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Medical Policy Manual

**Topic:** Applied Behavior Analysis for the Treatment of Autism Spectrum Disorders  
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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

**Autism Spectrum Disorders (ASDs)**

Autism Spectrum Disorders (ASDs) refer to a group of pervasive developmental disorders characterized by significant but varying degrees of social, communication, and behavioral impairments. ASDs may be accompanied by other conditions, such as epilepsy and cognitive impairment. As defined by the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders, 4th Edition\(^1\), the ASDs include:

- Autistic Disorder
- Asperger’s Disorder
- Pervasive Developmental Disorder, Not Otherwise Specified (PDD-NOS)

**Behavioral Interventions for ASDs**

Currently, there is no definitive treatment for ASDs. Given the high prevalence and the impact these disorders have on the affected families, effective, evidence-based treatment interventions are needed. A number of behavioral interventions aiming to improve core social, communication and behavioral deficits are available, however consensus is lacking on whether and which interventions are effective. In
addition, the specific ASD patient populations most likely to benefit from the existing interventions have not been clearly described. Finally, many interventions do not have published therapy protocols, so the way in which they are provided may vary significantly.

**Applied Behavior Analysis (ABA)**

ABA is defined in the 2011 Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Review as “an umbrella term describing principles and techniques used in the assessment, treatment, and prevention of challenging behaviors and the promotion of new desired behaviors. The goal of ABA is to teach new skills, promote generalization of these skills, and reduce challenging behaviors with systematic reinforcement.”[2]

The application of principles and techniques of ABA is not exclusive to the treatment of ASDs. Rather, ABA is a general approach to modifying human behavior. Its principles and techniques have been adapted to and employed in a wide range of fields, including health care, education, business, criminal justice, and human service animal training.[3,4] Likewise, a wide range of professionals and nonprofessionals may provide ABA-based therapy, including healthcare, business, and education professionals, lay individuals, and parents. See Policy Guidelines for additional discussion concerning ABA therapy providers.

**ABA-Based Behavioral Interventions for ASDs: Early Intensive Behavioral Intervention (EIBI)[2]**

Behavioral interventions in EIBI programs incorporate principles of ABA but differ in methods and settings.

*ABA-based EIBI with Published Therapy Protocols*

There are two intensive, ABA-based early intervention programs with published therapy protocols intended to improve the challenging behaviors specifically associated with ASDs:

- University of California, Los Angeles (UCLA)/Lovaas and
- Early Start Denver Model (ESDM).

The protocols provide guidance on methods and settings, thus reducing variability among the therapies offered by different providers. Although these EIBI programs are described as intensive, the recommended hours of one-on-one weekly instruction (25-40 hours/week) and overall duration of the therapy (12 weeks to 3 years overall duration) have not been firmly established. Advocates of these interventions also recommend that children with ASDs start therapy as early as possible, preferably before three years of age.

Despite the underlying similarities related to ABA principles, these two programs also have theoretical and implementation differences:

1. **UCLA/Lovaas**
   This program relies on one-on-one therapy sessions and discrete trial teaching (an instructional approach to teaching which involves repetition of a single-cycle instruction routine until the target skill is mastered).

2. **ESDM**
   This method combines ABA principles with developmental and relationship-based approaches
Behavioral interventions in this category incorporate principles of ABA; however they do not have published therapy protocols. The 2011 AHRQ report collectively refers to these interventions as UCLA/Lovaas-based interventions because of their overall similarity to the Lovaas model.

**MEDICAL POLICY CRITERIA**

Applied behavioral analysis (ABA)-based therapy is considered **investigational** for all indications, including but not limited to treatment of autism spectrum disorders.

**POLICY GUIDELINES**

As discussed in the Description above, because applied behavioral analysis (ABA)-based services are applied in a wide range of fields and settings, a broad range of professionals and nonprofessionals may provide ABA-based therapy. ABA training options range from professional certification, where university-level degrees in a field related to human behavior or education are prerequisites, to general certificate programs with no specific requirements regarding the level or type of prior education.[4]

Examples of the range of options for providers of ABA therapy include:

- **Board Certified Behavior Analyst**
  A Board Certified Behavior Analyst (BCBA) is required to have a Master’s or Doctorate (BCBA-D) degree in an ABA-related field such as psychology, human services, health services, or education.[5] A Board Certified Assistant Behavior Analyst (BCaBA) is required to have a Bachelor’s degree in an ABA-related field. Professionals with these certifications have specialized training in ABA therapy but may not have specialized training in autism spectrum disorders.

- **ABA Therapists**
  ABA therapists typically provide one-on-one patient instruction. There are no established educational requirements or certification credentials for these providers.[6]

- **ABA certificate programs**
  ABA certificate programs (or course work) are typically offered to individuals who are not seeking board certification, and who may or may not be professionals. In addition to health professionals, attendees at certificate programs may include special education teachers and other educators, social workers, human services professionals, and parents of autistic children.

