

Subject: Applied Behavioral Analysis Interventions for Autism Spectrum Disorders		Original Effective Date: 4/23/09
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PREFACE

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.

FDA INDICATIONS

The FDA does not regulate behavioral therapy programs.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage guidance (MCG) document and provide the directive for all Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.

CMS does not have a national coverage policy determination (NCD) for this topic and there are no Local Coverage Determinations (LCD's).

INITIAL COVERAGE CRITERIA

Applied behavioral analysis interventions used for Lovaas therapy, Intensive Behavior Intervention (IBI), Early Intensive Behavior Intervention, Discrete-Trial Training, Pivotal Response Training, and Natural Environment Training (NET) for autism spectrum disorders **are considered experimental and investigational** and not a covered benefit. There is insufficient evidence in the published medical literature to demonstrate long-term effectiveness and impact on health outcomes from these programs. The effectiveness of intervention strategies, characteristics of response and the duration and intensity of treatment have not been established and remain unproven.

Weaknesses in research design and analysis undermine the confidence of the reported study results (e.g., small sample sizes, nonrandomized methodologies, detail lacking regarding interventions, undefined therapies in control group, poorly defined or subjective outcome measures). The findings on whether more intensive treatment provides better outcomes were inconsistent making it difficult for conclusions to be drawn.

CONTINUATION OF THERAPY

Not Applicable

COVERAGE EXCLUSIONS

Not Applicable

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Applied Behavior Analysis (ABA) is the process of systematically applying interventions based upon the principles of learning theory to improve socially significant behaviors to a meaningful degree, and to demonstrate that the interventions employed are responsible for the improvement in behavior.^{1,2} These socially significant behaviors include reading, academics, social skills, communication, and adaptive living skills. Adaptive living skills include gross and fine motor skills, eating and food preparation, toileting, dressing, personal self-care, domestic skills, time and punctuality, money and value, home and community orientation, and work skills.

ABA methods are used to support persons with autism in the following six ways³:

- to increase behaviors (e.g., reinforcement procedures, increase on-task behavior, or social interactions);
- to teach new skills (e.g., systematic instruction and reinforcement procedures, teach functional life skills, communication skills, or social skills);
- to maintain behaviors (e.g., teach self control and self-monitoring procedures to maintain and generalize job-related social skills);
- to generalize or to transfer behavior from one situation or response to another (e.g., from completing assignments in the resource room to performing as well in the mainstream classroom);
- to restrict or narrow conditions under which interfering behaviors occur (e.g., modifying the learning environment); and
- to reduce interfering behaviors (e.g., self injury or stereotyping).

ABA is described as an objective discipline focusing on the reliable measurement and objective evaluation of observable behavior. Reliable measurement requires that behaviors are defined objectively. Vague terms such as anger, depression, aggression or tantrums are redefined in observable and quantifiable terms, so their frequency, duration or other measurable properties can be directly recorded.¹

ABA interventions require a demonstration of the events that are responsible for the occurrence, or non-occurrence, of behavior. ABA uses methods of analysis that yield reproducible demonstrations of how to accomplish specific behavior changes.² These behaviors can be evaluated within relevant settings such as schools, homes and the community. Intensive behavioral training is initiated usually by age 3. This highly structured and intensive program usually is conducted 25 to 40 hours weekly using one-to-one instruction by a trained therapist for typically 2 to 3 years.⁵ Parents are encouraged as active participants in the process and are taught to continue training at home. As these children master behaviors, well-trained therapists will start to take learners out of the classroom or home setting and into more natural settings, where they can practice and adapt their new skills to the real world.

A single case experimental design is used to evaluate the effectiveness of individualized interventions as an essential component of programs based upon ABA methodologies. This is a process that includes the following components³:

- selection of interfering behavior or behavioral skill deficit
- identification of goals and objectives
- establishment of a method of measuring target behaviors
- evaluation of the current levels of performance (baseline)
- design and implementation of the interventions that teach new skills and/or reduce interfering behaviors
- continuous measurement of target behaviors to determine the effectiveness of the intervention, and
- ongoing evaluation of the effectiveness of the intervention, with modifications made as necessary to maintain and/or increase both the effectiveness and the efficiency of the intervention.

