INTENSIVE BEHAVIORAL THERAPY FOR AUTISM SPECTRUM DISORDER

Policy Number: 2016T0202O

Effective Date: August 12, 2016

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Medical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Medical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Some states mandate benefit coverage for applied behavioral analysis for treatment of autism spectrum disorder. In those states, the applicable mandate must be followed.

Refer to the following documents for fully insured policies in Maryland:

- Habilitative Services for Essential Health Groups
- Autism Spectrum Disorder and Intensive Behavior Therapy (to access this Optum Coverage Determination Guideline (CDG), go to Optum Provider Express > Clinical Resources > Guidelines/Policies/Manuals > Coverage Determination Guidelines)

The following information also applies when the above Autism Spectrum Disorder and Intensive Behavior Therapy CDG is referenced for fully insured policies in Maryland:
MARYLAND COMAR 31.10.39 (Utilization Review Criteria for Treatment of Autism and Autism Spectrum Disorders) provides that Utilization Review for habilitative services for the treatment of autism and autism spectrum disorders cannot be more restrictive than the following:

- We may require a comprehensive evaluation of a child by the child’s primary care provider or specialty physician identifying the need for habilitative services.
- We may require a prescription from the child’s primary care provider or specialty physician that includes specific treatment goals.
- We may require an annual review by the prescribing primary care provider or specialty physician, in consultation with the habilitative services provider, that includes:
  - Documentation of benefit to the child;
  - Identification of new or continuing treatment goals; and
  - Development of a new or continuing treatment plan.

Scope
Criteria for habilitative services apply to behavioral health treatment, psychological care and therapeutic care provided for the treatment of autism an autism spectrum disorders.

Minimum Benefit
Denial of treatment cannot be based solely on the number of hours of habilitative services prescribed for:

- Less than or equal to 25 hours per week in the case of a child who is at least 18 months of age and who has not reached the child’s sixth birthday, or
- Less than or equal to 10 hours per week in the case of a child who has reached the child’s sixth birthday and who has not reached the child’s nineteenth birthday.
- Additional hours of habilitative services may be authorized if medically necessary and appropriate for the treatment of autism or autism spectrum disorders. Medical necessity and appropriateness will be determined based on the criteria in the standard Level of Care Guidelines.

Providers
Habilitative services are to be provided by providers who are appropriately licensed, certified or otherwise authorized in Maryland or another state or US territory.

Limitations
Benefits are to be authorized if a treatment goal identifies the location of the habilitative services as the child’s educational setting. However, Authorization is not required under an individualized education program or any obligation imposed on a public school by the Individuals With Disabilities Education Act, 20 U.S.C. 1400 et seq.

Payment may not be denied for applied behavior analysis services on the basis that it is experimental or investigational.

Essential Health Benefits for Individual and Small Group
For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Intensive behavioral therapy/applied behavioral analysis including Early Start Denver Model (ESDM) programs and Relationship Development Intervention (RDI) are unproven and not medically necessary for the treatment of autism spectrum disorder.

The effectiveness of specific behavioral interventions, the duration and intensity of the interventions and the characteristics of children who respond have not been established in the published medical literature. According to the 2014 Agency for Healthcare Research and Quality (AHRQ) Behavioral Interventions for Children with Autism Spectrum Disorder update, “the evidence is insufficient to adequately identify and target the children who are most likely to benefit (or not benefit) from specific interventions.” The authors of the AHRQ report also state that intervention response is likely moderated by both treatment and child factors, but exactly how these factors function is not entirely clear (Weitlauf et al. 2014). Additional studies are required to define optimal treatment approaches for autistic children with specific areas of deficit and to identify which treatment variables or components are responsible for
significant effect. Furthermore, it is not clear what the optimal age is to begin intensive behavioral therapy, how long intensive behavioral therapy should last, and the what the durability of treatment effect is when intensive behavioral therapy is stopped. These issues should be addressed using rigorous methodologies, including randomization, standardized protocols, use of blinded evaluators, treatments that adhere to specific models, and longitudinal designs to evaluate long-term outcome.

**APPLICABLE CODES**

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>0364T</td>
<td>Adaptive behavior treatment by protocol, administered by technician, face-to-face with one patient; first 30 minutes of technician time</td>
</tr>
<tr>
<td>0365T</td>
<td>Adaptive behavior treatment by protocol, administered by technician, face-to-face with one patient; each additional 30 minutes of technician time (List separately in addition to code for primary procedure)</td>
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<tr>
<td>0366T</td>
<td>Group adaptive behavior treatment by protocol, administered by technician, face-to-face with two or more patients; first 30 minutes of technician time</td>
</tr>
<tr>
<td>0367T</td>
<td>Group adaptive behavior treatment by protocol, administered by technician, face-to-face with two or more patients; each additional 30 minutes of technician time (List separately in addition to code for primary procedure)</td>
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<tr>
<td>0368T</td>
<td>Adaptive behavior treatment with protocol modification administered by physician or other qualified health care professional with one patient; first 30 minutes of patient face-to-face time</td>
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<tr>
<td>0369T</td>
<td>Adaptive behavior treatment with protocol modification administered by physician or other qualified health care professional with one patient; each additional 30 minutes of patient face-to-face time (List separately in addition to code for primary procedure)</td>
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<tr>
<td>0370T</td>
<td>Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present)</td>
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<tr>
<td>0371T</td>
<td>Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present)</td>
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<tr>
<td>0372T</td>
<td>Adaptive behavior treatment social skills group, administered by physician or other qualified health care professional face-to-face with multiple patients</td>
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<tr>
<td>0373T</td>
<td>Exposure adaptive behavior treatment with protocol modification requiring two or more technicians for severe maladaptive behavior(s); first 60 minutes of technicians' time, face-to-face with patient</td>
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<tr>
<td>0374T</td>
<td>Exposure adaptive behavior treatment with protocol modification requiring two or more technicians for severe maladaptive behavior(s); each additional 30 minutes of technicians' time face-to-face with patient (List separately in addition to code for primary procedure)</td>
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*CPT® is a registered trademark of the American Medical Association*
According to the 5th Edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5), autism spectrum disorder (ASD) is characterized by persistent deficits in social communication and social interaction, including deficits in social reciprocity, nonverbal communicative behaviors and skills in developing, maintaining, and understanding relationships. The 5th edition of DSM includes several significant changes over the previous edition, including combining several previously separate diagnoses such as Asperger's disorder, autistic disorder, pervasive development disorder, atypical autism, childhood autism, childhood disintegrative disorder, early infantile autism, and high-functioning autism under the single diagnosis of autism spectrum disorder (DSM-5).

