

INTENSIVE BEHAVIORAL THERAPY (IBT) / APPLIED BEHAVIOR ANALYSIS (ABA) FOR AUTISM SPECTRUM DISORDERS

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Relevant Diagnoses

Autism Spectrum Disorders

Related Clinical Policies & Guidelines:

- Treatment of Neurodevelopmental Disorders
- Complementary and Alternative Medicine (CAM)

INSTRUCTIONS FOR USE

This Behavioral Clinical Policy provides assistance in interpreting and administering behavioral health benefit plans that are managed by Optum and U.S. Behavioral Health Plan, California (doing business as OptumHealth Behavioral Solutions of California ("Optum-CA")). 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 Behavioral Clinical Policy is based. In the event of a conflict, the member's specific benefit plan document supersedes this Behavioral Clinical Policy.

All reviewers must first identify member eligibility, the member-specific benefit plan coverage, and any federal or state regulatory requirements that supersede the COC/SPD prior to using this Behavioral Clinical Policy. Other Policies and Coverage Determination Guidelines may apply. Optum reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

This Behavioral Clinical Policy is provided for informational purposes. It does not constitute medical advice.

Optum may also use tools developed by third parties that 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.

Use of this guideline may be extended to other conditions or age groups when benefits are mandated by regulation or customer contract.

School-based IBT services or services that are otherwise covered under the Individuals with Disabilities Education Act (IDEA) are not covered.

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

Refer to the following documents for fully insured policies in Maryland

Use the following criteria as specified in the Code of Maryland Regulations (MD COMAR 31.10.39.03. April 3, 2014)

- A. The utilization review criteria of a carrier or private review agent acting on behalf of a carrier to determine medical necessity or appropriateness may not be more restrictive for habilitative services for the treatment of autism and autism spectrum disorders than the criteria listed in this regulation.
- B. The carrier's criteria for habilitative services shall include criteria for behavioral health treatment, psychological care, and therapeutic care.
- C. Utilization review criteria of a carrier or private review agent acting on behalf of a carrier may require:
 - 1. A comprehensive evaluation of a child by the child's primary care provider or specialty physician identifying the need for habilitative services for the treatment of autism or autism spectrum disorder;
 - 2. A prescription from a child's primary care provider or specialty physician that includes specific treatment goals; and
 - 3. An annual review by the prescribing primary care provider or specialty physician, in consultation with the habilitative services provider, that includes:
 - i. Documentation of benefit to the child;
 - ii. Identification of new or continuing treatment goals; and
 - iii. Development of a new or continuing treatment plan.
- D. A carrier or private review agent acting on behalf of a carrier may not deny coverage based solely on the number of hours of habilitative services prescribed, for:
 - 1. 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
 - 2. 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.
 - 3. Notwithstanding §D(1) and (2) of this regulation, a carrier may authorize additional hours of habilitative services that are medically necessary and appropriate for the treatment of autism or autism spectrum disorders.
- E. A carrier may limit payment for habilitative services to payment for services provided by individuals who are licensed, certified, or otherwise authorized under the Health Occupations Article or similar licensing, certification, or authorization requirements of another state or U.S. territory where the habilitative services are provided.
- F. Location of services.
 - 1. A carrier may not deny payment for habilitative services if a treatment goal identifies the location of the habilitative services as the child's educational setting.
 - 2. Nothing in §F(1) of this regulation shall be construed to require a carrier to provide services to a child 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., as amended from time to time.
- G. A carrier or a private review agent acting on behalf of a carrier may not deny payment for applied behavior analysis on the basis that it is experimental or investigational.

Pre-Service Notification

Admissions to an inpatient, residential treatment center, intensive outpatient, or a partial hospital/day treatment program require pre-service notification. Notification of a scheduled admission must occur at least five (5) business days before admission. Notification of an unscheduled admission (including emergency admissions) should occur as soon as is reasonably possible. Benefits may be reduced if Optum is not notified of an admission to these levels of care. Check the member's specific benefit plan document for the applicable penalty and provision of a grace period before applying a penalty for failure to notify Optum as required.

Additional Information

The lack of a specific exclusion for a service does not necessarily mean that the service is covered. For example, depending on the specific plan requirements, services that are inconsistent with Level of Care Guidelines and/or prevailing medical standards and clinical guidelines may be excluded. Please refer to the member's benefit document for specific plan requirements.

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 document to determine benefit coverage.

COVERAGE RATIONALE

Intensive behavioral therapy is proven for the treatment of autism spectrum disorder in children when the following conditions are met:

- The intervention is a systematic approach, based on the principles of comprehensive applied behavior analysis (e.g., Early Intensive Behavioral Intervention, Intensive Behavioral Intervention Therapy);
- The intervention targets the core deficits of an autism spectrum disorder, as outlined by the current edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM);
- The intervention is delivered in a home or community setting using a low child-to-therapist ratio;
- The intervention is rendered directly by a Board Certified Behavior Analyst (BCBA), a licensed mental health clinician with additional documented training in applied behavior analysis, or a paraprofessional under the direct supervision of such professionals;
- The intervention is delivered with an appropriate level of intensity (e.g., per Behavior Analyst Certification Board standards) and includes ongoing measurement of efficacy the use of measurement tools and analysis of progress should be continuous, and treatment decisions based on objective analysis of assessment results.

Intensive behavioral therapy is unproven for any of the following:

- Any intensive behavioral therapy programs or interventions that do not meet all of the above proven conditions;
- Intensive behavioral therapy programs that are initiated once the individual is a developmental adolescent or adult:
- Intensive behavioral therapy programs that are not delivered by or under the supervision of an ABA-trained professional;
- Intensive behavioral therapy that targets mental disorders other than autism spectrum disorders as defined in the DSM.