- **Licensing**
  There are no uniform state licensing requirements specific to ABA providers.

In summary, educational, certification, and licensing requirements vary across the range of ABA therapy providers, and these requirements are continuing to evolve. Consequently, ABA-providers may be — but are not required to be — licensed healthcare professionals. They may have varying levels of formal ABA training, and they may or may not have specific training in autism spectrum disorders.

**SCIENTIFIC EVIDENCE**

**Background**
There are several issues which must be considered when evaluating the impact of behavioral interventions on the health outcomes of children with autism spectrum disorders (ASDs):

- Any behavioral intervention can result in both nonspecific and specific therapeutic effects. Nonspecific effects, sometimes called placebo effects, occur as a result of therapist contact, positive expectations on the part of the patient’s family and therapist, and other beneficial effects that occur as a result of being in a therapeutic environment. These nonspecific effects cannot be attributed to the treatment itself.
- In contrast, specific therapeutic effects are those that occur only because of the active therapy, above any nonspecific effects that may be present. When a specific behavioral therapy, such as ABA-based early intensive behavioral intervention (EIBI) for ASDs, is being considered, it is necessary to determine whether it has specific therapeutic effects and whether those effects surpass the benefits of any existing therapies (standard of care). In addition, each individual ASD patient is unique and has both known and unknown differences — clinical (e.g., level of cognitive, language, or behavioral impairment) and demographic (age, family characteristics). These patient differences may impact the treatment outcome in ways that cannot be quantified without a systematic study that accounts for those differences.

In order to isolate the specific therapeutic effects of a behavioral intervention and adequately control for nonspecific treatment effects and individual patient differences, well-designed randomized clinical trials (RCT) that compare the new behavioral therapy with the current standard of care are necessary. The RCT is the most rigorous and reliable study design for demonstrating a causal relationship between the therapy under investigation and the health outcome. This form of study is necessary in order to understand whether an intervention such as ABA-based EIBI can positively impact the health of children with ASDs.

At a minimum, a well-designed RCT has the following attributes:

- Written research protocol with Institutional Review Board approval
  A written research protocol is the main reference document for the study. It describes the roles and responsibilities of the study personnel and provides precise and detailed treatment methods, assuring that all participants assigned to a specific therapy in the study will be selected, managed, and treated (e.g., duration and type of treatment, type of provider) in the same manner. A well-written research protocol also includes clearly defined and clinically meaningful outcomes of interest. As a result, the collected data can be combined and meaningfully compared in the analysis. In addition, written research protocols facilitate replication/comparison for future research.

- Randomization
  Random treatment assignment to either a control (standard of care) or treatment (new therapy) study group promotes equal distribution of patient characteristics — clinical and demographic, known and unknown — across the study groups. In addition, randomization helps control for expected nonspecific effects as well as for the variable natural history of the condition being treated. Consequently, any difference in the outcome observed between the study groups may, with reasonable assuredness, be attributed to the treatment under investigation.

- Large study population
  Small studies limit the ability to rule out chance as an explanation of study findings. Further, small study populations limit the ability to reliably identify subgroups of patients (e.g., certain age or IQ level) that may have different treatment responses compared to the overall study population.
• Adequate follow-up
  Follow-up periods must be long enough to determine the durability of any treatment effects.

Literature Appraisal

The focus of the following evidence review is on published, exhaustive systematic reviews, which identified and appraised the validity and reliability of randomized controlled trials (RCTs) in which ABA-based EIBI is compared to other ASD treatments.[2,7,8] In addition, the RCTs published subsequent to these systematic reviews were also considered.

Technology Assessments


The 2011 AHRQ comparative effectiveness review includes a comprehensive, systematic review of evidence published over the last decade on behavioral (including ABA-based EIBI), educational, medical, allied health, and complementary and alternative medicine therapies for children with ASD. The review focused on several specific research questions for children 2-12 years of age, such as treatment outcomes, modifiers of treatment effectiveness and evidence for generalization of outcomes to other contexts, as well as on the evidence to support treatment decisions in children ages 0-2 at risk for an ASD diagnosis.

The AHRQ review identified 34 unique studies of early behavioral and developmental interventions. Of those studies, there is only one RCT investigating the UCLA/Lovaas method and one investigating the Early Start Denver Model (ESDM) interventions.

• Studies of UCLA/Lovaas Interventions

  The evidence on the UCLA/Lovaas interventions consists of one RCT and a number of non-randomized studies, including 3 non-randomized trials.