Behavioral therapy programs used to treat autism spectrum disorder are referred to as Intensive Behavioral Intervention (IBI), Early Intensive Behavioral Intervention (EIBI), or Applied Behavior Analysis (ABA) including Lovaas therapy. The Early Start Denver Model (ESDM) program includes ABA in combination with developmental and relationship-based approaches. This therapy involves highly structured teaching techniques that are administered on a one-to-one basis by a trained therapist, paraprofessional, and/or parent 25 to 40 hours per week for 2 to 3 years. In classic IBI therapy, the first year of treatment focuses on reducing self-stimulatory and aggressive behaviors, teaching imitation responses, promoting appropriate toy play, and extending treatment into the family. In the second year, expressive and abstract language is taught, as well as appropriate social interactions with peers. Treatment in the third year emphasizes development of appropriate emotional expression, pre-academic tasks, and observational learning from peers involved in academic tasks. In an IBI therapy session, the child is directed to perform an action. Successful performance of the task is rewarded with a positive reinforcer, while noncompliance or no response receives a neutral reaction from the therapist. Although once a component of the original Lovaas methodology, aversive consequences are no longer used. This instructional method is known as “discrete trial discrimination learning and compliance.” Food is usually most effective as a positive reinforcer for autistic children, although food rewards are gradually replaced with “social” rewards, such as praise, tickles, hugs, or smiles. Parental involvement is considered essential to long-term treatment success; parents are taught to continue behavioral modification training when the child is at home, and may sometimes act as the primary therapist (Hayes, 2014).

Applied behavior analysis includes the use of adaptive behavior treatment that consists of individual and family or group treatment, social skills training, and exposure treatment. Adaptive behavior treatment may be provided to patients presenting with deficient adaptive or maladaptive behaviors (e.g., impaired social skills and communication).

Relationship Development Intervention (RDI) is a program designed to guide parents of children with autism spectrum disorder (ASD) and similar developmental disorders to function as facilitators for their children's mental development. The intention of RDI is to teach parents to play an important role in improving critical emotional, social, and metacognitive abilities through carefully guided interaction in daily activities (Gutstein 2009).

**Summary of Clinical Evidence**

Conclusions from several meta-analyses and large-scale technology assessments have suggested that the evidence to support the use of Intensive Behavioral Therapy (IBT) for the treatment of autism spectrum disorder is promising. Studies have demonstrated medium to large effects of IBT on intellectual functioning, language related outcomes (IQ, receptive and expressive language, communication), acquisition of daily living skills and social functioning. These effects have been observed both relative to no intervention as well as in comparison to other treatments.

However, despite these promising outcomes, there are several weaknesses and limitations in the research to-date on Intensive Behavioral Therapy for the treatment of autism spectrum disorder. Several meta-analyses and large-scale assessments have concluded that there were major limitations in design and methodology in the studies they evaluated. In addition to the use of single case studies or small sample sizes, general quality standards of clinical studies were inconsistently used, including randomization to group assignment, blind assessments, intent-to-treat analysis, and the use of prospective designs. Although random-effects meta-analysis and sensitivity analysis may partially compensate for some of these deficits, problems were identified at the meta-analysis level as well. One review of five recent meta-analyses observed that all of the meta-analyses had at least one methodological limitation, such as calculation of effect size based on small samples, inclusion of nonrandomized studies, and lack of standardized comparison or control groups.

These research weaknesses suggest the need for future research using stronger methodology to replicate current findings and demonstrate clear effectiveness and generalization of effect. In addition, comparisons of particular Applied Behavior Analysis (ABA) interventions are needed, as well as measurement of the treatment fidelity of the
various interventions provided. Future research also needs to identify the characteristics of children who respond best to particular treatments, as well as to identify the duration and intensity of treatment needed to produce positive outcomes.

Findings from the specific studies are presented below. The focus of the clinical evidence review is on technology assessments and published meta-analyses and systematic reviews that evaluated the reliability and validity of randomized controlled trials that compared IBT to other treatments for autism spectrum disorder.

**Clinical Trials**

The original work by Lovaas (1987) studied the effect of intensive behavioral therapy on IQ levels in 19 children. Subjects in the experimental group had an average gain of 30 points while the IQ levels of control group subjects were unchanged. While this is considered a landmark study, the small sample size and lack of long term follow up limits the generalizability of the findings. The Lovaas study had potential selection bias due to inclusion/exclusion criteria, lack of randomization, the questionable sensitivity of measurement instruments and the relevance of study endpoints. McEachin et al. (1993) evaluated the long term effect of intensive behavioral therapy (IBT)/ applied behavioral analysis (ABA) on the subjects involved in the Lovaas study and concluded that the children maintained the gains in IQ. The authors concluded that the long term follow up established the impact of the treatment, but the sample size remained small and the impact of the increased IQ was not correlated with changes in social or interpersonal functioning. Both studies excluded low-functioning autistic subjects.