According to many recent systematic reviews and meta-analyses, early intervention based on applied behavior analysis is associated with positive outcomes for children with autism spectrum disorders. Currently, there is insufficient evidence to determine which children are most likely to benefit (or not benefit) from specific interventions. Recent progress has been made in systematizing intervention approaches and measuring treatment fidelity. Intervention research for adolescent and young adult populations and for primary diagnoses other than autism spectrum disorders remains very limited.

The requested service or procedure must be reviewed against the language in the member's benefit document. When the requested service or procedure is limited or excluded from the member's benefit document, or is otherwise defined differently, it is the terms of the member's benefit document that prevails.

Per the specific requirements of the plan, health care services or supplies may not be covered when inconsistent with Level of Care Guidelines and/or evidence-based clinical guidelines.

Utilization Management Criteria

All services must be provided by or under the direction of a properly qualified behavioral health provider.

DEFINITIONS

Diagnostic and Statistical Manual of Mental Disorders (DSM): A manual produced by the American Psychiatric Association which provides the diagnostic criteria for mental health and substance-related disorders and other problems that may be the focus of clinical attention. Unless otherwise noted, the current edition of the DSM applies.

Proven Services: Services or technologies that, after a review of the evidence, demonstrate they can be safely and effectively administered to a defined patient population, under a set of specific conditions that are clearly identified. A service found to be proven does not necessarily indicate that the service is covered. The member's specific benefit plan must be referenced to determine coverage, limitations, and exclusions.

Scientific Evidence: The results of controlled clinical trials or other studies published in peer-reviewed, medical literature generally recognized by the relevant medical specialty community.

Unproven Services: Services including medications that are not consistent with prevailing medical research that has determined the services to not be effective for treatment of the condition and/or not to have the beneficial effect on behavioral health outcomes due to insufficient and inadequate clinical evidence from well-conducted randomized controlled trials or cohort studies in the prevailing published peer-reviewed literature. Unproven services and all services related to unproven services are typically excluded. The fact that an unproven service, treatment, device, or pharmacological regimen is the only available treatment for a particular condition will not result in benefits if the procedure is considered to be unproven in the treatment of that particular condition.

DESCRIPTION OF SERVICES

According to the 5th Edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5), autism spectrum disorder (ASD) is characterized by social communication impairments and restricted, repetitive patterns of behavior. 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 (American Psychiatric Association, 2013).

Intensive behavioral therapy programs used to treat autism spectrum disorder are often referred to as Intensive Behavioral Intervention (IBI), Early Intensive Behavioral Intervention (EIBI), or Applied Behavior Analysis (ABA). These interventions aim to reduce problem behaviors and develop alternative behaviors and skills in those with Autism Spectrum Disorder. In a typical 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. For children with maladaptive behaviors, plans are created to utilize the use of reinforcers to decrease problem behavior and increase more appropriate responses. Although once a component of the original Lovaas methodology, aversive consequences are no longer used. 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).

CLINICAL EVIDENCE

Summary of Clinical Evidence

Conclusions from several recent systematic reviews and meta-analyses suggest that the evidence to support the use of intensive behavioral therapy for ASDs has improved, particularly over the last decade. A number of these studies report medium to large effects of intensive behavioral therapies on improvements in communication and reductions in maladaptive behavior. The National Autism Center, in a two-phase review of 1164 studies, found the strongest evidence to be for comprehensive behavioral treatment for children (primarily up to age 9), often referred to as ABA programs or early intensive behavioral interventions (EIBI). Similarly, in a 2014 review, the Agency for Health Research and Quality (AHRQ, 2014) found the strongest evidence for ABA-based early intensive behavioral and developmental interventions in children up to age 12.

Many reviews note that few studies have randomly selected their subjects or enrolled large samples. The AHRQ (2014) has called for a greater need to study interventions across settings. Many authors also note that an enhanced understanding of which interventions are most effective for specific children with ASDs is necessary, and will need to be included in future research.

While the quantity of research on intensive behavioral therapies for adolescent and adults with ASDs has increased in recent years, the evidence remains inconclusive on the efficacy of these interventions in older populations.

Systematic Reviews/Meta-Analyses

Brugha and colleagues (2015) conducted a systematic review of outcome measures used in treatment trials for older adolescents and adults with an autism spectrum disorders (ASD). Included studies were required to have a focus on treating core ASD symptoms and associated conditions of ASD in adolescents and adults (age > 15). Additionally, the evaluation of therapy must have been compared with the same treatment at a different dose or intensity, an alternative intervention and/or placebo or usual care. The study must have also incorporated at least one standardized or quantitative outcome measure of effectiveness associated with improvement of core/associated or secondary features of ASD. A total of 30 articles (19 of which involved pharmacological treatments) were identified that met inclusion criteria. Selected studies included randomized and placebo-controlled trials, retrospective assessment studies, case series and open label or case-control trials. The review found that use of outcome measures varied with frequent use of non-standardized assessments, and very little use of measures designed specifically for individuals with ASD or of instruments focusing on core ASD deficits, such as communication or social functioning. The authors conclude that although there are now many well controlled treatment trials for children with ASDs, adult intervention research is very limited. The lack of valid and reliable outcome measures for adults with ASDs compromises attempts at treatment evaluation.

