Health Technology Clinical Committee
Findings and Coverage Decision
Topic: Applied Behavioral Analysis (ABA or ABA Therapy) based Behavioral Interventions for the Treatment of Autism Spectrum Disorder
Meeting Date: June 17, 2011
Final Adoption: September 16, 2011

Number and Coverage Topic
20110617A – Applied Behavioral Analysis (ABA or ABA Therapy) based Behavioral Interventions for the Treatment of Autism Spectrum Disorder

HTCC Coverage Determination

ABA based behavioral interventions for treatment of Autism Spectrum Disorder is a covered benefit with conditions

HTCC Reimbursement Determination

- Limitations of Coverage
  - Certain Applied Behavioral Analysis based behavioral interventions are a covered benefit for the treatment of Autism Spectrum Disorder when the following conditions are met:
  - The Early Intensive Behavioral/developmental Intervention (EIBI) using either the UCLA/Lovaas model or Early Start Denver Model (ESDM) are both covered with evidence development. Coverage will be provided for individuals receiving ABA as part of investigations meeting the following criteria
    1. A study must compare patients who do and do not receive ESDM or UCLA/LOVAAS early intensive behavioral intervention and have as its goal to monitor, evaluate, and improve clinical outcomes. In addition, it must meet the following basic criteria:
       - Appropriate characterization of children using validated and standardized assessment tools
       - Appropriate description of the intervention and comparator
       - Appropriate outcomes to be studied, identified in advance, measured using validated and specified measures, and studied for an appropriate time frame. Health outcomes must include either ASD severity or core ASD symptoms.
       - Identify in advance the method used to establish an adequate sample size to assess the outcome(s) identified
         - Identify the minimum clinical significant difference
    2. Written protocol and registration with clinical trials.gov and agreement to post results
    3. Institutional Review Board review and approval
    4. Certification that investigators have not been disqualified.
Non-Covered Indicators
- Applied Behavioral Analysis based behavioral interventions not using either the UCLA/Lovaas model or Early Start Denver Model (ESDM) within an investigational setting meeting the criteria.

Agency Contact Information

<table>
<thead>
<tr>
<th>Agency</th>
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<td>Public Employees Health Plan</td>
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<td>Health and Recovery Services Administration</td>
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Health Technology Background

The Applied Behavioral Analysis (ABA or ABA Therapy) based Behavioral Interventions for the Treatment of Autism Spectrum Disorder topic was selected and published in December 2009 to undergo an evidence review process. The supplemental information published was commissioned by the Washington HTA program to: (1) excerpt the behavioral intervention component of the systematic review conducted for AHRQ by Warren et al. 2011 and (2) to provide supplemental information on guidelines, cost and coverage policies to meet Washington's HTA program requirements.

The HTA program strives to make economical use of state resources and not duplicate high quality clinical evidence reviews. In this case, WA State was a nominator to AHRQ for the topic of ABA Therapy of treatment of Autism, and this topic was incorporated into the broader systematic review that AHRQ conducted on all therapies for treatment of Autism Spectrum Disorders. Thus, a separate clinical evidence search is not applicable here, as the clinical evidence search and summary is included in the systematic review prepared for the Agency for Healthcare Research and Quality (AHRQ), Comparative Effectiveness of Therapies for Children with Autism Spectrum Disorders, (Warren et al., 2011).

Applied behavioral analysis (ABA) is a general intervention approach for the treatment of ASD. It is a systemic application, at any time during a child’s day, of behavioral principles to modify behavior. Some ABA techniques involve instruction that is directed by adults in a highly structured fashion, while others make use of the learner’s natural interests and follow his or her initiations. Other techniques teach skills in the context of ongoing activities. All skills are broken down into small steps or components, and learners are provided many repeated opportunities to learn and practice skills in a variety of settings, with abundant positive reinforcement.