  In the one small (n=28) RCT that met AHRQ inclusion criteria (Smith et al., 2000; AHRQ reference 114), a clinic-based intensive intervention (25 hours per week for the first year, followed by reduced intervention for 1-2 years thereafter) was compared to a parent-based program (3-9 months of parent training) in children around 36 months of age with a mean intelligence quotient (IQ) of 51. Although this trial was an attempt to replicate the findings from the original Lovaas study, the average 15 point increase in IQ that was observed in the intensive treatment group was “much more tempered than that of original noncontrolled Lovaas study.”[2] Even with the observed increase, the average IQ in the intensive treatment group remained deficient. In addition, this study failed to demonstrate post-treatment differences in adaptive or challenging behavior between the treatment groups. As IQ increases were primarily observed in the children with pervasive developmental disorder, not otherwise specified (PDD-NOS), the AHRQ report concluded that this study “demonstrated a less dramatic impact for the population of children for whom this approach is often recommended (i.e., children with classically defined Autistic Disorder) compared with what was previously reported.”[2]

  Looking at the overall strength of evidence for the UCLA/Lovaas interventions, the AHRQ report concluded that although some studies suggest benefits in areas of cognitive language and adaptive functioning in some children, the studies fail to adequately describe the subgroups of children who responded to the interventions.
The AHRQ report categorized the overall strength of evidence for UCLA/Lovaas-based interventions in improving language, cognitive, educational, and adaptive outcomes and ASD symptom severity as low (Table 27, AHRQ report).

• Studies of ESDM

The evidence on ESDM interventions consists of one RCT and one non-randomized study. The RCT (Dawson et al, 2010; AHRQ reference 290) evaluated the effectiveness of the ESDM intervention in 48 children 18-30 months of age with a diagnosis of ASD. The children were randomly assigned to either intensive ESDM intervention (n=24; 31 hours per week, 15 from a therapist and 16 from parents) or to an intervention commonly available in the community (18 hours of individual and group intervention). After 2 years, the ESDM group displayed significant improvements in IQ and adaptive behavior skills (except socialization), as well as greater change in ASD diagnosis (shift from Autistic Disorder to PDD-NOS). While these results appear promising, they are inconclusive and suggest the need for additional research. The AHRQ report notes several significant limitations, including:

- Failure of the diagnostic shifts to match clinically significant improvements in terms of ADOS severity scores and measurements of restricted and repetitive behaviors (i.e., RBS scores);[2]
- Inability to identify how core ASDs symptoms change in response to ESDM;
- Small study population; and
- Failure to replicate the findings of this study in other studies.

The AHRQ report categorized the overall strength of evidence for ESDM interventions in improving cognitive, language, and adaptive outcomes as insufficient.

• Overall evidence on UCLA/Lovaas and ESDM

Although individual evidence on UCLA/Lovaas and ESDM interventions is limited in both quantity and quality, the AHRQ report concludes that the combined research on the two interventions “suggests a benefit of early intensive approaches for some children that should continue to be studied.”[2] However, the report also stresses the need for continued improvements in the study methodology and for reliable, large, multisite RCTs to confirm these preliminary findings. Small sample sizes, different treatment approaches, different intensity and duration of the interventions, different inclusion and baseline assessment criteria, as well as different outcome measurements over different periods of time are identified in the report as the key shortcomings in the current evidence. The report also points out that the UCLA/Lovaas and ESDM interventions have not been sufficiently and adequately compared in the literature. In addition, there is currently a lack of understanding of how the current research findings translate into real communities. Finally, the report raises an alert that no studies of behavioral interventions report harms of the studied interventions and that this aspect of research should not be overlooked.

In discussing the direction of future research, the AHRQ report identifies several areas where reliable evidence is needed to understand the following:

- Which children are likely to benefit from specific interventions
- Whether specific functional components of the multi-component interventions drive effectiveness
• Modifiers of intervention effectiveness (e.g., how the family characteristics modify treatment)
• How outcomes reported in the research setting translate to home or school settings
• Feasibility and accessibility of intensive treatment interventions
• Whether behavioral interventions may be associated with potential harms

Cochrane Review[9]

A 2012 Cochrane Review included five studies (1 RCT, 4 nonrandomized clinical trials; total n=203), all of which were included in the above AHRQ comparative effectiveness review. As with the AHRQ review, the authors rated the overall quality of the evidence as low. In discussing the implications for clinical practice, the authors state:

“There is some evidence that EIBI is an effective treatment for children diagnosed with an ASD. The evidence points to gains in the areas of IQ, adaptive behavior, socialization, communication, and daily living skills, with the largest gains made in IQ and the smallest in socialization. The primary issue is that the quality of the evidence to support the use of EIBI is quite limited, that is, we only have evidence from a handful of studies that are not of the optimum design. Only one study used a RCT design and across studies there were small sample sizes. We strongly recommend that decisions about the use of EIBI for children with ASD be made on a case by case basis. It is important that providers of EIBI are aware of the limited quality of the current evidence and use clinical decision-making guidelines, such as seeking the family’s input and drawing upon prior clinical experience, when making recommendations to clients on the use EIBI.”