Roth and colleagues (2014) conducted a meta-analysis of published behavioral interventions for adolescents and adults diagnosed with an autism spectrum disorder (ASD). The authors set objectives of (a) identification of the overall effects of the behavioral interventions for adolescents and adults with ASD using a "nonoverlap of all pairs" effect size, and (b) assessment of the certainty of evidence, an evaluation system of a study's design and methodology, to determine the confidence to place in the results of the included studies. A total of 43 articles met inclusionary criteria, yielding data for 110 participants ranging in age from 12 to 45 years. Articles were classified as having suggestive (74.4%), preponderant (9.3%), or conclusive (16.3%) certainty of evidence. The most common reason studies did not receive a conclusive certainty of evidence classification was missing treatment integrity data. Three quality indicators (generalization, maintenance, social validity) of single-case research were also examined. Results suggested that the behavioral interventions in 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; however, three-fourths of the reviewed studies did not include treatment integrity. The authors conclude that the overall evidence is promising for use of behavioral interventions for this adolescent/adult population; however, additional research and dissemination are needed to fill the gap between research and practice.

Walton and Ingersoll (2013) reviewed research examining social skill interventions for youth and adults with an autism spectrum disorder (ASD) and severe to profound intellectual disability (S/PID), and pointed out weaknesses and challenges in this literature. Seventeen studies examining interventions for improving positive social behaviors in adolescents or adults with ASD and S/PID were included in this literature review. After the studies to be included were identified, articles were grouped into several broad treatment categories based on similarity of treatment methods. The review suggests that a variety of interventions from several theoretical perspectives (video modeling, developmental, peer-mediated, behavioral, structured teaching) have been examined for use in this population, with a number of successes reported. These programs have targeted social skills with a number of different interaction partners, including teachers or therapists (developmental and behavioral interventions), peers (behavior and peer-mediated interventions), and direct care staff (structured teaching interventions). The authors conclude that the findings of this review are unable to recommend a specific treatment, and a next step in treatment development would be further manualization and protocol development to enable replication of various findings on a larger scale.

McDonald and Machalicek (2013) conducted a systematic review of intervention research for adolescents with autism spectrum disorders (ASDs) between the years 1980 and 2011. Articles had to include at least one adolescent (age 12-21) with a diagnosis of ASD, and study the implementation of an empirical design to evaluate the effects of an educational, behavioral, or psychosocial intervention and report distinguishable outcome data. A total of 102 included studies were classified into seven categories: (1) social skills; (2) communication skills; (3) challenging behavior; (4) academic skills; (5) vocational skills; (6) independence and self-care; and (7) physical development. Participants were divided into three age groups (12-14 years; 15-17 years; 18-21 years) to compare interventions and domains across age. The studies were set primarily in school settings, followed by clinical, institutional and community settings. Antecedent and behavioral intervention combinations were by far the most common intervention package (22%), followed by teacher implemented antecedent and behavioral intervention (8%), teacher implemented antecedent approaches (7%), behavioral intervention and self-management interventions (5%), and antecedent, behavioral intervention, and technology-based approaches (4%). The remaining 39% of interventions utilized a wide range of combinations. The majority of studies (86%) reported positive findings. Comparative effectiveness, on the other hand, was difficult to determine due to variations in intervention procedures, specific skills targeted, participant characteristics, and other factors. Effectiveness for interventions combinations was also difficult to ascertain without comparison to the interventions singly. The authors conclude that encouraging findings include a range of effective approaches for younger adolescents, with three approaches demonstrating consistent positive findings: antecedent manipulations, behavioral interventions, and technology-based interventions.

Bishop-Fitzpatrick and colleagues (2013) conducted a systematic review of psychosocial interventions for adults with autism spectrum disorders (ASDs). The authors examined the evidence base of such interventions for adults with ASD to determine common themes in treatment approaches and evaluate the evidence of their efficacy. A total of 1217 studies were reviewed, though only 13 met inclusion criteria. Over three-quarters of the studies had less than 20 participants. All ABA studies were single case, and reported positive benefits of treatment, although the maintenance of this benefit varied between subjects. The authors conclude that despite evidence of the benefits of psychosocial interventions for adults with ASD, there are significant limitations to the current evidence base. Due to the small number of studies for this population, the authors were unable to conduct a meta-analysis of the adult ASD literature. As a consequence, clear estimates of effect size for different types of psychosocial interventions are not available. It is suggested that new research conducted on psychosocial interventions for adults should use more rigorous and adequately powered methodology and carefully select outcome measures which are congruent with the intervention type and research questions.

Strauss and colleagues (2013) synthesized six meta-analyses of early intensive behavioral interventions (EIBI) for young children with autism spectrum disorders. The three components of the synthesis were (a) descriptive analysis, (b) effect size analysis, and (c) mediator analysis via partial correlation and linear regressions. The majority of interventions followed the behavioral manual developed by Lovaas and colleagues. In the majority of interventions, children in the comparison groups followed a less specific eclectic school-based approach or a less intensive treatment-as-usual (TAU) at the center of reference. The mean duration of ABA programs without parent inclusion was 37 months, while programs favoring parent inclusion in skill generalization had duration of approximately 20 months. The following outcomes were measured with standardized instruments and complete pre-post data reported: full-scale IQ (19 studies), receptive and expressive language totals (11 studies), and adaptive behavior composites (15 studies). Change in IQ was the primary outcome across studies. Results suggest that EIBI leads generally to positive medium-to-large effects for the three outcome measures. Analysis by type of delivery format revealed that EIBI programs that include parents in treatment provision are more effective. The authors note that a self-contained meta-analysis is needed based on updated literature research that is extended to parent inclusion as study selection criteria. Randomization to group assignment was implemented twice in the included studies, and the allocation to treatment or control groups upon therapist availability or parental preference raises internal validity concerns. The literature also lacked comparisons between EIBI and approaches other than eclectic. It is acknowledged that differences may be partly the result of differences in treatment intensity, frequency of supervision, staff and parent training, and as such a dose-response or fidelity effect rather than related to the approach itself. In order to control these variables, the authors suggest sound comparison intervention groups which are comparable in intensity, duration, training, fidelity, and supervision requirements, as well as in child intake characteristics.