A range of interventions are available for the treatment of ASD and the symptoms commonly associated with ASD (e.g., anxiety, sensory difficulties). Treatments for ASD focus on improving core deficits in social communication, as well as addressing challenging behaviors to improve functional engagement in developmentally appropriate activities. Common behavioral strategies used in the treatment of ASD are based on learning theory and make use of procedures such as reinforcement, prompting, and shaping techniques to increase the rate of positive behaviors and reduce the frequency of unwanted behaviors. Positive reinforcement and other principles to build communication, play, social, academic, self-care, work, and community living skills and to reduce problem behaviors in individuals with ASD have been used by behavioral therapists.

The comprehensive, public and peer reviewed Applied Behavioral Analysis (ABA or ABA Therapy) based Behavioral Interventions for the Treatment of Autism Spectrum Disorder supplemental report is
An independent group of eleven clinicians who practice medicine locally meet in public to decide whether state agencies should pay for the health technology based on whether the evidence report and other presented information shows it is safe, effective and has value. The committee met on March 18th, reviewed the report, including peer and public feedback, and heard public and agency comments. Meeting minutes detailing the discussion are available through the HTA program or online at http://www.hta.hca.wa.gov under the committee section.

Committee Findings

Having considered the evidence based technology assessment report and the written and oral comments, the committee identified the following key factors and health outcomes, and evidence related to those health outcomes and key factors:

1. Evidence availability and technology features

   The evidence based technology assessment report indicates:

   - An evidence based technology assessment report on therapies for treatment of children with Autism Spectrum Disease (ASD), including Applied Behavioral Analysis (ABA) based behavioral interventions, was prepared by a federal research agency’s (AHRQ) national evidence based practice centers, Vanderbilt University. The public, comprehensive evidence report of about 900 pages for ASD Therapies, including ABA identified 4,120 potentially relevant articles, and included a detailed review of 159 studies; 78 of which were for Behavioral interventions; of which 34 papers on 30 trials included ABA based interventions. HTA, through its evidence based contractor, extracted the ABA Based behavioral intervention section of the AHRQ report and supplemented it with information required by the HTA program about agency experience, guidelines, coverage, and cost information. Both reports are published online and were subject to extensive public, peer, expert review and comments.

   - Autism spectrum disorders (ASD) are a group of pervasive developmental disorders characterized by impairments in communication, behavior and social interaction, and by repetitive patterns of behaviors and interests. Prevalence is estimated to be 1 in 110 children, with variation across states. Expression and severity of symptoms of ASDs differ widely. Treatments of ASD symptoms associated with ASD include a range of behavioral, psychosocial, educational, medical, and complementary approaches that vary by a child’s age and developmental status. There is no definitive evidence or consensus on most appropriate treatments. Common behavioral interventions used in the treatment of ASD are based on learning theory and use procedures such as reinforcement, prompting, and shaping techniques to increase the rate of positive behaviors and reduce the frequency of unwanted behaviors. Positive reinforcement and other principles to build communication, play, social, academic, self-care, work, and community living skills and to reduce problem behaviors in individuals with ASD have been used by behavioral therapists.

   - ABA is not a treatment or intervention: it is a method or technique used in many behavioral interventions to promote desirable behaviors and decrease undesirable behaviors using systematic reinforcement. There are numerous interventions in educational, community, behavioral health interventions that use ABA methods to treat many different conditions. ABA is a systemic application, at any time during a child’s day, of behavioral principles to modify behavior. Some ABA techniques involve instruction that is directed by adults in a highly structured fashion, while others make use of the learner’s natural interests and follow his or her initiations. Other techniques teach skills in the context of ongoing activities. All skills are broken down into small steps or components, and learners are provided many repeated
opportunities to learn and practice skills in a variety of settings, with abundant positive reinforcement.

- The committee also reviewed information provided by the state agencies, and public members; and heard comments from the evidence reviewer, clinical expert, HTA program, agency medical directors and the public.

2. **Is the technology safe?**

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is safe. Summary of committee considerations follows.

- The AHRQ conducted systematic review (Warren et. al.) did not have a specific key question focused on safety.

