extensive literature reviews of related treatments (e.g., National Standards Project, NPDC) have not recognized the treatment package as having an emerging evidence base; authorities are in agreement about the level of evidence.
☐ There are no published studies supporting the proposed treatment package.

☐ **There exists evidence that the treatment package is potentially harmful.**
  ☐ Authoritative bodies have expressed concern regarding safety/outcomes.
  ☐ Professional bodies (i.e., organizations or certifying bodies) have created statements regarding safety/outcomes.

Notes: At this level, please specify if the treatment is reported to be potentially harmful, providing documentation

References Supporting Identification of Evidence Levels:

Chambless, D.L., Hollon, S.D. (1998). Defining empirically supported therapies. *Journal of Consulting and Clinical Psychology, 66(1)* 7-18.

Chorpita, B.F. (2003). The frontier of evidence---based practice. In A.E. Kazdin & J.R. Weisz (Eds.). *Evidence-based psychotherapies for children and adolescents* (pp. 42---59). New York: The Guilford Press.

Odom, S. L., Collet-Klingenberg, L., Rogers, S. J., & Hatton, D. (2010). Evidence-based practices in interventions for children and youth with autism spectrum disorders. *Preventing School Failure, 54(4),* 275-282.

Section Four: Literature Review

Literature reviewed for current determination:

Carpenter, D. M., Ledbetter, C., & Moore, A. L. (2016). LearningRx Cognitive Training effects in children ages 8-14: A radomized controlled trial. Applied Cognitive Psychology, 30, 815-826. (not reviewd because participants did not have a developmental disability)

Hill, O. W., Serpell, Z., & Faison, M. O. (2016). The efficacy of the LearningRx Cognitive Training Program: Modality and transfer effects. The Journal of Experimental Education, 84(3), 600-620. (not reviewed because participants did not have a developmental disability)

Literature reviewed for previous determinations:

**Carpenter, D. (2009). Testing the effects of LearningRx: 2009 control group study. Unpublished report. Colorado Springs, CO: University of Colorado – Colorado Springs. http://www.learningrx.com/downloads/2009-control-group-study-29-july-09.pdf

**Jedlicka, E. J. (2012). The real-life benefits of cognitive training. Unpublished dissertation. Minneapolis, MN: Capella University. http://www.learningrx.com/downloads/Dissertation_Jedlicka_2012.pdf

**LearningRx. (2011). 2011 report of LearningRx training results. Colorado Springs, CO: Author. http://www.learningrx.com/brain-train

LearningRx. (2014). 2014 report of LearningRx training results (expanded edition). Colorado Springs, CO: Author. http://www.learningrx.com/brain-training-results.htm#downloadForm

Luckey, A. J. (2009). Cognitive and academic gains as a result of cognitive training. Unpublished dissertation. Tempe, AX: Arizona State University.

**Marachi, R. (2006). Statistical analysis of cognitive change with LearningRx training procedures. Unpublished report. Northridge, CA: California State University at Northridge. http://www.learningrx.com/downloads/2005-test-results-all-graduates.pdf

Pfister, B. E. (2012). The effect of cognitive rehabilitation therapy on memory and processing speed in adolescents. Unpublished dissertation. Minneapolis, MN: Capella University.

**Materials submitted to DHS for review.