Treatment Intervention Advisory Committee Review and Determination

Date: April 28, 2017

To: DHS/DLTC

From: Wisconsin Department of Health Services Autism and other Developmental Disabilities Treatment Intervention Advisory Committee: Lana Collet-Klingenberg, Ph.D. (Chairperson), Shannon Stuart (Interim-Chairperson)

RE: Determination of Mendability as a proven and effective treatment for individuals with autism spectrum disorder and/or other developmental disabilities

☐ This is an initial review

☒ This is a re-review. The initial review was 1/31/14; re-reviews on 10/31/14 and 10/30/15.

Section One: Overview and Determination

Please find below a statement of our determination as to whether or not the committee views Mendability as a proven and effective treatment for children with autism spectrum disorder and/or other developmental disabilities. 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 DHS/DLTC, 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 practice is in regard to quality research. We do not make funding decisions.

Description of proposed treatment

Mendability (the copyrighted name of the treatment package) is described by its developers as sensory enrichment therapy. The website is at: https://www.mendability.com and makes scientific claims and now includes two references to research, one reviewed in the October 2015 review (Woo & Leon, 2013) and the other reviewed in this re-review (Woo, Donnelly, Steinberg-Epstein, & Leon, 2015). The authors of the two peer reviewed articles documenting its effectiveness described it as "daily exposure to multiple sensorimotor stimuli, distributed throughout the day." Parents of the children in the study received a kit that include scented oils, a variety of textures, manipulatives, pictures of a variety of paintings and objects, music/CD player, water bowls, and Play-Doh. Parents were also given a list of other materials to provide such as a wooden plank for a walking exercise, soap and oils, a bowl, metal spoons, ice, blindfold, noise maker, picture book, cookie sheet, oven dish, mirror, ball, pill, markers and music with matching pictures. The children received stimulation with the materials in a very scripted fashion throughout the day each day (e.g., fragrance exposure four times a day as well as at night, classical music once a day, 4-7 additional sensorimotor enrichment exercises twice a day).

Synopsis of review

In the case of Mendability please refer to the attached reference listing that details the reviewed research. The committee's conclusions regarding Mendability include the following findings:

- The previous re-review in October 2015 described the only research article found specific to the practice titled, "Mendability." The authors of this research (and creators of the Mendability program) include in the article's reference list and on the Mendability website many references to research and other publications that are not specific to the practice as defined. Many of these sources refer to rodent studies, other treatments specific to ASD, and descriptions of the types and possible causes of ASD and while perused to determine appropriateness for inclusion in this review, were deemed unacceptable so are not included here.

- The previous re-review in October 2015 described the Woo and Leon (2013) study (cited on the website) that focused on the systematic application of sensory enrichment therapy, which they term "Environmental Enrichment" (i.e., Mendability) over a six-month period resulted in significantly greater improvement, or gains, in both Childhood Autism Rating Scale scores and Leiter-R Visualization and Reasoning scores compared to the standard care group (controlling for pre-intervention, or baseline, scores) with 28 male children between the ages of 3 and 12 years with a diagnosis of autism. There are concerns regarding the rigor of this study related to validity of parent provided data as parents were part of both treatment and data reporting. Further concerns relate to the size of the group (28) and power of findings.

- Since the October 2015 re-review two additional studies have been located. One is an extension of the Woo & Leon, 2013 study, *Environmental Enrichment as a Therapy for Autism: A Clinical Trial Replication and Extension* by Woo, Donnelly, Steinberg-Epstein, & Leon. This was a peer-reviewed paper published in *Behavioral Neuroscience*. The focus was on children with Autism (moderate to severe) aged 3-6. There were three groups, a control, partial treatment (excluded olfactory, olfactory/tactile and music exercise) and a full treatment group. Participants were recruited from the first authors clinic and began with 97 participants and concluded with 50 after 6 months (control N = 27; final N = 22; partial N = 30; final N = 13; full N = 34; final N = 15). Possible explanation included too much time to set-up and complete daily exercises, some newly diagnosed and searched/found alternative treatments as to why 48% dropped out of the study. The differences between the results for the partial and full treatment group were not seen as significant therefore the authors pooled the data from these two groups (N = 28) to compare to the control group (N =22). All continued standard care and some similar measures as the Woo & Leon 2013 (Leiter-R) with the addition of the ADOS, Reynell Developmental Language Scales, Short Sensory Profile (parent completed) and parent daily logs (not collected for controls; used to assess compliance). Findings were similar in that improvements in the Leiter-R (+13,34 vs + 7.43), Reynell (+7.42 vs + 3.63), and Short profile (+11.36 vs. +2.85) were observed for the combined treatment group compared to the control group at 6 months. The authors indicated that 21% of those in the combined treatment group no longer met criteria for Classic Autism (though still on the spectrum) and none of the controls changed categories. There continue to be methodological, enrollment, and procedural limitations of this study that were similar and expanded from the Woo & Leon, 2013 study.