**Systematic Reviews/Meta-Analyses**

Roth et al. (2014) evaluate the effectiveness of behavioral interventions for adolescents and adults with autism spectrum disorders (ASD) by conducting a meta-analysis of published single-case research studies. A new metric for calculating effect size in single-case research, nonoverlap of all pairs, was utilized. In addition, the certainty of evidence, a system to evaluate research methodology, was applied to the reviewed articles. Forty-three articles were identified in the study. Results suggested that the behavioral interventions in the areas of academic skills, adaptive skills, problem behavior, phobic avoidance, social skills, and vocational skills have medium-to-strong effect sizes. Medium-to-high confidence in findings was noted for 81% of the studies in the meta-analysis; however, three-fourths of the reviewed studies did not include treatment integrity, which may affect the ability to draw conclusions about the effectiveness of the interventions. According to the authors, the evidence is promising for the use of behavioral interventions for this population; however, additional research and dissemination are needed to fill the gap between research and practice in order for practitioners to meet the increasing demand as individuals with ASD age.

Bishop-Fitzpatrick et al. (2013) conducted a systematic review of all peer-review studies evaluating psychosocial interventions for adults with ASD. A total of 1,217 studies were reviewed, only 13 met inclusion criteria. The majority of studies were single case studies or non-randomized controlled trials, and most focused on applied behavior analysis or social cognition training. Effects of psychosocial treatment in adults with ASD were largely positive ranging from $d = 0.14 - 3.59$, although the quantity and quality of studies is limited. According to the authors, there is substantial need for the rigorous development and evaluation of psychosocial treatments for adults with ASD.

Strauss et al. (2013) completed a comprehensive synthesis of six meta-analyses of early intensive behavioral interventions (EIBI) for young children with autism spectrum disorders published from 2009 to 2011. The intent of the analysis was to consider the extent of parent inclusion in different treatment delivery formats. The analysis was completed by obtaining standardized mean difference effect sizes for 13 comparative studies ordered by comparison study type and 22 mean change effect sizes ordered by treatment delivery type. Results of the analysis suggested that EIBI leads generally to positive medium-to-large effects for three available outcome measures: intellectual functioning, language skills and adaptive behaviors. Although favorable effects were apparent across comparative studies, analysis by type of delivery format revealed that EIBI programs that include parents in treatment provision are more effective. Mediator analyses suggest that treatment variables and child characteristics impact program effectiveness when accounting for the extent of parent inclusion. Overall sample sizes of the studies used in this analysis were relatively small with a range in studies from 9-158 children.

Virues-Ortega et al. (2013) used meta-analytical procedures to examine the pooled clinical effects of Treatment and Education of Autistic and Related Communication Handicapped Children (TEACCH) in a variety of outcomes. A total of 13 studies were selected for meta-analysis totaling 172 individuals with autism exposed to TEACCH. Standardized measures of perceptual, motor, adaptive, verbal and cognitive skills were identified as treatment outcomes. Inverse-variance weighted random effects meta-analysis supplemented with quality assessment, sensitivity analysis, meta-regression, and heterogeneity and publication bias tests were used. The results suggested that TEACCH effects on perceptual, motor, verbal and cognitive skills were of small magnitude in the meta-analyzed studies. Effects over adaptive behavioral repertoires including communication, activities of daily living, and motor functioning were within the negligible to small range. There were moderate to large gains in social behavior and maladaptive behavior. According to the authors, the effects of the TEACCH program were not moderated by aspects of the intervention such as duration (total weeks), intensity (hours per week), and setting (home-based vs. center-based).
Reichow et al. (2012a) conducted an overview of five meta-analyses of IBI for young children that were published from 2009 to 2010. Meta-analyses included in the overview were those from Eldevik et al. (2009), Reichow and Wolery (2009), Spreckley and Boyd (2009), Virués-Ortega (2010), and Makrygianni and Reed (2010). Four of the five meta-analyses concluded that IBI was an effective intervention for many children with ASD. According to the author, all five of the meta-analyses had at least one methodological limitation, including calculation of effect size based on small samples (in some cases without reference to a control group), inclusion of nonrandomized studies, over-inclusion of participant data, and lack of standardized comparison or control groups. The author concluded the overview of the five selected meta-analyses by stating that it appeared that the average effects of IBI were strong and robust. However, the author noted that information on patient characteristics associated with best outcomes is needed. In addition, better knowledge of the treatment components (e.g., intensity, duration, level of treatment fidelity, therapist experience and/or training) necessary to achieve optimal outcomes is also required.

Reichow et al. (2012b) conducted a Cochrane review and meta-analysis of the evidence for the effectiveness of early intensive behavioral intervention (EIBI) in increasing the functional behaviors and skills of young children with autism spectrum disorders (ASD). One randomized control trial (RCT), and four clinical control trials (CCTs) in which assignment to treatment was based on parental preference were included in the review, representing a total of 203 participants, all younger than 6 when they began treatment. Children in the EIBI treatment groups showed more positive outcomes than those in the generic special education comparison groups. Mean effect sizes were as follows: for adaptive behavior $g = 0.69$, for full scale IQ $g = 0.76$, for expressive language $g = 0.50$, for receptive language $g = 0.57$, for daily communication skills $g = 0.74$, for socialization $g = 0.42$, and for daily living skills $g = 0.55$. The authors concluded that while there is some evidence that EIBI is an effective behavioral treatment for some children with ASD, the heavy reliance on data from non-randomized studies makes the quality of the evidence low and limits the ability to draw strong conclusions about effects of EIBI for children with ASD. According to the authors, additional studies using RCT research designs are needed.