Virues-Ortega and colleagues (2013) conducted a meta-analysis of 13 studies, totaling 172 individuals with autism exposed to the Treatment and Education of Autistic and Related Communication Handicapped Children (TEACCH) therapy program. The authors looked to evaluate the TEACCH program effect over a variety of standardized outcomes and to identify specific characteristics of the sample that could be reliably associated with increased intervention effectiveness. Standardized measures of perceptual, motor, adaptive, verbal, and cognitive skills were identified as treatment outcomes. Six between-group and seven pre-post trials were identified for inclusion. Results indicated that TEACCH effects on perceptual, motor, verbal, and cognitive skills were of small magnitude. 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. The overall effect of the intervention across all outcomes was moderate and effects seemed to increase with age. The adult population experienced the greatest overall benefit. The authors note that due to the limited number of appropriately designed studies, the evidence base for the TEACCH program has not been established as effective or ineffective. Therefore, the analysis should be considered a preliminary evaluation pointing to the outcomes that demonstrate greater promise.

Reichow and colleagues (2012) systematically reviewed 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 (ASDs). This Cochrane review focused on randomized control trials (RCTs), quasi-randomized control trials, or clinical control trials (CCTs) in which EIBI was compared to a no-treatment or treatment-as-usual control condition. Participants must have been less than six years of age at treatment onset and assigned to their study condition prior to commencing treatment. All outcome data were continuous, from which standardized mean difference effect sizes with small sample correction were calculated. Random-effects meta-analysis was conducted where possible. The researchers identified one RCT and four CCTs with a total of 203 participants. All studies used a treatment-as-usual comparison group. The results of the four CCTs were synthesized using a random-effects model of meta-analysis of the standardized mean differences. Positive effects in favor of the EIBI treatment group were found for all outcomes (adaptive behavior, IQ, expressive language, receptive language, daily communication skills, socialization, and daily living skills). The authors note that due to the inclusion of non-randomized studies, there is a high risk of bias and the overall quality of evidence was rated as "low" using the GRADE system, which rates the quality of evidence from meta-analyses to determine recommendations for practice. They conclude that there is some evidence that EIBI is an effective behavioral treatment for some children with ASD. However, the current state of the evidence is limited because of the reliance on data from non-randomized studies due to the lack of RCTs. Additional studies using RCT research designs are needed to make stronger conclusions about the effects of EIBI for children with ASDs.

Reichow (2012) provided an overview of 5 meta-analyses of early intensive behavioral intervention (EIBI) for young children with ASDs published in 2009 and 2010. The author found many differences between the reviewed meta-analyses, leading to different estimates of effect and overall conclusions. The different definitions of EIBI were largely responsible for the differences in which studies were included in each meta-analysis, resulting in large differences in the total number of studies within each meta-analysis (ranging from 4 to 22). The other inclusion criterion likely to have had a significant effect on the conclusions of each meta-analysis is the research design. In the evaluation of EIBI, studies using multiple research designs with many different types of comparison groups have been conducted. No reviewed meta-analysis restricted inclusion to randomized control trials, but rather to group research design studies. The author concludes that EIBI can be a powerful intervention capable of producing large gains in IQ and/or adaptive

behavior for many young children with ASDs. Despite their differences, 4 of 5 meta-analyses reached the conclusion that EIBI is an effective intervention. Collectively, EIBI is the comprehensive treatment model for individuals with ASDs with the greatest amount of empirical support and should be given strong consideration when deciding treatment options for young children with ASDs. Further data providing information on the child characteristics that are most likely to be associated with best outcomes are needed. Additional knowledge on the characteristics of EIBI programs outside of treatment studies is also needed. Guidelines focusing on the intensity, duration, level of treatment fidelity, and therapist experience and/or training necessary to achieve optimal outcomes should also be more closely measured and reported in future research.

Warren and colleagues (2011a) published a systematic review of early intensive intervention for autism spectrum disorders for children aged 12 and younger. Thirty-four unique studies met inclusion criteria: 17 of these were case series, and 2 were randomized controlled trials. The researchers rated one study as "good quality", 10 as "fair quality", and 23 as "poor quality". Overall, the strength of the evidence ranged from insufficient to low. Studies of Lovaas-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. This review did not incorporate a selection of studies with fewer than 10 participants, many of which used the single-subject design methods that are common in the behavioral literature.

Peters-Scheffer and colleagues (2011) investigated the effectiveness of early intensive behavioral intervention (EIBI) based on ABA via meta-analysis in young children with autism spectrum disorders (ASDs). A total of 11 studies with 344 children with ASD (average age ranging from 34 to 66 months) were included in the analysis. One study was a fully randomized control trial. Results found that experimental groups receiving EIBI outperformed the control groups on IQ, non-verbal IQ, expressive and receptive language, and adaptive behavior. Results varied considerably between studies and participants. Differences may have been attributable to treatment intensity, EIBI quality, intensity of supervision, participant characteristics, and the control group treatment, if any. Further research should determine which child characteristics beside baseline IQ and age at start of treatment are related to treatment outcome. The authors conclude that results need to be interpreted cautiously, since studies in this area contain several methodological limitations including small sample sizes, non-randomized assignment to groups, non-uniform assessment protocols, use of quasi-experimental designs, lack of equivalent groups, lack of adequate fidelity measures, unknown characteristics of comparison conditions, and selection bias. Despite the potential limitations, this meta-analysis demonstrated that EIBI has a moderate to large effect in young children with autism on full scale and non-verbal and adaptive behavior.