When discussing implications for future research, the Cochrane review authors identified the need for RCTs with larger sample sizes. Among the specific areas identified for further research were:

• The impact of EIBI on parental health and wellbeing as well as overall family quality of life
• Variables (child or parent) that predict which children will or will not respond to treatment
• Comparative effectiveness studies to determine if EIBI is more effective than other active ASD treatments

The researchers discussed the need for researchers to establish guidelines for the minimum number of hours per week children must receive EIBI and a core set of outcome measures that can be used across researchers. Also cited as research needs were better delineation of the active ingredients of EIBI under study, and better descriptions of the control group interventions, as well as the degree to which those practices overlap with the treatment group.

Washington State Health Care Authority (WSHCA) Health Technology Assessment[7]

The WSHCA report is largely based on the 2011 AHRQ review and therefore it reached similar conclusions concerning the evidence.[7]

BlueCross BlueShield Association (BCBSA) Technology Evaluation Center (TEC) Assessment[8]

In 2009, BCBSA TEC published a systematic review of the evidence on the effectiveness of EIBI therapy (UCLA/Lovaas). The review found the evidence to be weak, limited both in quality and consistency of results. The review identified only 2 RCTs of EIBI, both of which are discussed in detail in the 2011 AHRQ report (see above).
Other Randomized Controlled Trials (RCTs)

No RCTs of the UCLA/Lovaas or ESDM model have been published subsequent to the 2011 AHRQ report.

Clinical Practice Guidelines

- U.S. Department of Health & Human Services Agency for Healthcare Research and Quality National Guideline Clearinghouse\(^{[10]}\)

  A search of the National Guideline Clearinghouse failed to identify evidence-based guidelines addressing the treatment of ASDs.

- American Academy of Child and Adolescent Psychiatry (AACAP) Practice Parameters\(^{[11]}\)

  The 1999 AACAP Practice Parameters for the assessment and treatment of children, adolescents, and adults with autism and other pervasive developmental disorders does not specifically address ABA-based interventions, including EIBI. The AACAP states that the treatment plan for ASDs should address behavioral adjustment; however, it does not make specific therapy recommendations for behavioral adjustments. Further, the guideline also states that “treatments proposed should be based on solid, empirical evidence.”\(^{[11]}\)

- American Academy of Pediatrics (AAP)\(^{[12]}\)

  The 2007 AAP clinical report on management of children with ASDs provides a brief summary of evidence for educational (including ABA-based) and medical interventions. ABA-therapy is described in the report as well documented and beneficial. However, the goal of the AAP report is not to “indicate an exclusive care of treatment or serve as standard of medical care.” In accordance with the purpose of the document, no specific recommendations regarding ABA-based or any other interventions are provided. The brief review of the evidence for the ABA-intervention is not based on a systematic review of evidence. Study inclusion criteria for the review are not described, and validity and reliability of the referenced studies are not addressed.

Summary

Applied behavior analysis (ABA) is a general term describing principles and techniques used to modify challenging behaviors.\(^{[2]}\) UCLA/Lovaas and Early Start Denver Model (ESDM) are intensive, ABA-based early intervention programs with published therapy protocols intended to modify behaviors associated with ASDs. With the publication of studies that suggested some improvement in outcomes, the popularity, demand, and utilization of these interventions has grown significantly. However, the overall body of evidence is limited and of low quality, and inconsistent results are reported concerning the impact of ABA therapy on health outcomes. Some studies failed to demonstrate a benefit from ABA therapy, while others report modest benefits.

In 2011, the AHRQ published an independent and comprehensive systematic review of accumulated evidence on interventions for ASDs.\(^{[2]}\) The review concluded that the overall level of evidence is low in quality and that studies reporting benefit did not adequately describe the children with ASDs who are most likely to benefit from these interventions. Per the report, “not all children receiving such [UCLA/Lovaas, ESDM] interventions demonstrate rapid gains, with some data suggesting that many
children continue to display prominent areas of impairment and that subgroups may account for a majority of change within certain samples.” It was determined that the suggested benefits from ABA therapy described in early research need to be adequately studied in more rigorous, randomized studies that can provide more reliable and definitive answers.

In summary, the current evidence on the efficacy of ABA-based interventions in modifying challenging behaviors associated with ASDs consists of studies of inferior quality. Consequently, it is not known whether ABA-based interventions lead to clinically meaningful and sustainable improvements. In addition, it is not known which children on the spectrum are likely to benefit from specific interventions. Therefore, ABA-based therapy is considered investigational for all indications, including but not limited to treatment of autism spectrum disorders.

REFERENCES

CROSS REFERENCES

None

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