- ABA based behavioral interventions used in a variety of settings including the trials related to treatment for Autism Spectrum Disorder did not report adverse events (though it was not specifically a study question) and overall ABA has not been associated with adverse events.

- No major adverse events, morbidity or mortality was reported.

3. **Is the technology effective?**

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is effective. Summary of committee considerations follows.

- As noted previously, ABA is a method employed in behavioral interventions based on a learning theory and aimed at reducing certain behavior and promoting other behavior through reinforcement, promotion and shaping techniques. Treatment goals focus on reduction of core deficits in communication, social interactions, restricted behaviors because reducing these fundamental deficits may help children develop greater functional skills and independence.

- The evidence based technology assessment report indicates that there are over 100 different outcome measures included in the studies analyzed. The outcomes were grouped into 14 categories including adaptive behavior; adverse events/harms; anger; anxiety; ASD symptom severity; challenging behavior; hyperactivity; IQ/ cognition; joint attention; social skills; language/ communications; repetitive behavior motor/sensory; and sleep. There are no evidence or expert consensus based standards for appropriate or standard outcomes nor clinically meaningful improvement.

- All ABA based behavioral interventions included in the systematic review were rated as having an insufficient strength of evidence, except ESDM due to the poor quality of individual trials; lack of consistency; and important study limitations in terms of outcomes; reporting; number of patients; and/or quality of design. ESDM rated as insufficient for 10 or 14 outcome categories; and a low strength of evidence for 4 of 14 outcome categories (adaptive behavior, ASD symptom severity, IQ/Cognitive development, language/communication).

- Significant evidence limitations are present for all ABA based behavioral interventions including very few well-controlled trials. Most studies report on short-term outcomes and the degree to which those outcomes translate to functional outcomes over time is largely unknown. The range of treatment approaches evaluated in the literature may not match those that are available in practice, and the highly controlled treatment environments may not translate to outcomes that can be achieved in the community. Fidelity to treatment in the community may be limited, particularly for those interventions that are not manualized. Of the published trials, many have small sample sizes, different treatment approaches, varying durations of treatment, different follow-up times and outcome measures, and cover a variety of treatment intensities. It is difficult to compare data between studies and to make inferences...
for the general population due to the heterogeneity of study designs. Many observational studies and non-controlled studies lack a description of study methods and a detailed description of applied interventions. It is difficult to identify subpopulations of children with ASD who might better respond to treatments based in ABA theory, based on current evidence.

- The OHSU evidence report focused on the clinical evidence on ABA Based behavioral interventions for ASD, as reported in the more comprehensive Warren et al systematic review of multiple interventions for ASD. The report includes two categories of behavioral treatments that are based on or use ABA methods/techniques. These two categories contain a total of six models, and include a total of 30 studies, 11 rated fair, and 19 rated poor.

  - Under the first category, Early Intensive Behavioral/developmental Interventions (EIBI) is a more prescriptive, generally manualized program, with proponents recommending therapy as early as possible, preferably before age three. EIBI typically includes preschool children in intensive (10 to 40 hrs/wk) treatment in a variety of settings there are three programs that had 26 studies: (1) UCLA/Lovaas model; (2) Early Start Denver Model (ESDM); and (3) Parent Training Model focused on pivotal behaviors. Both UCLA/Lovaas and ESDM programs involve high intensity instruction using ABA techniques but have several differences. The UCLA/Lovaas method uses one-on-one therapy sessions and discrete trial teaching. The ESDM uses ABA principles with developmental and relationship-based approaches for young children.

  - Under the second category, Play/Interaction based Interventions using ABA based behavior management, imitation, behavioral drills and child directed training within a relationship or developmental approach in preschool through elementary aged children, there are three programs that had 6 studies: (4) Play Interaction – Parent Focused Model; (5) Play Interaction- Joint Attention Model; and (6) Play Interaction- Imitation Model.