Eldevik and colleagues (2010) conducted an individual participant data meta-analysis of intensive behavioral intervention outcomes against those of control/comparison interventions. The analysis also explored predictors of outcome in children who had received intensive behavioral intervention. The gathered individual participant data was from 16 group design studies on behavioral intervention for children with autism; a total of 309 children received behavioral intervention, 39 received comparison interventions, and 105 were in a control group. The authors note that the most significant limitation of the individual participant data meta-analysis is the quality of the studies entering the review. Specifically, there is a lack of true random assignment to groups, except for two studies, and use of different assessment instruments both within and across studies. There is also variability in the duration of treatment and a lack of measures of intervention fidelity. Results of the analysis found that 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. Reliable change in adaptive behavior was achieved for 20.6% vs. 5.7% and 5.1%, 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. The authors conclude that results should be viewed as preliminary; future researchers conducting meta-analyses will need to incorporate research quality selection criteria when the body of randomized studies available for analysis is larger.

Makrygianni and Reed (2010) conducted a meta-analysis of 14 studies reviewing the effectiveness of behavioral intervention programs for children with Autistic Spectrum Disorders (ASDs). The purpose of the analysis was to evaluate the magnitude of the effectiveness of behavioral early intervention programs (EIPs), comparing both prepost treatment performances and behavioral-control outcomes, and to study the impact of various different factors on these outcomes. The meta-analysis demonstrated that EIPs are effective in improving the intellectual, language, communication, and social abilities of children with ASD, and had a moderate to high effect on the adaptive behavioral improvement in children. The authors found evidence that behavioral EIPs are quite effective in changing different developmental aspects of children with ASD, and that they are much more effective than eclectic programs. Factors that have been distinguished as important for the efficacy of the EIPs are intensity and duration of the program, the

age of children at intake, the adaptive behavioral abilities of the children at intake, and parent training. Most of the included studies in the meta-analysis are characterized by some methodological limitations, whose impact on the result cannot be estimated. Some of the limitations of included studies are: small sample size; lack of comparison groups, matched groups, or random assignment; and use of a variety of measures in the same study.

Virues-Ortega (2010) identified 22 studies that measured the effectiveness of long-term, comprehensive ABA interventions for young children with autism. Meta-analytic methods, including quality assessment, sensitivity analysis, meta-regression, dose response meta-analysis, and meta-analysis of studies of different methods were implemented. The author notes that randomization to group assignment was seldom implemented in the studies found, and the use of quasi-random assignment strategies raises various ethical and internal validity concerns. Other general quality standards of clinical studies, including blinding, intention to treat analysis, and use of prospective designs were inconsistently observed. Results from the meta-analysis suggest 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.

Eldevik and colleagues (2009) performed a systematic literature search for studies reporting effects of early intensive behavioral intervention (EIBI) and identified 34 studies, 9 of which were controlled designs having either a comparison or a control group. A meta-analysis was completed that yielded a standardized mean difference effect size for two outcome measures: change in full-scale intelligence and/or adaptive behavior composite. Effect sizes were generally considered by the authors to be large and moderate, respectively. The authors conclude that EIBI produces large to moderate effect sizes for changes in IQ and adaptive behavior composite (ABC) scores for children with autism spectrum disorders (ASDs) when compared with no intervention controls and eclectic provision. Based upon the results, they recommend that EIBI should be an intervention of choice for children with ASD. However, the authors note that randomized controlled trials comparing EIBI to other interventions are still needed. In particular, studies are needed where the comparison intervention is of similar intensity and where staff receives similar training and supervision.

Reichow and Wolery (2009) completed a 3-part comprehensive synthesis of early intensive behavioral intervention (EIBI) for young children with autism. The three components of the synthesis were descriptive analyses, effect size analyses, and a meta-analysis. Data of 14 samples from 13 research reports were analyzed. An assessment of research report rigor was also conducted to provide an overall assessment of the methodological qualities of each study. Three studies received the highest rating (strong), five received the middle rating (adequate), and five received the lowest rating (weak). Two of the 13 studies used true experimental designs. All samples employed procedures and/or measures to ensure or document treatment adherence; 1 of 13 studies used direct measures, and 12 studies used indirect measures. All studies contained reference to a treatment manual, though no verification existed on their use. Differences existed in all characteristics of intervention across studies. Using a random effects model, the mean effect size was 0.69, which was statistically significant. This was defined by the authors as a large effect, and suggests EIBI is, on average, an effective treatment for children with autism. No controls existed for maturation. Thus, while the effect sizes were often large, they cannot be attributed to EIBI exclusively. The authors conclude that the findings of the current synthesis were mixed. Although the data and findings of this synthesis can be used to make claims about the effectiveness of EIBI (particularly in relation to IQ scores), the synthesis also exposed many knowledge gaps. For example, a greater number and diversity of studies may be needed to draw definitive conclusions.

Spreckley and Boyd (2009) reviewed the effectiveness of applied behavior intervention (ABI) programs for preschool children with an autism spectrum disorder (ASD) in cognitive, adaptive behavior, and language development. ABI is based on the theory of applied behavioral analysis and may be known as applied behavior analysis intervention (ABAI) or intensive behavioral therapy (IBT). Systematic reviews, randomized, and quasi-randomized controlled trials of ABI were reviewed. Quantitative data on cognitive, language, and behavior outcomes were extracted and pooled for meta-analysis. A total of thirteen studies met inclusion criteria, and of these, four studies had adequate data for meta-analysis: two were randomized clinical trials, and two were quasi-randomized trials. However, all the comparison groups received some form of intervention, in some cases including ABI at reduced intensity compared with intervention groups. The meta-analyses of these studies showed that ABI did not result in significant improvement in cognitive, language, or adaptive behavioral outcomes compared with standard care. The authors note that further research is needed to investigate the cause and nature of ASD in various subgroups and should be sufficiently powered to evaluate critical periods for intervention, the optimum intensity, and mode of delivery for achieving successful outcomes.