The Early Intensive Behavioral Intervention (EIBI) Program is designed for young children and utilizes a modified and highly structured approach to teaching based in the principles of ABA which is much closer to play therapy than establishing tasks through complex skills. A continuation of this program, designed to service older students on the autism spectrum, is the Systematic Ecologically Structured Instruction (SESI) program. The first year of treatment generally focuses on reducing aggressive and self-stimulatory behaviors, promoting appropriate toy play, teaching imitation responses and extending these treatment processes into the family setting.⁵ The second year of training focuses on appropriate social interactions with peers and expressive and abstract language skill. In the third year, emphasis is on development of appropriate emotional expression, observational learning from peers involved in academic learning and preacademic tasks.

Various terms have been used to describe ABA-based interventions for children with autism: the Lovaas UCLA model or Lovaas therapy, Intensive Behavior Intervention (IBI), Early Intensive Behavior Intervention, Applied Verbal Behavior (though, similar to ABA, this is a framework for the application of the science of Verbal Behavior), Discrete-Trial Training, Pivotal Response Training, and Natural Environment Training (NET). Each may use a unique system of instruction, each may identify different behaviors of focus, but each is based on the science of ABA.

GENERAL INFORMATION

Summary of Medical Evidence

Two trials were considered the strongest evidence in the literature.^{6,16,17} The first study randomly assigned children with pervasive developmental disorders to intensive treatment (n= 7 with autism, 8 with pervasive developmental disorder not otherwise specified—NOS) or parent training groups (n= 7 with autism, 6 with pervasive developmental disorder NOS).¹⁶ The intensive treatment group averaged 24.52 hours per week of individual treatment for one year, gradually reducing hours over the next 1 to 2 years. The parent training group received 3 to 9 months of parent training. The groups appeared similar at intake on all measures; however, at follow-up the intensive treatment group outperformed the parent training group on measures of intelligence, visual-spatial skills, language, and academics, though not adaptive functioning or behavior problems. The study limitations included weakness in design based upon very small sample size and differences in the treatment and outcomes compared. A clinic run program for 25 hours per week was compared with special education classes for 10-15 hours a week combined with a parent training program. The evidence is insufficient to determine if EIBI is more effective than the control treatment.

The second study randomly assigned 24 children to a clinic directed group replicating parameters of EIBI developed at UCLA or parent training that received intensive treatment but less supervision by trained staff.¹⁷ Similar outcomes were reported in both groups for cognitive, language, adaptive, social and academic measures after four years. There was no statistically significant difference in the rate of improvement between the two groups.

Lovaas performed a nonrandomized study on 19 children participating in EIBI for 40 hours per week.¹⁸ Two control groups were included: Group 2 had 10 or fewer hours per week and group 3 included subjects from another study. It was reported after a 3-4 year follow-up that 47% of the participants in the EIBI group had achieved above average IQ levels. Only one child from group 2 achieved this result. This was one of the first studies reporting information that supported the effectiveness of such treatment. A second study published longer term data that continued to report positive results from EIBI therapy.²² Many limitations have been reported^{19,20,21} with the study methodology and designs from both of these reports: lack of randomization, use of multiple instruments to measure the same outcome, timing of follow-up not clear, testing was performed by a single graduate student after 20 minutes of testing, teachers' observations of the children's functioning were not reported, treatment integrity inadequately reported, and a focus on IQ and school placement but overlooking other important factors such as socialization and communication were study flaws.

A nonrandomized comparative study of 25 autistic patients ages 4 to 7 with IQ scores of 50 or higher were assigned to Intensive behavioral therapy (IBI) or eclectic therapy.²³ All patients received 20 hours of therapy per week and were evaluated at 1 year. The results reported significantly greater mean gains in IQ scores, language skills, and composite scores on Vineland Adaptive Behavior scales in IBI therapy compared with eclectic therapy. The study limitations were reported as small sample size, nonrandomized study with short treatment and short follow-up. The IQ was > 50 which is indicative of high-functioning participants. A long term follow-up of this study was conducted with continuation of improvements in IQ by a mean of 25 points in the IBI versus 7 points in the eclectic group ($p<0.05$) and behavior in the IBI group ($P,0.05$).²⁴ The majority of the gains

were noted in the first year. Behavior and socialization improvements were noted between the first year and this long term.

A prospective nonrandomized comparative study evaluated 44 patients with autism ages 22 to 54 months diagnosed with autism.²⁵ Parents selected either EIBI (n=28) 1:1 home based intervention based on Lovaas methods or autism specific nurseries with eclectic approach. Many of the children had additional treatments. Both groups showed improvement in age equivalent scores. There were no significant differences in language, play, cognitive ability or autism severity between the groups. Both groups had similar outcomes at the two year follow-up. The reported study limitations were nonrandomized study with unblinded independent examiners, small sample size and many uncontrolled variables.