In a project supported by the Agency for Healthcare Research and Quality (AHRQ), Warren et al. (2011a) published a systematic review of early intensive intervention for autism spectrum disorders for children aged 12 and younger. Thirty-four studies met inclusion criteria: 17 of these were case series, and 2 were randomized controlled trials. The authors rated 1 study as good quality, 10 as fair quality, and 23 as poor quality. Overall, the strength of the evidence ranged from insufficient to low. The authors concluded that studies of Lovaa-based approaches and early intensive behavioral intervention variants and the Early Start Denver Model (ESDM) resulted in some improvements in cognitive performance, language skills, and adaptive behavior skills in some young children with ASDs. The authors note that confidence (strength of evidence) in the effect of UCLA/Lovaas-based interventions is low because of the need for additional, confirmatory research, a lack of high-quality RCTs, and no studies that have directly compared effects of promising manualized treatment approaches. The evidence base for interventions for very young children, including the ESDM is insufficient. On balance, however, the combined research on UCLA/Lovaas-based interventions and the ESDM suggests a benefit of early intensive approaches for some children that should continue to be studied.

Peters-Scheffer et al. (2011) conducted a meta-analysis to evaluate the effectiveness of comprehensive early intervention behavioral interventions (EIBI) in young children with autism spectrum disorders (ASD). The meta-analysis included 11 studies ($n=344$ children). There was one randomized controlled trial ($n=28$); the other studies were controlled pre-test or post-test designs. The randomized controlled trial showed statistically significant differences in favor of EIBI for full scale IQ and non-verbal IQ. Results for all other outcome measures were not statistically significant. The authors concluded that children who received EIBI showed higher IQ, non-verbal IQ, expressive and receptive language and adaptive behavior than those in the control groups and stated that the results strongly support EIBI in the treatment of ASD. According to the Centre for Reviews and Dissemination (CRD), this meta-analysis had potential for reviewer error and bias in study selection and data extraction. It was unclear whether the chosen method of synthesis was appropriate, given the level of statistical and clinical heterogeneity acknowledged by the authors. The CRD also stated that given that results for the randomized controlled trial were not consistent with other studies on outcomes other than IQ, the authors' conclusion does not reflect the total evidence presented and may be overstated.

Makrygianni and Reed (2010) conducted a meta-analysis of 14 studies of Early Intensive Behavioral Intervention (EIBI) in children with autism spectrum disorders. The authors concluded that the results of this meta-analysis suggest that behavioral early interventional programs (EIPs) are effective in changing different developmental aspects of children with ASD, and they are much more effective than eclectic programs. Factors that have been identified as important for the efficacy of the EIPs are the intensity and the duration of the program, the age of the children at intake, the adaptive behavioral abilities of the children at intake, and parent training. According to the authors, further studies and meta-analyses are necessary. In particular, these should address the limitation of the studies included in the meta-analysis. Limitations of these studies include small sample size; the lack of comparison group, matched groups, or random assignment of the children; and the use of a variety of measures in the same study.
Virués-Ortega (2010) conducted a systematic review with a meta-analysis, meta-regression, and dose-response meta-analysis of ABA interventions for autism in early childhood. Twenty-two studies were included in the review. Results suggested that long-term, comprehensive ABA intervention leads to (positive) medium to large effects in terms of intellectual functioning, language development, acquisition of daily living skills and social functioning in children with autism. Although favorable effects were apparent across all outcomes, language-related outcomes (IQ, receptive and expressive language, communication) were superior to non-verbal IQ, social functioning and daily living skills, with effect sizes approaching 1.5 for receptive and expressive language and communication skills. Dose-dependent effect sizes were apparent by levels of total treatment hours for language and adaptation composite scores. The authors noted that randomization to group assignment was seldom implemented in the studies included in the review.

Eldevik et al. (2009) completed a meta-analysis that included 9 studies with controlled designs having either a comparison or a control group for Early Intensive Behavioral Intervention (EIBI). The investigators concluded that EIBI treatment results in large to moderate effect sizes for change in IQ and adaptive behavior, respectively, relative to no intervention or eclectic treatment in children w/ ASD. They suggested that, for now, EIBI should be considered a treatment of choice for children with ASD. The authors noted that randomized controlled trials comparing EIBD to other interventions are still needed, in particular, where the comparison intervention is of similar intensity.

Eldevik et al. (2010) gathered individual participant data from 16 group design studies on behavioral intervention for children with autism. In these studies, 309 children received behavioral intervention, 39 received comparison interventions, and 105 were in a control group. More children who underwent behavioral intervention achieved reliable change in IQ (29.8%) compared with 2.6% and 8.7% for comparison and control groups, respectively, and reliable change in adaptive behavior was achieved for 20.6% versus 5.7% and 5.1%, respectively. These results equated to a number needed to treat of 5 for IQ and 7 for adaptive behavior and absolute risk reduction of 23% and 16%, respectively. Within the behavioral intervention sample, IQ and adaptive behavior at intake predicted gains in adaptive behavior. Intensity of intervention predicted gains in both IQ and adaptive behavior.