Agency for Healthcare Research and Quality (AHRQ) Reports

An AHRQ systematic review of behavioral intervention therapies for children (0-12 years) with autism spectrum disorders (ASDs) was published in 2011 (Warren, et al 2011b). This review included 183 articles, representing 159 unique studies, and accepted any study design except for individual case reports. The review excluded studies with fewer than 10 total participants receiving interventions. Included studies of early intensive behavioral and developmental interventions were conducted primarily in preschool and young children (initially ages 2-7 years);

questions remain about how these approaches apply to and benefit younger children (under 2) at risk for ASD. Roughly 40% of studies in this review did not use a comparison group, which presents substantial challenges for assessing effectiveness at a population level or for conducting comparative effectiveness research. Even in studies with a comparison group, sample size was frequently insufficient to draw conclusions, and the authors note that larger multisite trials are needed across all treatment types. The researchers also noted a strong tendency for authors to present data on numerous outcomes without adjusting for multiple comparisons. Duration of treatment and follow-up was generally short, with few studies providing data on long-term outcomes after cessation of treatment. In sum, the authors conclude that while some therapies hold promise and warrant further study, substantial needs exist for continuing improvements in methdologic rigor in the field and for larger, potentially multisite studies of existing interventions. New studies should better characterize children, both phenotypically and genotypically, to move towards personalization of treatments for improved outcomes.

A comparative effectiveness review (Lounds Taylor, et al 2012) by the AHRQ focused on interventions for adolescents and young adults (ages 13-30) with autism spectrum disorders (ASDs). The report notes that interventions used to treat ASDs may include a range of behavioral, psychosocial, educational, medical, and complementary approaches focused on the transitional process and improving outcomes for parents/families of individuals with ASDs during adolescence and adulthood. The goal of the review was to examine the effects of available interventions for this population, focusing particularly on the following outcomes: core symptoms of ASD (impairments in social interaction, communication, and repetitive behavior); medical and mental health comorbidities; functional behaviors and independence; the transition to adulthood; and family outcomes. Studies were grouped into quality levels of "good", "fair", or "poor". A total of 32 studies were included in the qualitative synthesis. Of these studies, 10 were randomized controlled trials. The authors found most studies to be of "poor" quality, five were of "fair" quality (primarily of medical interventions), and none were of "good" quality. The strength of the evidence across all interventions and outcomes was insufficient, as studies were typically of poor quality, addressed disparate interventions and outcomes, and lack replication. The authors conclude that overall, there is a dearth of evidence in all areas of care for adolescents and young adults with ASDs, and it is urgent that more rigorous studies be developed and conducted. It is unlikely that large scale implementation of interventions will be considered until a stronger evidence base is developed, despite growing numbers of individuals with need, and some small studies demonstrating initial promise. A fruitful area for consideration may be identifying programs/interventions that are appropriate candidates for developing treatment manuals to encourage standardized replication of promising approaches.

A 2014 report from the AHRQ (Weitlauf, et al 2014) focused on more recent studies of behavioral interventions for autism spectrum disorders (ASDs) in children 0-12 years. The review excluded studies with fewer than 10 total participants receiving interventions. The 2014 reviewers note that since the review conducted in 2011, there has been a significant increase in the quantity and quality of studies investigating behavioral interventions. These newer studies strengthened the ability to make conclusions about the effectiveness of behavioral interventions. For example, of the 45 comparative studies of behavioral interventions (29 RCTs) in the 2011 review, the authors considered only two as "good" quality. In contrast, among the new studies described in the more current (2014) review, 19 studies were of "good" quality, and 48 of the 65 included studies were RCTs. The 2014 reviewers found that early intervention based on high-intensity applied behavior analysis over extended timeframes was associated with improvement in cognitive functioning and language skills (with a moderate strength of evidence), relative to community controls in some groups of young children. Other results from the 2014 AHRQ Report are as follows:

- Improvements were most often seen in cognitive abilities and language acquisition, with less robust and consistent improvements seen in adaptive skills, core ASD symptom severity, and social functioning. Many of the reviewed studies did not follow children beyond the late preschool or early school years.
- The identified intervention approaches were found to still vary substantially, and it is continually challenging to predict long-term functional and adaptive outcomes on an individual level. At this time, the evidence is insufficient to adequately identify and target the children who are most likely to benefit (or not benefit) from specific interventions.
- Although researchers are attempting to manualize approaches and operationalize and measure treatment
 fidelity, manualizing intensive interventions for a heterogeneous patient population is intrinsically challenging.
 However, recent progress toward this end has shown that children may respond differentially to early
 intensive approaches.
- Measuring appropriate outcomes is a primary methodolgoic concern in the ASD literature. Although more studies are reporting primary and secondary outcomes measures, continued improvements in reporting will benefit the field.

The authors of the 2014 AHRQ Review conclude that a growing evidence base suggests that behavioral interventions are associated with positive outcomes for children with ASD. Yet despite improvements in the quality of the included literature, a need remains for studies of interventions across settings and continued improvements in methodologic rigor. Substantial scientific advances are needed to move toward an enhanced understanding of which interventions are most effective for specific children with ASD and to isolate elements or components of interventions most associated with effects.