  - **EIBI – UCLA/Lovaas.** Studies of UCLA/Lovaas-based interventions have the most and highest level of evidence of any of the six models of ABA based behavioral interventions identified with clinical evidence and is based on a more structured (use of manual) intervention. The UCLA/Lovaas clinical evidence suggests improvements in cognitive performance, language skills. However, strength of evidence is currently low due to significant evidence limitations; meaning that further research is likely to change confidence in the estimate of effect and is also likely to change the estimate.

    - 7 fair quality trials and 14 poor quality studies were identified. The fair quality trials included 272 children total; with an average of 40 children per study. One was an RCT and six were prospective cohort design. Age typically included 18 to 42 month old children; though one study of 27 children included up to age 7. The early intensive behavioral interventions based on ABA methods varied in intensity (10 to 40 hrs) and were compared to eclectic interventions; parent directed EIBI and may not have included manuals or protocols. Studies most commonly assessed IQ, with language, communication, adaptive behavior after 9 months and up to 3 year; although in some studies these were not specified in advance or powered adequately.

    - IQ/Cognitive: 5/7 trials reported sig. over comparator; 1 trial reported no difference between groups
    - Adaptive Behavior: 3 trials reported no sig. difference between groups; 2 trials reported sig. improvement over comparator/s
    - Challenging Behavior: 1 trial reported no sig. difference between groups
    - Expressive language/socialization: 1 trial reported no sig. difference and 1 trial reported a sig. improvement over comparator
    - Autism Severity: 1 trial reported no sig. difference between groups
14 additional poor quality cohorts found inconsistent results; 5 case series had mixed results; and 6 chart reviews were included.

### EIBI – Early Start Denver Model

One good quality RCT studying Early Start Denver model based intervention, also based on a more structured (use of manual) intervention was included and one poor quality case series. Although some positive results are reported for the effects of intensive interventions that use a developmental framework, such as ESDM, evidence for this type of intervention is currently insufficient because few studies of sufficient size and quality have been published to date.

- The RCT study included 48 children; mean age of 38 months and compared to community based interventions. At 1 year, significantly greater increase in IQ was reported; but no differences in adaptive behavior; as 2 years significantly greater IQ, receptive/expressive language; adaptive behavior reported but no change in Autism severity or repetitive behaviors.

### EIBI – Parent Training Model focused on Pivotal Behaviors

Four studies, 2 fair and 2 poor studying parent training models focused on pivotal behaviors were included. However due to small quantity, quality, and size, and low or mixed findings, the overall strength of evidence was insufficient.

- The two fair quality RCT studies included 52 children; with a mean of 23 months, ranging from 24-51 months comparing home based parent intervention with treatment as usual or community based intervention over one year. In one trial; no differences between groups in nonverbal IQ; autism severity; words/gestures occurred and intervention group had decrease in IQ. In the other trial, intervention group had significant improvement in AOS and expressive vocabulary scores; but no other significant differences.

- Two additional poor quality studies reported mixed results.

### Play Interaction-based interventions

The majority of these interventions consisted of a combination of adult directed behavioral drill and child direct milieu teach approach that incorporates ABA methods and developmental procedures of responsive and interactive methods in a table top structure context; parent led ABA based behavior management strategies; or adult imitation of child’s behavior. Children studied were generally between 3 to 6 years old, except for parent focused training up to age 12. The overall strength of evidence is based on 6 total studies; 1 fair quality and 5 poor quality RCTs and is insufficient due to lower quality evidence; low patient and number of studies; and mix of reported effect.

- Evidence from one fair quality trial of 58 children on **joint attention model of play interaction** compared to symbolic play or a control reported no differences between groups in growth of receptive or expressive language; both intervention groups has greater growth in expressive language. (Kasari 2006, 2008).

- Evidence from 3 poor quality trials; children generally 3 to 6 with an outcome most frequently assessed of social behaviors, found that the **imitation based play interaction intervention** group had greater improvements in time engaged, social interest. (Field 2001 Heimann 2006; Escalona 2002).