A Systematic review and meta-analysis of early intensive behavioral intervention (EIBI) based on the UCLA model for young children with autism was conducted by Reichow and Wolery in January 2009. The findings of this review suggest that the UCLA program is an effective treatment, on average, for children with autism. However, based on a review of individual data, there appeared to be a small subpopulation of patients who did not respond to EIBI. Limitations of the studies selected for the review included that participants were not selected randomly and study sample sizes were small.

Spreckley and Boyd (2009) reviewed the effectiveness of applied behavior intervention programs for preschool children with autism spectrum disorder (ASD). Thirteen studies met the inclusion criteria. Six of these were randomized comparison trials with adequate methodologic quality. 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. There was no additional benefit over standard care for expressive language; SMD of 0.37, for receptive language; SMD of 0.29 or adaptive behavior; SMD of 0.30. The authors concluded that 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.

Ospina et al. (2008) conducted a meta-analysis of behavioral and developmental interventions for autism spectrum disorders. Meta-analyses of three controlled clinical trials showed that Lovaas treatment was superior to special education on measures of adaptive behavior, communication and interaction, comprehensive language, daily living skills, expressive language, overall intellectual functioning and socialization. High-intensity Lovaas was superior to low-intensity Lovaas on measures of intellectual functioning in two retrospective cohort studies. Pooling the results of two randomized controlled trials favored developmental approaches based on initiative interaction compared to contingency interaction in the amount of time spent in stereotyped behaviors and distal social behavior, but the effect sizes were not clinically significant. No statistically significant differences were found for: Lovaas versus special education for non-verbal intellectual functioning; Lovaas versus Developmental Individual-difference relationship-based intervention for communication skills; computer assisted instruction versus no treatment for facial expression recognition; and TEACCH versus standard care for imitation skills and eye-hand integration. The authors concluded that while this review suggests that Lovaas may improve some core symptoms of ASD compared to special education, these findings are based on 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.
An AHRQ systematic review of behavioral intervention therapies for children (0-12 years) with autism spectrum disorder (ASD) was published in 2011 (Warren et al. 2011b). In 2014, this report was updated, focusing on more recent studies of behavioral interventions (Weitlauf et al. 2014).

**AHRQ 2011 Review of Behavioral Intervention Therapies for Children with ASD**

The 2011 AHRQ comparative effectiveness review of behavioral intervention therapies for children (0-12 years) with ASD evaluated behavioral interventions, educational interventions, medical and related interventions, allied health interventions, and complementary and alternative medicine interventions. The review focused on treatment outcomes, modifiers of treatment effectiveness, evidence for generalization of outcomes to other contexts, and evidence to support treatment decisions in children ages 0-2 years at risk for an ASD diagnosis. For early intensive behavioral and development interventions, a total of 34 studies from 30 study populations met the inclusion criteria. Of these, 23 studies evaluated the University of California at Los Angeles (UCLA)/Lovaas-based interventions or other variants of IBI. Eight studies were rated as fair quality, and the remaining 15 were rated as poor quality. There was one randomized controlled trial of the UCLA/Lovaas-based treatment. The authors concluded that there was some evidence supporting early and intensive behavioral and developmental intervention, including a UCLA/Lovaas-focused approach and a developmentally focused Early Start Denver Model approach. Both approaches were associated with larger improvements in cognitive performance, language skills, and adaptive behavior skills relative to eclectic treatments in subgroups of children. Data were considered preliminary, but promising, for intensive intervention in children less than 2 years of age. However, the strength of evidence was considered low, and replication of the results necessary to allow more definite conclusions. In addition, the authors suggested future studies should focus on which children are most likely to benefit from early intensive interventions (Warren et al., 2011b).

**AHRQ 2014 Update of Behavioral Interventions for Children with ASD**

The 2014 AHRQ update of behavioral interventions for children with autism spectrum disorder (Weitlauf et al. 2014) included 65 unique studies comprising 48 randomized trials and 17 nonrandomized comparative studies (19 good, 39 fair, and 7 poor quality) published since the prior review. AHRQ defines behavioral interventions to include early intensive behavioral and developmental interventions, social skills interventions, play/interaction-focused approaches, interventions targeting symptoms commonly associated with ASD, and other general psychosocial approaches. The AHRQ findings from the 2014 update are presented below.

**AHRQ Selected Key Questions and Findings**

- Among children ages 2–12 with ASD, what are the short- and long-term effects of available behavioral treatment approaches?

  AHRQ identified 25 new studies (reported in 37 publications) addressing early intensive behavioral and developmental interventions (8 good, 13 fair, and 4 poor quality). Improvements were most often seen in cognitive abilities and language acquisition, with fewer improvements seen in adaptive skills, core ASD symptom severity, and social functioning. According to AHRQ, the long-term impact of these early skill improvements is not yet clear, and many studies did not follow children beyond late preschool or early school years.

AHRQ states the following regarding the strength of the evidence for interventions on core and commonly associated symptoms in children with ASD:

- Early intervention based on high-intensity applied behavior analysis over extended timeframes was associated with improvement in cognitive functioning and language skills (moderate strength of evidence for improvements in both outcomes) relative to community controls in some groups of young children. The magnitude of these effects varied across studies, potentially reflecting poorly understood modifying characteristics related to subgroups of children. Early intensive parent training programs modified parenting behaviors during interactions; however, data were more limited about their ability to improve developmental skills beyond language gains for some children (low strength of evidence for positive effects on language).