- The second study, *Environmental Enrichment Therapy for Autism: Outcomes with Increased Access* by Aronoff (Chairman/Co-Founder of Mendability website), Hillyer (identified as a Security Officer and Product Development Manager on the Mendability website) & Leon (2016). This study was published in *Neural Plasticity,* which indicates the manuscripts are peer-reviewed. It is also an open-source journal that requires authors to pay $2,000 upon acceptance of their manuscript for publication. This study included 1,002 children in a retrospective (from pre and post parent report) non-concurrent multiple baseline (MBL) design (however no MBL graphs were presented or discussed). The study had parents self-select to identify their child as having autism to enroll across the spectrum (559 identified as having an autism dx; 41 Asperger's dx; 30 "probable" autism; 31 PDD; 18 ADHD; 10 global DD; 42 "other" disorders, 271 no diagnosis identified by the parent. The age range was from 1-18; 835 paid to use the online Mendability site program and 167 received the program at no cost. The mendability, enriched environment was individualized for each participant via the use of an online software program and delivered in the form of worksheets every two weeks for up to 7 months. These were to be used 1-2 times per day plus 4-6 olfactory or tactile stimuli presented as well. The children were also participating in other therapies. Evaluation was based on OT review of the parent completed worksheets and parent ratings to 301 questions probing symptoms of autism from 0 (could not be worse) to 5 (not a problem). Parents completed ratings each 2 week period until they self-selected to stop participating in the study. The range of participation was 1 to more than 6 months (174 1 month; 144 2 months; 81 3months, 65 4 months, 79 5 months, 59 6 months and 400 for more than 6 months). The authors reported that an "intention to treat" analysis demonstrated significant overall gains for a wide variety of symptoms such as memory , motor skills, attention span, eating, sleeping, communication, and mood/autism symptoms. They identified compliant (parents completed 10+ worksheets in 6 months) and noncompliant (parents completed 1-3 worksheets but remained in treatment for 6 months) parents. They found both groups improved significantly with compliant parent children doing better overall. There are a number of limitations in the recruitment, methodology, reporting of results, and data collection with this study.

- Neither the National Standards Project's 2009 report or the National Professional Development Center on Autism Spectrum Disorders initial review in 2009 found any evidence to support the use of a Sensory Integration Treatment Package. Recently the National Professional Development Center on Autism Spectrum Disorders published a follow up review, dated 2014, in which they identified two sensory-based treatments as having some support in the research literature, but still considered as insufficient evidence. These practices are Sensory Diet and Sensory Integration and Fine Motor Intervention.

- Finally, the most recent search of Ebscohost and other academic search engines revealed only two press releases; one detailing that the organization had earned The Joint Commission's Gold Seal of Approval for Behavioral Health Care, and another that they had released a new version of their program at the 2015 Autism Society of America Conference.

These recent findings were also taken into consideration as part of this determination recommendation.

The committee's conclusions regarding Mendability:

- There are limited data available to draw meaningful conclusions about its efficacy with three research studies (Woo & Leon, 2013; Woo et al., 2015, Aronoff et al., 2016) that include several methodological limitations.
- To date, no authoritative bodies have recognized this as having an evidence base.
- There are many research articles referenced by the developers of Mendability that was not directly conducted to evaluate Mendability and some are conducted with rats rather than with people.

In sum, it is the decision of the committee that Mendability meets criteria for Level 4, insufficient evidence (DHS 107 – Experimental Treatment).

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: DLTC-TIAC Treatment Review Evidence Checklist

Name of Treatment: Craniosacral Therapy

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: Three published studies lack experimental control and high quality methodology for evaluation of results.

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

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Date: October 30, 2015

Committee Members Completing Initial Review of Research Base: Jenny Asmus, Lana Collet-Klingenberg

Committee Decision on Level of Evidence to Suggest the Proposed Treatment is Proven and Effective: *Level 4 – Insufficient Evidence (Experimental Treatment)*

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

April 2017 Literature Reviewed:

Aronoff, E., Hillyer, R., and Leon, M. Environmental Enrichment Therapy for Autism: Outcomes with Increased Access (2016). *Neural Plasticity*, (2016) 2016, 23 pages. doi:10.1155/2016/2734915

Woo, C.C., Donnelly, J.H., Steinberg-Epstein, R., & Leon, M. (2015). Environmental enrichment as a therapy for autism: A clinical trial replication and extension. *Behavioral Neuroscience*, *129*, 412-422.

October 2015 Literature Reviewed:

Woo, C.C., & Leon, M. (2013). *Environmental enrichment as an effective treatment for autism: A randomized controlled trial*. Behavioral Neuroscience, 127(4), 487-497.