A nonrandomized retro and prospective mixed comparative study of 42 autistic children between 30 and 42 months with 5 dropouts was conducted comparing EIBI with usual school based care.²⁶ Parents selected 1:1 home based care or individualized intervention based on Lovaas methods for an average of 25.6 hours per week. The two year follow-up showed significant differences in intelligence measures, daily living skills, language, and positive social behavior in the EIBI group. IQ was the main indicator of treatment effect with effect size 0.77 indicating moderate effect. The study limitations included small sample size, nonrandomized study, examiners not blinded to treatment group, and many uncontrolled variables.

A prospective nonrandomized comparative study of autistic children comparing 21 EIBI patients receiving 35-40 hours of intensive treatment weekly with 21 children receiving services from public schools.²⁷ At 3 years the EIBI children had significant improvements in IQ ($p<0.05$), VAB composite scores ($p<0.01$) VAB daily living scores and communication scores ($p<0.05$) compared with children in the compared group. The study limitations reported were small sample size, nonrandomized study design, and a community setting whereas parents controlled the treatment. There were significantly more parents with higher education levels, a 2 parent household and children with autism versus other pervasive disorders in the EIBI group. Some of the assessments were performed by outside evaluators.

A prospective nonrandomized comparative study of 61 children of which (n=45) with autism and (n=16) with other pervasive development disorders.²⁸ Children were 48 months or younger and assigned into one of three groups by parent choice: IBI (n=29), autism educational program (n=16) or generic educational programming (n=16). Assessments were performed by independent examiners at 2 months and 14 months. There were no significant difference in mean scores between the autism program and the general education groups. The IBI group had higher mean scores in all skill domains with a significant difference in all domains with the exception of motor skills. Learning rates were higher in the IBI group except for motor skills which were similar among all three groups. The study limitations included nonrandomized study, nonblinded examiners, no long term follow-up, treatment and diagnosis mix were different among the groups, and the integrity of interventions were not examined.

A prospective nonrandomized comparison study of nine children with autism was performed.²⁹ ABA/Lovaas applied behavioral analysis techniques were performed mainly in the home setting by therapists appointed by the parents and supported by a supervisor (n=9). The second group, the Lancashire Under Fives Autism Project (LUFAP) (n=8) was developed by a team of teachers, therapists and educational psychologists in Lancashire and was delivered in mainstream preschool settings with the support of a Special Support Assistant (SSA), a

visiting teacher and a speech and language therapist. The parents, teachers, therapists and assistants, were positive about the impact of both programs. Data from a reduced sample indicated that all the children made progress as measured on the Vineland and the Bayley scales. The progress made by those in the LUFAP program was reported as more encouraging than those on the ABA/Lovaas Program; although, this may be attributable to initial group differences. The study limitations included small sample size and group participant differences.

A retrospective nonrandomized comparative study of 22 children with autism between 26 and 47 months was performed to evaluate children undergoing intensive treatment versus school based services.³⁰ The IBI group mean IQ increased and mean symptom severity ratings decreased. There was no change in the control group. The only statistically significant difference between the groups was with IQ scores. The study limitations included small sample size, lack of randomization, retrospective design, short time frame for follow-up, subjective evaluation of symptom severity, and potential differences in treatment processes.

Several other single arm³¹⁻³⁶, uncontrolled studies were performed evaluating various treatment processes with intensive behavioral analysis. The outcomes varied for these studies. Methodological flaws, small sample sizes, integrity of interventions were not always evaluated, there was short term follow-up in many studies, nonblinded examiners, and different assessment outcome testing was performed within study groups. These limitations made it difficult to evaluate the true treatment effects. Autistic children exhibit a wide spectrum of behaviors. Treatment protocols must be targeted to address various behaviors and individual needs making it difficult to appropriately measure outcomes.⁵ Symptoms may change due to the nature of the disease further complicating the assessment of study treatment effects.

