

Treatment Intervention Advisory Committee Review and Determination

Date: July 25, 2014

To: DHS/DLTC

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

RE: Determination of Hyperbaric Oxygen Therapy 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 Date of initial review

Section One: Literature Review and Determination

Please find below a statement of our determination as to whether or not the committee views Hyperbaric Oxygen Therapy 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, a listing of the literature considered, and the treatment review evidence checklist. 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.

In the case of Hyperbaric Oxygen Therapy, please refer to the attached reference listing that details the reviewed research. The committee's conclusions regarding Hyperbaric Oxygen Therapy include:

- There is a lack of evidence supporting effectiveness of Hyperbaric Oxygen Therapy
- Only one study related to Hyperbaric Oxygen Therapy use with Autism.
- Documented concerns for potential harm and warnings of danger of Hyperbaric Oxygen Therapy

In sum, it is the decision of the committee that Hyperbaric Oxygen Therapy has committee found it has no proven efficacy and, in fact, may be harmful. Therefore we recommend a Level 5 rating – experimental with potential for harm.

Description of Proposed Treatment:

Hyperbaric Oxygen Therapy (HBOT) involves inhaling up to 100% oxygen at a pressure greater than one atmosphere (atm) in a pressurized chamber. Most typical indications for HBOT involve the use of hyperbaric pressures above 2.0 atm. Higher atmospheric pressures are used to treat conditions such as carbon monoxide poisoning and to improve wound healing. In some studies, the use of oxygen appears to enhance neurological function. Because of these outcomes, some investigators have used HBOT to treat certain neurological disorders, including chronic and traumatic brain injury, as well as fetal alcohol syndrome, and clinical improvements in these patients have been observed. Given this background,

some physicians have also applied similar lower hyperbaric pressures of 1.3 to 1.5 atm in autistic individuals, with oxygen concentrations ranging from 21% to 100%.

Synopsis of Review Findings:

The materials found related to Hyperbaric Oxygen Therapy only included one experimental study on children diagnosed with Autism. The study is a trial study only and focuses on the effect HBOT has on brain chemicals and not on behavioral outcomes. On the basis of the lack of research to review, we have to recommend a level 5 – untested to this treatment.

Literature Reviewed

Rossignol, D. A., Rossignol, L.W., James, S. J., Melnyk, S., and Mumper, E. (2007). The effects of hyperbaric oxygen therapy on oxidative stress, inflammation, and symptoms in children with autism: an open-label pilot study. *BMC Pediatrics*, 7-36.

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: Hyperbaric Oxygen 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 exists ample high quality studies that demonstrate experimental control and favorable outcomes of treatment package
 - o Minimum of two group studies or five single subject studies or a combination of the two
 - o Studies were conducted across at least two independent research groups
 - o 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 exists at least two high quality studies that demonstrate experimental control and favorable outcomes of treatment package
 - o Minimum of one group study or two single subject studies or a combination of the two
 - o Studies were conducted by someone other than the creator/provider of the treatment
 - o 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
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- 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:

Aetna considers the use of systemic HBOT experimental and investigational for treatment of autism because there is insufficient evidence in the medical literature establishing that systemic HBOT is more effective than conventional therapies (retrieved April 24, 2014, from Aetna Clinical Policy bulletin, aetna.com).

The FDA cautions against HBOT with the following statements (taken from consumer information publication, retrieved April 24, 2014, from - <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM366015.pdf>):

- hyperbaric oxygen therapy (HBOT) has not been clinically proven to cure or be effective in the treatment of cancer, autism, or diabetes.
- Patients receiving HBOT are at risk of suffering an injury that can be mild (such as sinus pain, ear pressure, painful joints) or serious (such as paralysis, air embolism). Since hyperbaric chambers are oxygen rich environments, there is also a risk of fire.

Date: July 25, 2014

Committee Members Completing Initial Review of Research Base: Brooke Winchell, Ph.D., Lana Collet-Klingenberg, Ph.D.

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.

Version date 4.14.14

TIAC EBP Literature Review
Article Inclusion Checklist Answers and Rationale

Article Reference:	Rossignol, D. A., Rossignol, L.W., James, S. J., Melnyk, S., and Mumper, E. (2007). The effects of hyperbaric oxygen therapy on oxidative stress, inflammation, and symptoms in children with autism: an open-label pilot study. <i>BMC Pediatrics</i> , 7-36.
IV Description	Hyperbaric Oxygen Therapy (HBOT) involves inhaling up to 100% oxygen at a pressure greater than one atmosphere (atm) in a pressurized chamber. Most typical indications for HBOT involve the use of hyperbaric pressures above 2.0 atm. Higher atmospheric pressures are used to treat conditions such as carbon monoxide poisoning and to improve wound healing. In some studies, the use of oxygen appears to enhance neurological function. Because of these outcomes, some investigators have used HBOT to treat certain neurological disorders, including chronic and traumatic brain injury, as well as fetal alcohol syndrome, and clinical improvements in these patients have been observed. Given this background, some physicians have also applied similar lower hyperbaric pressures of 1.3 to 1.5 atm in autistic individuals, with oxygen concentrations ranging from 21% to 100%.
DV	The primary dependent variable were levels of oxidative stress and levels of inflammation (Inflammatory marker – C Reactive protein)
# in study	N = 18
Age ranges	3-16 years old
Diagnoses	Autism
Study Results	Results of the study indicate children with autism; HBOT at a maximum pressure of 1.5 atm with up to 100% oxygen was safe and well tolerated. HBOT did not appreciably worsen oxidative stress and significantly decreased inflammation as measured by CRP levels. Parental observations support anecdotal accounts of improvement in several domains of autism.
Reviewer Comments	<p>Positive Comments:</p> <ul style="list-style-type: none"> • HBOT well-tolerated, no adverse effects with participants. <p>Concerns:</p> <ol style="list-style-type: none"> 1) Trial study with major design issues. No placebo-control group 2) Study only measures a brain chemical, not behavioral outcomes (i.e., parent report only). 3) Small sample size 4) Comparison groups not equal 5) Double-blind, controlled trials studies must be completed to provide definitive evidence for the efficacy of HBOT for the treatment of individuals with autism