- Evidence from 2 poor quality trials of **parent focused play interaction** for children from 2 to 12, compared to wait list controls found significant reductions in child challenging behavior at 6 months and duplicated in wait list control (Whittingham 2009; Gulsrud 2007).
4. **Special Populations?**

- The degree of severity of deficits at baseline; and characteristics such as baseline IQ, social responsiveness and imitation skills
- The diagnosis of the child (PDD-NOS vs. ASD)
- Age of child (particularly very young 18 month to 3 years) at baseline
- Provider type (licensure, professional, parent)
- Intervention setting (home; clinic; other)
- Duration and frequency of intervention

5. **Is the technology cost-effective?**

The committee discussed multiple key factors that were important for consideration in their overall decision on whether the technology has value and is cost-effective. Summary of committee considerations follows.

- The evidence based technology assessment report indicates that total lifetime per capita cost of direct medical treatment for an individual with ASD is estimated to be $305,956, with a total lifetime societal cost of $3.2 million (Ganz, 2007). Given the high cost of treatment, the large number and variety of available treatments, and constrained budgets, state policymakers need to determine which treatments are likely to improve outcomes for children with ASD, so they can better target the use of limited state resources.

- The AHRQ commissioned evidence review is for clinical studies only and does not include a review of cost effectiveness analysis.

- The evidence based technology assessment report indicates that currently 27 states that mandate coverage, there are four types of benefit limits included in current state mandates: overall maximum benefit amounts per year, lifetime maximum benefit amounts, a specific to ABA maximum benefit amount per year, and a lifetime maximum benefit amount specific to ABA. Maximum overall benefit amounts in coverage mandates range from $36,000 to $75,000 per year with most coverage mandates explicating stating that the limits include ABA therapy. The overall maximum benefits are also commonly broken down by age, with the overall benefit maximum for older children (age 7 to 12 and older) ranging from $12,000 to $27,000 per year. Lifetime maximum benefit amounts range from $125,000 to $200,000. Coverage limits specific to ABA therapy range from $30,000 to $50,000 per year, with one state (FL) having a lifetime maximum benefit for ABA therapy of $108,000. Similar to overall benefit limits, ABA specific benefit amounts are also commonly broken down by age, with the benefit maximum for older children (age nine and older) between $12,000 and $35,000 per year.

- The evidence based technology assessment report indicates that no Washington State agency covers ABA therapy for autism; however, other services that are commonly identified as components or alternatives to ABA are covered when provided under a treatment plan of medically necessary therapies.

- Washington state utilization and cost information indicates that with a 50% usage by eligible population of a $50,000 yearly limit (last proposed legislation); the costs, depending on prevalence estimates would range from $70 million to $101 million per year.

6. **Medicare Decision and Expert Treatment Guidelines**

Committee reviewed and discussed the expert guidelines as identified and reported in the technology assessment report.
The Centers for Medicare and Medicaid Services (CMS) has no National Coverage Determination.

27 US states have mandated ABA Therapy benefits; though such legislative policies may not be based on scientific outcomes; the types of mandate vary widely.

- The age limits for state mandates of autism coverage differ significantly. For example, 4 states limit coverage to children 6 years or younger; 5 states set coverage limits for children aged up to 10 through 17 years; 5 states limit coverage to children aged 18 years or younger. Many of the age limits are further segmented into age groups as maximum benefits limits in many states are differentiated by age.

- There are four types of benefit limits included in current mandates: overall maximum benefit amounts per year; lifetime maximum benefits; a specific ABA maximum per year; or a specific ABA maximum per lifetime. Maximum yearly amounts range from $36,000 to $75,000 per year.

- Included services vary in specificity, with most mandates covering diagnosis and treatment of ASD.

- Some state mandates limit applicability to certain entities such as state regulated insurance plans or state employee plans.

- Provider licensure requirements, if any vary widely as well; with most states not having minimum educational or practical experience requirements.