Meta-Analysis/Systematic Reviews

A systematic review was conducted from review of 31 studies (12 trials and 9 cohort studies) with a total of 770 participants analyzing the use of discrete trial training and Lovaas therapy for autism spectrum disorders.⁹ Study results were inconsistent. There were no statistically significant findings in studies that compared discrete trial training to no treatment.¹⁰⁻¹² The authors concluded “while this review suggests Lovaas may improve some core symptoms of autism spectrum disorder (ASD) compared with special education, these findings are based upon pooling of a few, methodologically weak studies with few participants and relatively short-term follow-up. As no definitive behavioral or developmental intervention improves all symptoms for all individuals with ASD, it is recommended that clinical management be guided by individual needs and availability of resources.”⁹

A systematic review and meta-analysis was performed reviewing quantitative data from thirteen studies and pooling the results for meta-analysis.¹³ Six of these were randomized comparison trials with reported adequate methodological quality to review the effectiveness of applied behavior intervention (ABI) programs for preschool children with ASD in their cognitive, adaptive behavior, and language development.

Meta-analysis of 4 studies concluded that, compared with standard care, ABI programs did not significantly improve the cognitive outcomes of children in the experimental group who scored a standardized mean difference (SMD) of 0.38 (95%CI -0.09 to 0.84; $P = .1$). There was no additional benefit over standard care for

expressive language; SMD of 0.37 (95%CI -0.09 to 0.84; $P = .11$), for receptive language; SMD of 0.29 (95%CI -0.17 to 0.74; $P = .22$) or adaptive behavior; SMD of 0.30 (95%CI -0.16 to 0.77; $P = .20$). The authors concluded “Currently there is inadequate evidence that ABI has better outcomes than standard care for children with autism. Appropriately powered clinical trials with broader outcomes are required.” The differences in control groups and study variability make it difficult to conduct a meta-analysis as results are questionable with such variations.

A systematic review included eleven studies, two studies were randomized-control trials evaluating early intensive behavioral interventions (EIBI) for young children with autism.¹⁴ EIBI resulted in improved outcomes mainly on a group analysis (primarily measured by IQ) compared to the comparison groups. There was considerable variability in outcomes on an individual level with some evidence that initial IQ unrelated to age was correlated with progress. This review provides evidence for the effectiveness of EIBI for some, but not all, preschool children with autism. The study quality was not rated which is a key component in systematic review analysis.⁶ Meta-analysis is generally not warranted with wide variations across studies making comparisons difficult.⁶

A systematic review of early intensive behavioral and developmental interventions for young children with autism spectrum disorders (ASDs) was conducted and published in 2011. Thirty-four studies were evaluated. Seventeen studies were case series; 2 were randomized controlled trials. 1 study was rated as good quality, 10 as fair quality, and 23 as poor quality. Overall the strength of the evidence ranged from insufficient to low. 1 randomized controlled trial of an early intensive developmental intervention approach (the Early Start Denver Model) and studies of University of California Los Angeles/Lovaas-based interventions and variants reported clinically significant gains in language and cognitive skills in some children. Specific parent-training approaches yielded gains in short-term language function and some challenging behaviors. The authors concluded that Lovaas-based approaches, the Early Start Denver Model and early intensive behavioral intervention variants resulted in some improvements in cognitive performance, language skills, and adaptive behavior skills in some young children with ASDs, although the literature is limited by the quality of the evidence.³⁸

Another systematic review with a meta-analysis, meta-regression, and dose-response meta-analysis of ABA interventions for autism in early childhood was conducted in 2010. Twenty-two studies were included in the review. Results suggested that long-term, comprehensive ABA intervention leads to positive effects in terms of intellectual functioning, language development, acquisition of daily living skills and social functioning in children with autism. Although favorable results were evident across all outcomes, language-related outcomes (IQ, receptive and expressive language, communication) were superior to non-verbal IQ, social functioning and daily living skills. The authors indicated that randomization to group assignment was rarely applied in the studies included in the review.³⁷

A 3-part comprehensive synthesis of the early intensive behavioral intervention (EIBI) for young children with autism based on the University of California at Los Angeles Young Autism Project method was conducted.¹⁵ The synthesis consisted of three components: descriptive analyses, effect size analyses, and a meta-analysis. The authors report methodological limitations and caution against over interpretation of the findings but conclude “The findings suggest EIBI is an effective treatment, on average, for children with autism.”¹⁵ The

heterogeneity of the various interventions used in the studies and the significant methodological weaknesses reported should preclude the use of a meta-analysis with conclusions regarding effective outcomes.⁶

Hayes, Cochrane, UpToDate, MD Consult etc.