Other Reports

Zwaigenbaum and colleagues (2015) reviewed evidence for autism spectrum disorder (ASD) interventions for children aged < 3 years, based on peer-reviewed articles published up to December 2013. A total of 24 randomized controlled, quasi-experimental, and open-label studies were reviewed by the working group. Because few studies focused exclusively on this age group, studies in which participants included some children aged > 3 years were assessed as long as there was sufficient information to draw inferences about younger children. Compared with early intervention models evaluated for preschool-aged children (aged 3–5 years), programs for children aged < 3 years were more likely to use developmental approaches, more intensively involve parents, and target social communication. These studies varied in sample size and severity of diagnosis, dose (level of intensity/frequency of service delivery), duration, agent (parent, therapist, or a combination), and format of delivery (parent-managed/home-based and/or center-based in a clinic or school) of the intervention. Some interventions were comprehensive, defined as addressing multiple core ASD deficits, while others targeted specific areas of functioning. Based on the review, the working group offered a number of recommendations, including the following:

- Current best practices for interventions for children aged < 3 years with suspected or confirmed ASD should include a combination of developmental and behavioral approaches and begin as early as possible.
- Current best practices for children aged < 3 years with suspected or confirmed ASD should have active involvement of families and/or caregivers as part of the intervention.
- Interventions should enhance developmental progress and improve functioning related to both the core and associated features of ASD, including social communication, emotional/ behavioral regulation, and adaptive behaviors.
- Future research should prioritize well-defined sampling strategies, rigorous investigative design, fidelity of implementation, and meaningful outcome measurements.
- Research is needed to determine the specific active components of effective interventions, including but not limited to the type of treatment provided, the agent implementing the intervention(s) (parent, therapist, teacher, or combination), consistency of service provision across environments and between providers, and duration of treatment and hours per week.
- Adopting a common set of research-validated core measures of ASD symptoms (including but not limited to
 cognitive function, communication, and adaptive behavior) that can be used across multiple sites will facilitate
 comparisons across studies of children with ASD aged < 3 years.

Wong and colleagues (2013) authored a report describing a process for the identification of evidence-based practices (EBPs) for children, youth, and young adults with autism spectrum disorder (ASD). A national set of reviewers were recruited and trained to evaluate articles from the literature using a standard article evaluation process. To qualify for the review, study participants had to be between birth and 22 years of age, and identified as having an ASD. The focused intervention practice examined in a study had to be behavioral, developmental, and/or educational in nature. The design of the study had to compare an experimental or treatment condition to at least one other condition in which the treatment was not implemented or an alternative intervention condition was implemented. Focused intervention practices had to generate behavioral, developmental, or academic outcomes. Studies had to employ an experimental group design, quasi-experimental design, or single case design. A total of 1,090 intervention articles were evaluated, with a total of 456 intervention articles meeting inclusion criteria. Of these, 48 utilized a group design (mostly randomized controlled trials), and the remaining 408 articles were single case design. The majority of the participants in studies were children between the ages of 6 and 11. Relatively few studies included children below three years of age, and a small number of studies included participants above 12 years of age - with this number declining as participant age increased. Although studies in the literature incorporated a wide range of outcomes, the reviewed research focused primarily on outcomes associated with the core symptoms of ASD: social, communication, and challenging behaviors. Results of the report found a total of twenty-seven practices that met criteria for being evidence-based. These practices consist of interventions that are fundamental applied behavior analysis techniques, assessment and analytic techniques that are the basis for intervention, and combinations of primarily behavioral practices used in a routine and systematic way that fit together as a replicable procedure. No practices were exclusively supported through group design methodologies. The authors note that the review falls short of specifically identifying EBPs for adults with ASDs.

Maglione and colleagues (2012) published recommended guidelines and further research needs of nonmedical interventions for children with ASDs. The guidelines were developed by a technical expert pane (TEP) consisting of practitioners, researchers, and parents. A systematic overview of research findings was presented to the panel; guideline statements were then drafted, discussed, debated, edited, reassessed, and presented for formal voting. A total of 33 systematic reviews and 68 intervention studies met inclusion criteria. The authors note the evidence that comprehensive intervention programs (i.e., "intensive" interventions) are effective at improving core deficits of ASD is of moderate strength. Although controlled studies have been conducted, few have randomly selected subjects or enrolled large samples. Several meta-analyses of programs based on the ABA method have been conducted to increase statistical power, and have found promising results in the areas of language, adaptive skills, and IQ. Evidence is insufficient to suggest the superiority of one behavioral curriculum over others. There is moderate evidence that greater intensity of treatment (hours per week) and greater duration (in months) lead to better outcomes.

Developmentally based intensive programs and environmental programs such as TEACCH had a lower strength of evidence. The review identified significant heterogeneity in outcome measures used in trials of interventions for ASD. Many measures appeared to lack previous validation studies, and outcome measures were occasionally reported in nonstandardized ways, both of which limited the ability to pool results across studies.

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 Phase 1 of the National Standards Project (NSP1). The NSP1 reviewed 775 peer reviewed studies published between 1957 and 2007 that utilized a variety of interventions pertaining to the treatment of autism spectrum disorders (ASDs). The NSP1 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 inter-observer 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. Based on this scoring system, the NSP1 identified 11 established treatments, defined as treatments that produce beneficial outcomes and are known to be effective for individuals on the autism spectrum. The 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 Story-based 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 largely reinforced the findings of Phase 1. For children and adolescents under age 22, the authors found additional empirical support for interventions that are behaviorally based. The authors indicated that in spite of the growing population of adults with ASD, there is lesser empirical research to guide intervention for this population (National Autism Center 2015).

Professional Societies

American Academy of Pediatrics (AAP): The AAP published clinical guidelines for the management of autism in 2007 that were reaffirmed in 2010 and again in 2014. The guidelines state that children who receive early intensive behavioral treatment have been shown to make substantial, sustained gains in IQ, 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. 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 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 & Johnson, 2007, reaffirmed 2014).