- National Autism Center (NAC), 2009 (rated poor quality) – The National Autism Center (NAC) released a report in 2009 titled the National Standards Project, and is directed towards parents, caregivers, educators, and service providers who make ASD treatment decisions (NAC, 2009). The National Standards Project main goals include: (1) describing the strength of evidence around educational and behavioral treatments for ASD; (2) providing the age, diagnosis, and skills/behaviors associated with treatment options; (3) identifying the limitations of the evidence for treatments of ASD; and (4) providing guidance for integrating evidence-based practice into ASD treatment (NAC, 2009). The guideline groups interventions into treatment categories. The categories represent treatments that are substantially similar or have the same core characteristics. It was difficult to know exactly which interventions were included in some of the categories. The strength of the evidence was rated by the NAC as established, emerging, unestablished, or ineffective/harmful. The NAC guideline was rated as poor quality and does not give specific recommendations for interventions or treatment categories. Rated as poor quality because: lack of methodological rigor; no clear link
between evidence and recommendation; recommendation not specific; lack of applicability to practice and potential conflict of interest.

- **New Zealand Guidelines Group (NZGG), 2008 (rated fair quality)** – The *New Zealand Autism Spectrum Disorder Guideline*, published by the New Zealand Guidelines Group (NZGG) in 2008, provides a best evidence summary targeted at primary care providers, educational professionals, policy makers, funders, parents, carers, specialists, and others who make treatment decisions regarding individuals with ASD (NZGG, 2008). The NZGG guideline conducted a systematic review of the evidence. The guideline specifically discusses the evidence surrounding the identification and diagnosis of ASD, continuing assessments, and access to services and treatments for individuals with ASD, and is rated as fair quality. One of the main reasons for the fair quality rating was the lack of a direct link between the ABA-based recommendations and the evidence. Rated as fair quality because: involvement of funding bodies not stated; recommendations not specific; and applicability to practice not clear. Literature review was limited to systematic reviews (no primary studies included). 10 reviews of ABA identified (4 very good quality, 4 good quality, 2 fair quality). Of the 4 very good quality reviews, 2 found the evidence to be insufficient to make recommendations, 1 concluded that there was no clear answer regarding the most effective therapy for ASD and 1 concluded that EIBI should be the intervention of choice, but that there were substantial threats to the validity of that conclusion.

- **Scottish Intercollegiate Guidelines Network (SIGN), 2007 (rated good quality)** – the *Scottish Intercollegiate Guidelines Network* (SIGN) published *Assessment, Diagnosis and Clinical Interventions for Children and Young People with Autism Spectrum Disorders: A National Clinical Guideline* in 2007 to provide an evidence base and give recommendations for the assessment and clinical treatment of ASD. The guideline includes discussion on how multiple disciplines and multiple agencies and how they can work together to best meet the needs of individuals with ASD at all levels of care (SIGN, 2007). The guideline was rated as good quality because: rigor of development was robust and clearly described for both evidence and recommendations; low risk for conflicts of interest and recommendations are specific and applicable to practice.

### Committee Decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and agency and state utilization information. The committee concluded that the current evidence on ABA Therapy demonstrates that there is sufficient evidence to cover with conditions Applied Behavioral Analysis based behavioral interventions for treatment of Autism Spectrum Disorder. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted to cover with conditions ABA Therapy. The HTCC draft decision indicates that overall, the evidence is insufficient, but two of the most studied ABA based interventions: the UCLA /Lovaas and ESDM models of early intensive behavioral interventions have some (though still low quality) evidence that shows a possible effect on certain outcomes for some individuals with ASD.

For UCLA/Lovaas and ESDM models of early intensive behavioral intervention, key uncertainties relate to the substantial quality and applicability limitations of the evidence, and the appropriate outcomes and change; type of children that may benefit, and the appropriate frequency and setting of treatment. Coverage is appropriate within a research setting where added safety, patient protections, monitoring, and clinical expertise are present; and important health outcomes are being studied, with an ultimate goal of addressing the key uncertainties.
Health Technology Clinical Committee Authority

Washington State’s legislature believes it is important to use a scientific based, clinician centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority, through its Health Technology Assessment program to engage in a process for evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and takes public input at all stages. Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State Health Technology Clinical Committee (HTCC) determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases their decisions on evidence of the technology’s safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.