- Social skills interventions varied in scope and intensity and showed some positive effects on social behaviors for older children in small studies (low strength of evidence for positive effects on social skills). Although there are now higher quality studies of social skills interventions that demonstrate positive effects, the ability to determine effectiveness continues to be limited by the diversity of the intervention protocols and measurement tools (i.e., no consistent outcome measures used across studies). Studies also included only participants considered “high functioning” and/or with IQ test scores >70, thus limiting generalization of results to children with more significant impairments. Maintenance and generalization of these skills beyond the intervention setting are also inconsistent, with parent and clinician raters noting variability in performance across environments.

- Studies of play/interaction-based approaches reported that joint attention interventions may demonstrate positive outcomes in preschool-age children with ASD when targeting joint attention skills (moderate strength of evidence); data on the effects of such interventions in other areas were limited (low strength of evidence for positive effects on play skills, language, social skills).
Among children ages 2–12, what are the modifiers of outcome for different behavioral treatments or approaches?

AHRQ states the following:
Among the potential modifiers or moderators of early intensive ABA-based interventions, younger age at intake was associated with better outcomes for children in a limited number of studies. Greater baseline cognitive skills and higher adaptive behavior scores were associated with better outcomes across behavioral interventions, but these associations were not consistent. In general, children with lower symptom severity or less severe diagnoses improved more than participants with greater impairments. Many studies restricted the range of participants' impairment at baseline (e.g., recruiting only participants with IQs >70), limiting understanding of intervention impact on broader populations. Studies assessing parental responsiveness to children's communication typically reported better outcomes in children whose parents were more aligned with the child's communication versus those who attempted to redirect or were less synchronized. Regarding intervention-related factors, duration of treatment had an inconsistent effect. Some studies reported improved outcomes with more intervention time and others reported no association. Overall, most studies were not adequately designed or controlled to identify true moderators of treatment response.

What is the evidence that effects measured at the end of the treatment phase predict long-term functional outcomes?

AHRQ states the following:
Few studies assess end-of-treatment effects that may predict outcomes. Several early intensive behavioral and developmental interventions are associated with changes in outcome measures over the course of very lengthy treatments, but such outcomes usually have not been assessed beyond treatment windows.

What is the evidence that specific intervention effects measured in the treatment context generalize to other contexts (e.g., people, places, materials)?

AHRQ states the following:
Few studies included in the review explicitly measured generalization of treatment effects to different conditions or locations. The majority of the social skills and behavioral intervention studies targeting associated conditions attempted to collect outcomes based on parent, self, teacher, and peer report of targeted symptoms (e.g., anxiety, externalizing behaviors, social skills, peer relations) at home, at school, and in the community. Although such ratings outside of the clinical setting may be suggestive of generalization in that they improve outcomes in the daily context/life of the child, in most cases, these outcomes are parent reported and not confirmed with direct observation. Behavioral intervention studies rarely measured outcomes beyond the intervention period, and therefore it cannot assume that effects were maintained over time.

What evidence supports the use of a specific behavioral treatment approach in children under the age of 2 who are at high risk of developing ASD based on behavioral, medical, or genetic risk factors?

AHRQ states the following:
In the studies addressing interventions for younger children, children who received behavioral interventions seemed to improve regardless of intervention type. None of the fair or good quality studies compared treatment groups to a no treatment control group. Most outcome measures of adaptive functioning were based upon parent report, and the effect of parental perception of treatment efficacy on perception (and report) of child functioning was generally not explored.

AHRQ Comments Regarding Limitations of the Evidence

AHRQ states that despite improvements, the existing literature still has significant methodological concerns that in many ways continue to limit the strength of the report’s conclusions. According to AHRQ, evidence for the impact of intensive ABA-based interventions on cognitive, language, and adaptive skills and ASD symptoms also highlights important limitations of current treatment modalities. First, even children who demonstrate clinically significant improvements in these areas often continue to display substantial impairment in these and other areas over time. Second, not all children receiving intensive ABA-based intervention showed robust improvements in these areas. Thus, it is still challenging to predict long-term functional and adaptive outcomes on an individual level. The AHRQ also states that although children receiving early intensive developmental and behavioral intervention commonly display substantial improvements, the magnitude of these effects varies across studies and may indicate subgroups showing variable responses to particular interventions. Intervention response is likely moderated by both treatment and child factors. Despite multiple studies of early intensive treatments, intervention approaches still vary substantially, which makes it difficult to evaluate what these unique treatment and child factors may be. According to the authors, the evidence is insufficient to adequately identify and target the children who are most likely to benefit (or not benefit) from specific interventions. Additionally, the AHRQ states that little data on the practical effectiveness or feasibility of these treatments beyond research studies exist, and questions remain about whether reported findings would generalize on a larger scale within communities.
**AHRQ Conclusions**

AHRQ states that considerable and consistent evidence suggests that early behavioral and developmental intervention based on the principles of applied behavior analysis (ABA) delivered in intensive (>15 hours per week) and comprehensive (i.e., addressing numerous areas of functioning) form can significantly affect the development of some children with ASD. AHRQ also states that despite improvements, the existing literature still has significant methodological concerns that in many ways continue to limit the strength of the report’s conclusions. According to AHRQ, substantial scientific advances are needed to enhance the understanding of which interventions are most effective for specific children with ASD and to isolate the elements or components of interventions most associated with effects (Weitlauf et al. 2014).

**AHRQ 2012 Review on Interventions on Adolescents and Young Adults with ASD**

In 2012, the AHRQ published a comparative effectiveness review of the effects of available interventions on adolescents and young adults (ages 13 to 30) with ASD, falling into the following approaches: behavioral, educational, adaptive/life skills, vocational, medical, and allied health. The authors identified 8 studies of the behavioral intervention approach that met their criteria for review, of which there was a single case series that examined the effects of an intensive, comprehensive intervention approach. This study was rated by AHRQ as being of poor quality due to its lack of control group, lack of detailed description of the intervention, and a lack of blinded assessors. Results suggested improvement in adaptive skills and high levels of family satisfaction with services for 34 adolescents receiving treatment in a residential treatment setting over the course of 2 years. The authors of the report concluded that “given the lack of adequate comparison group in this setting, there is very little information surrounding the impact of comprehensive behavioral intervention approaches for this population” (Lounds, et al., 2012).