A Hayes Directory report has been published regarding intensive behavioral intervention therapy for autism. The therapy has potential but unproven benefit. The majority of studies were nonrandomized with few patients and lacked information outlining the interventions studied. Study quality was poor with methodological flaws. Additional studies are needed to determine which variables are responsible for the treatment effects, define specific treatment approaches and to determine appropriate settings for therapy.

2011 Hayes Directory Report Update: There is some evidence that suggests that treatment of young autistic children with intensive behavioral intervention (IBI) therapy may promote gains in cognitive function, language skills, and adaptive behavior. However, although almost all studies suggested improvements in children treated with IBI compared with other treatments, most studies had major limitations in design and methodology, including lack of randomization procedures, small sample sizes, and a lack of blinded assessments to determine treatment effects. Additionally, despite findings by Lovaas that some high-functioning autistic children who undergo IBI therapy can achieve normal school performance and behavior; these results have not been replicated by other researchers.⁵

UpToDate⁴⁰

Intensive behavior programs may improve the main symptoms of ASD but it remains unclear whether one type of intensive behavioral intervention is better than another, how to measure and validate which children with ASD will respond maximally to intensive behavioral interventions, and whether intensive behavior programs should be recommended over other types of treatment programs.

Professional Organizations

The American Academy of Neurology (AAN), Child Neurology Society and the American Academy of Child and Adolescent Psychiatry (AACAP) do not have position statements on the treatment of autism. The AACAP does have a practice parameter but it does not mention intensive behavioral therapy.^{44 45}

The BlueCross BlueShield Technology Evaluation Center conducted a review of early intensive behavioral interventions based on applied behavioral analysis among children with autism spectrum disorders.⁶ Two randomized-control trials, nine nonrandomized comparative studies and five single arm studies were abstracted. The evidence was considered weak and not of high quality. Design and analysis weaknesses and inconsistent study results have undermined the confidence in the reported results. The authors conclude “based upon the weakness of the available evidence, we are uncertain about the effectiveness of early intensive behavioral analysis among children with autism spectrum disorders...the findings on whether more intense treatment leads to better outcomes were inconsistent, and no conclusions can be drawn.”⁶

The Scottish Intercollegiate Network performed evidence review and recommendations for autism spectrum disorders.⁷ The recommendation indicated “the Lovaas program should not be presented as an intervention that

will lead to normal functioning.”⁷ The studies reviewed were described as methodologically flawed with the concern that study enrollees were high functioning children making it difficult to adequately interpret results.

American Academy of Pediatrics (AAP)⁸

The AAP first published clinical guidelines for the management of autism in 2007 and reaffirmed 2010. In the guidelines, the AAP stated that “children who receive early intensive behavioral treatment have been shown to make substantial, sustained gains in IQ (intelligence quotient), language, academic performance, and adaptive behavior as well as some measures of social behavior, and their outcomes have been significantly better than those of children in control groups” However, the process used for development of these guidelines are not described and the recommendations are not found to be based on a systematic review of the literature.

The New Zealand Guidelines Group (NZGG) in 2010 published a guideline on Applied Behavioral Analysis and made the following recommendations: Interventions and strategies based on ABA principles should be considered for all children with ASD and early intensive behavioral intervention (EIBI) should be considered as a treatment of value for young children with ASD to improve outcomes such as cognitive ability, language skills, and adaptive behavior. These guidelines were based on grade A-B evidence and notably there was variability in outcomes and insufficient research comparing high quality intensive other treatment with EIBI to allow comparison of treatment effectiveness.⁴³

CODING INFORMATION

CPT	Description: N/A
	CMS and AMA do not have established codes for applied behavioral analysis

HCPCS	Description: NOT COVERED
H0031	Mental health assessment, by nonphysician
H0032	Mental health service plan development by nonphysician
H2012	Behavioral Health Day Treatment, per hour
H2019	Therapeutic behavioral services, per 15 min

ICD-9	Description
94.33	Behavior therapy (Hospital Procedure Code)
299.00	Autistic disorder, current or active state
299.01	Autistic disorder, residual state

ICD-10	Description
F84.0	Autistic Disorder
8E0ZXY5	Meditation (Hospital Procedure Code)

GZ51ZZZ	Individual Psychotherapy Behavioral (Hospital Procedure Code)
GZ58ZZZ	Individual Psychotherapy Cognitive Behavioral (Hospital Procedure Code)

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