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 Chelation as a proven and effective treatment for individuals with autism spectrum disorder and/or other developmental disabilities

This is a re-review; the initial review was 10/31/14 and the second review was 10/30/15

Section One: Overview and Determination

Please find below a statement of our determination as to whether or not the committee views Chelation 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 the 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

Chelation is a chemical ablation procedure that typically involves patients receiving succimer to reduce the presence of heavy metals (e.g., lead, copper, cadmium, and mercury). It was hypothesized that such metals, especially the presence of mercury found in the MMR vaccination caused ASD.

Chelation is approved for lead removal and for some other medical procedures involving heart treatments but was found to be (a) ineffective in reducing ASD symptoms and (b) a procedure with a high degree of risk in that succimer was found in lower animals to produce permanent developmental disabilities in persons where lead was not present. The existence of that data plus others questioning Chelation's efficacy led the NIHM to terminate clinical trials on the basis of ethical considerations of the risks entailed.

Synopsis of review

In the case of Chelation, please refer to the attached reference list detailing reviewed research. No new studies have been found with this review. Thus, the committee's conclusions regarding Chelation from the previous reviews are maintained, including:

1. A lack of proven efficacy and indeed comparison studies indicating no treatment effects.
2. The FDA's and AMA's concerns regarding health risks in the use of Chelation (succimer, in particular).
3. The current ethical declarations against the use of Chelation from medial and behavioral researchers.

4 The pattern of possessing little data in the context of excessive efficacy claims that led researchers and practitioners to question the effects of marketing-vs-data to support Chelation's use.

In sum, it is the decision of the committee that Chelation receive a rating of *Level 5 – Untested (Experimental Treatment) &/or Potentially Harmful*

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: Chelation

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: Chelation is repeatedly reported to be harmful and clinical trials were stopped thus indicating that its use should not be considered.

Date: 4/28/17
Committee Members Completing Initial Review of Research Base: Lana Collet-Klingenberg, Jenny Asmus

Committee Decision on Level of Evidence to Suggest the Proposed Treatment is Proven and Effective: Level 5--*Untested (Experimental Treatment) &/or Potentially Harmful*

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

Davis, T. EDITORIAL: Unsubstantiated treatments for individuals with autism., (2010). Developmental Neurorehabilitation, August, 13(4): 231–233.

Tonya N. Davis a,, Mark O'Reilly, Soyeon Kang, Russell Lang, Mandy Rispoli, Jeff Sigafoos, Giulio Lancioni, Daelynn Copeland, Shanna Attai, Austin Mulloy (2013). Chelation treatment for autism spectrum disorders: A systematic review
Research in Autism Spectrum Disorders, Research in Autism Spectrum Disorders 7 (2013) 49–55

Giuseppe De Palma, • Simona Catalani, •Anna Franco, • Maurizio Brighenti, • Pietro Apostoli. (2011). Lack of Correlation Between Metallic Elements Analyzed in Hair
by ICP-MS and Autism Published online: 19 April 2011. J Autism Dev Disord (2012) 42:342–353. DOI 10.1007/s10803-011-1245-6

Mike Mitka (2008). Chelation Therapy Trials Halted. Journal off the American Medical Association. Medical News & Perspectives | November 19, 2008--*JAMA.* 2008;300(19):2236. doi:10.1001/jama.2008.607. http://jama.jamanetwork.com.ezproxy.library.wisc.edu/article.aspx?articleid=182916

Burton Norman Seitler, PhD. (2011) Intricacies, Complexities, and of Research on Autism Treatments: An Examination of Seven Treatment Approaches Limitations. *Ethical Human Psychology and Psychiatry, Volume 13, Number 2.* DOI: 10.1891/1559-4343.13.2.155

Donald Smith & Barbara J. Strupp (2013) The Scientific Basis for Chelation: Animal Studies and Lead Chelation. Published online: 12 October 2013 *J. Med. Toxicol*. (2013) 9:326–338 DOI 10.1007/s13181-013-0339-2