**Other Technology Assessments**

The National Autism Center conducted a complex multifaceted review of educational/behavioral treatments for individuals under the age of 22 with a diagnosis of Autistic Disorder, Asperger’s Syndrome, or PDD-NOS, and reported results in the Phase 1 National Standards Project (NSP1). The NSP reviewed 775 peer reviewed studies published between 1957 and 2007 that utilized a variety of interventions pertaining to the treatment of ASD. The NSP review occurred across disciplines including psychologists, speech-language pathologists, educators, occupational or physical therapists and behavior analysts. Steps were taken to establish a high level of reliability amongst reviewers, including creating a coding manual, training raters to a specified criterion, and evaluation of the field reviewer’s level of interobserver agreement. Reviewers used a scientific rating scale to consistently evaluate the scientific merit of each study included in the analysis, a large proportion of which were single case studies. Scores were assigned based on five critical dimensions of scientific rigor and used to determine the extent to which the interventions were effective. Studies were then placed into a strength of evidence classification system which was broken down into four categories: established, emerging, unestablished or ineffective/harmful category. Based on this scoring system, the NSP identified 11 established treatments, defined as treatments that produce beneficial outcomes and are known to be effective for individuals on the autism spectrum. The overwhelming majority of these interventions were developed in the behavioral literature (e.g., applied behavior analysis, behavioral psychology, and positive behavior support). The 11 established treatments were Antecedent Package; Behavioral Package; Comprehensive Behavioral Treatment for Young Children; Joint Attention Intervention; Modeling; Naturalistic Teaching Strategies; Peer Training Package; Pivotal Response Treatment; Schedules; Self-management; and Storybased Intervention Package (National Autism Center 2009).

The National Autism Center Phase 2 (NSP2) report reviewed studies published between 2007 and February of 2012. According to the authors, NSP2 reinforced the findings of Phase 1. For children and adolescents under age 22, there is now more empirical support for interventions that are behaviorally based. The authors indicated that in spite of the growing population of adults with ASD, there is little empirical research to guide intervention for this population (National Autism Center 2015).

A Technical Expert Panel (TEP) consisting of practitioners, researchers, and parents used the findings of a systematic review of scientific evidence to develop consensus guidelines on nonmedical interventions in children with autism spectrum disorders (ASDs). The panel agreed that children with ASD should have access to at least 25 hours per week of comprehensive intervention to address social communication, language, play skills, and maladaptive behavior. The panel agreed that there is moderate strength evidence that comprehensive intervention programs, often referred to as intensive interventions, are effective at improving core deficits of ASD. They conclude that few of the controlled studies that have been conducted included random selection of their subjects or enrolled large samples, that there is insufficient evidence to suggest one behavioral curriculum is superior to another, that few studies can demonstrate which program components are effective, and few studies have long-term follow-up of patients. Their review of the evidence suggested that there was some evidence that greater intensity of treatment (hours per week) and greater duration (in months) led to better outcomes. The strength of the evidence was found to be lower for developmentally based intensive programs and environmental programs such as TEACCH. Based on identified gaps, the panel recommends that future research focus on five top research priorities: assessment and monitoring of outcomes,
addressing the needs of pre/nonverbal individuals with ASDs, understanding the needs of adolescents and adults with ASDs, identifying the strategies that are most effective at impacting core deficits, and identifying the most effective strategies, dose, and duration of ASD interventions (Magilone, et al., 2012).

The New Zealand Ministry of Health (2010) reviewed the evidence in a technical review on Applied Behavioral Analysis and made the following recommendations:

- Interventions and strategies based on [Applied Behavior Analysis] principles should be considered for all children with autism spectrum disorders.
- [Early intensive behavioral interventions] should be considered as a treatment of value for young children with autism spectrum disorders to improve outcomes such as cognitive ability, language skills, and adaptive behavior.

According to the New Zealand review, there is evidence that behavioral interventions produce beneficial results in behavioral deficits and excesses occurring in children diagnosed with ASD. Of the all measured outcomes reported in the 508 journal articles reviewed, 70% demonstrated beneficial effects. In no case was harm reported as a result of behavioral intervention (New Zealand Ministry of Health 2010).

The Blue Cross and Blue Shield Association's Technology Evaluation Center published a report evaluating early intensive behavioral intervention (EIBI) for autism. The objective of the report was to conduct a systematic review of the research literature on the use of EIBI among young children with autism, pervasive developmental disorder, or Asperger's disorder. The report indicated that overall, the quality and consistency of results of this body of evidence are weak. Consequently, no conclusions could be drawn from this literature on how well EIBI works. The report states that weaknesses in research design and analysis, as well as inconsistent results across studies, undermine confidence in the reported results. Based on the weakness of the available evidence, the Tech Assessment was uncertain about the effectiveness of EIBI for autism spectrum disorders (Blue Cross and Blue Shield Tech Assessment, 2009).

The Blue Cross Blue Shield Association published a special report for early intensive behavioral intervention and other behavioral interventions for autism spectrum disorder in 2015. One of the objectives of this analysis was to review comparative studies of early intensive behavioral intervention (EIBI) and evaluate patient or intervention characteristics that might moderate treatment effects. The authors identified very few studies that appropriately analyzed whether improvements due to EIBI interact with child, treatment, or other variables. One study showed a greater effect of EIBI on IQ in younger children (Flanagan et al. 2012). Another showed a greater effect of EIBI on males (Boyd et al. 2014). According to the authors, these findings are potential signals of differential treatment effects and may provide the basis for further research. Most studies included in the analysis had modest sample sizes, and thus the statistical power to detect interactions was low. The authors concluded that there is very little scientific evidence that patient or environmental characteristics impact the efficacy of EIBI programs. It should be noted that this conclusion does not address the overall efficacy of EIBI, rather it only addresses the evidence regarding interacting and/or moderating characteristics (Mark et al. 2015).

The Scottish Intercollegiate Guidelines Network (SIGN) published evidenced-based clinical guidelines for the assessment, diagnosis, and clinical interventions for children and young people with autism spectrum disorders. SIGN recommends that the Lovaaas program should not be presented as an intervention that will lead to normal functioning. The report recommends that behavioral interventions should be considered to address a wide range of specific behaviors in children and young people with ASD, both to reduce symptom frequency and severity and to increase the development of adaptive skills (SIGN, 2007).

The National Institute for Health and Care Excellence (NICE) published clinical guidelines for the management and support of children and young people on the autism spectrum in 2013. The guidelines include the following recommendations for psychosocial interventions:

- Consider a specific social-communication intervention for the core features of autism in children and young people that includes play-based strategies with parents, carers and teachers to increase joint attention, engagement and reciprocal communication in the child or young person. Strategies should:
  - Be adjusted to the child or young person's developmental level
  - Aim to increase the parents', carers', teachers' or peers' understanding of, and sensitivity and responsiveness to, the child or young person's patterns of communication and interaction
  - Include techniques of therapist modeling and video-interaction feedback
  - Include techniques to expand the child or young person's communication, interactive play and social routines

  The intervention should be delivered by a trained professional. For pre-school children consider parent, carer or teacher mediation. For school-aged children consider peer mediation.

A portion of the NICE guidelines speak to the methodologies of studied interventions for children and young people with autism. This section states that although the overall quality of the research of interventions for autism has improved considerably over the past decade, as demonstrated particularly by the growth in randomized control trials.
Behavioral therapy programs are not subject to regulation by the FDA.

**Professional Societies**

**American Academy of Pediatrics (AAP)**

The AAP published clinical guidelines for the management of autism in 2007 that were reaffirmed in 2010. The AAP states 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. They further state that there is a growing body of evidence that supports the efficacy of certain interventions in ameliorating symptoms and enhancing functioning, but much remains to be learned. The AAP also states that proponents of behavior analytic approaches have been the most active in using scientific methods to evaluate their work, and most studies of comprehensive treatment programs that meet minimal scientific standards involve treatment of preschoolers using behavioral approaches. However, there is still a need for additional research, including large controlled studies with randomization and assessment of treatment fidelity. Empirical scientific support for developmental models and other interventions is more limited, and well-controlled systematic studies of efficacy are needed (Myers and Johnson, 2007).

**American Academy of Child and Adolescent Psychiatry (AACAP)**

The AACAP published practice parameters for the assessment and treatment of children and adolescents with autism spectrum disorder (Volkmar et al., 2014) which recommends that clinicians should help families obtain appropriate, evidence-based, and structured educational and behavioral interventions for children with autism spectrum disorder (ASD). According to the practice parameter, behavioral interventions such as applied behavioral analysis (ABA) are informed by basic and empirically supported learning principles. The authors note that “Structured educational and behavioral interventions have been shown to be effective for many children with ASD and are associated with better outcome. As summarized in the National Research Council (NRC) report, the quality of the research literature in this area is variable, with most studies employing group controls or single-subject experimental methods. In general, studies employing more rigorous randomized group comparisons are sparse, reflecting difficulties in random assignment and control comparisons. Other problems include lack of attention to subject characterization, generalization of treatment effects, and fidelity of treatment implementation. Despite these problems, various comprehensive treatments approaches have been shown to have efficacy for groups of children, although none of the comprehensive treatment models has clearly emerged as superior.” The AACAP practice parameter also indicates that ABA techniques have been repeatedly shown to have efficacy for specific problem behaviors, and ABA has been found to be effective as applied to academic tasks (Koegel et al., 2003, n=2), adaptive living skills (Leblanc et al., 2005, n=3), communication (Jones et al., 2007, n=2), social skills (Pierce and Schreibman, 1995, n=2), and vocational skills (Lattimore et al., 2006, n=4).

A review of the clinical studies referenced by AACAP in the 2014 AACAP practice parameter for applied behavioral analysis found that these studies were uncontrolled or had very small study populations.

**Additional Search Terms**

Bayley Scales of Infant Development (BSID), childhood aphasia, dysphasia, echolalia, fragile-X syndrome, functional speaking ability, Merrill-Palmer (M-P), mutism, operant conditioning, Personality Inventory for Children (PIC), tactile defensiveness, Mifne Method.

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

Behavioral therapy programs are not subject to regulation by the FDA.
REFERENCES


### POLICY HISTORY/REVISION INFORMATION

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| 08/12/2016 | • Updated benefit considerations:  
               o Removed/replaced language pertaining to state mandated benefit coverage guidelines for fully insured group policies in Maryland; added reference links to the policies titled *Autism Spectrum Disorder and Intensive Behavior Therapy* and *Habilitative Services for Essential Health Groups* for applicable details  
               o Archived previous policy version 2016T0202N  |