American Academy of Child and Adolescent Psychiatry (AACAP): The AACAP published a practice parameter for assessment and treatment of children with autism spectrum disorders (ASDs) in 2014. The parameter states that structured educational and behavioral interventions have been shown to be effective for many children with ASD and are associated with better outcomes. The quality of the research literature in this area is variable, with most studies using group controls or single-subject experimental methods. In general, studies using more rigorous randomized group comparisons are sparse, reflecting difficulties in random assignment and control comparisons. Other problems include lack of attention to subject characterization, generalizations of treatment effects, and fidelity of treatment implementation. Despite these problems, various comprehensive treatment approaches have been shown to have efficacy for groups of children, although none of the comprehensive treatment models has clearly emerged as superior. The parameter further states that applied behavior analysis (ABA) techniques have been repeatedly shown to have efficacy for specific problem behaviors, and ABA has been found to be effective when applied to academic tasks, adaptive living skills, communication, social skills, and vocational skills. Because most children with ASDs tend to learn tasks in isolation, an explicit focus on generalization is important (Volkmar, Siegel, Woodbury-Smith, et al 2014).

U.S. FOOD AND DRUG ADMINISTRATION

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

CENTERS FOR MEDICARE AND MEDICAID SERVICES

Medicare does not have a National Coverage Determination (NCD) for intensive behavioral therapy for autism spectrum disorder.

A Centers for Medicare and Medicaid Services (CMS) Informational Bulletin, published July 7, 2014, titled *Clarification of Medicaid Coverage of Services to Children with Autism* states that "all children [up to the age of 21], including children with an Autism Spectrum Disorder (ASD), must receive Early and Periodic Screening, Diagnostic and Treatment (EPSDT) screenings designed to identify health and developmental issues, including ASD, as early as possible. . . EPSDT also requires medically necessary diagnostic and treatment services. When a screening examination indicates the need for further evaluation of a child's health, the child should be appropriately referred for diagnosis and treatment without delay . . . Ultimately, the goal of EPSDT is to assure that children get the health care they need, when they need it – the right care to the right child at the right time in the right setting."

A follow-up CMS FAQ document, published September 24, 2014, titled *Medicaid and CHIP FAQs: Services to Address Autism* states that CMS has not mandated ABA services for children under 21 with an Autism Spectrum Disorder (ASD). Instead, the FAQs note that "Applied Behavior Analysis (ABA) is one treatment modality for ASD. CMS is not endorsing or requiring any particular treatment modality for ASD. State Medicaid agencies are responsible for determining what services are medically necessary for eligible individuals. States are expected to adhere to long-standing EPSDT obligations for individuals from birth to age 21, including providing medically necessary services available for the treatment of ASD."

UTILIZATION MANAGEMENT CRITERIA

Prior authorization is required for intensive behavioral therapy (IBT) / applied behavior analysis (ABA).

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

Admission Criteria

- See "Common Criteria and Best Practices for All Levels of Care", available at: https://www.providerexpress.com/content/ope-provexpr/us/en/clinical-resources/guidelines-policies/locg.html
 https://www.providerexpress.com/content/ope-provexpr/us/en/clinical-resources/guidelines-policies/locg.html
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- The member is diagnosed with Autism Spectrum Disorder (ASD) AND
- The criteria from the <u>Coverage Rationale</u> section of this document are met, unless otherwise mandated by regulation or customer contract.
- There are acute changes in the member's signs and symptoms, and/or psychosocial and environmental factors, and the member's current condition can be safely, efficiently, and effectively assessed and/or treated. Examples include:
 - o Reducing problem behavior such as aggression or self-injury;
 - Increasing socially appropriate behavior;
 - The acquisition of communication and social skills;
 - o Learning to tolerate changes in the environment and activities.

AND

- The member is not in imminent or current risk of harm to self, others, and/or property AND
- As indicated, the member's family and other natural resources are engaged to participate in the member's treatment where clinically necessary to generalize ABA skills to the natural environment. If for some reason this is not possible in full or part, the treatment plan addresses this.
 AND
- A clinical assessment indicates the member's baseline level of functioning and how the member will benefit from highly structured IBT interventions.

Evaluation & Treatment Planning:

- Once an ASD diagnosis has been established:
 - A functional assessment is used to maximize the effectiveness and efficiency of behavioral support interventions (Myers & Johnson, reaffirmed 2014). The assessment may incorporate information such as interviews with caregivers, structured rating scales, direct observation data, and attention to coexisting medical conditions (Behavior Analyst Certification Board, 2014)
 - Targets include areas such as the following:
 - Communication skills;
 - Language skills;

- Social interaction skills;
- Restricted, repetitive patterns of behavior, interests, or activities;
- Self-injurious, violent, destructive or other maladaptive behavior.
- o A credentialed provider with IBT expertise is identified to provide treatment. Examples include (e.g., Behavior Analyst Certification Board, 2014):
 - A Masters or Doctoral-level provider that is a Board Certified Behavior Analyst (BCBA);
 - A licensed behavioral health clinician who has attested to having sufficient expertise and has been credentialed to provide ABA services;
 - A Board Certified Assistant Behavior Analyst (BCaBA) or non-licensed individual under the direct supervision of a BCBA or licensed behavioral health clinician who takes responsibility for the member's care that does either of the following:
 - Assist in the initial or concurrent assessment of the member's deficits or adaptive behaviors;
 - Implement a treatment plan that has been developed by a BCBA or licensed behavioral health clinician;
 - Paraprofessional interventions must be directly supervised with the member present at least 1 hour per month, up to 8 hours per month, not to exceed 1 hour for every 10 hours of direct care provided.
- Outcome-oriented interventions targeting specific baseline behaviors are identified in a treatment plan describing the frequency, intensity, duration and progress that will be continuously updated.
 - Treatment planning a minimum of 1 hour per month up to 8 hours per month (not to exceed 1 hour for every 10 hours of direct service).
 - o As clinically indicated, the treatment plan addresses how the parents/guardians will be trained in management skills that can be generalized to the home.
 - The treatment plan is in sync with the member's Individual Family Service Plan (IFSP) / Individualized Education Plan (IEP).
- All components of the member's care are tracked and updated througout the duration of services.

Treatment

- The IBT intervention seeks to address all of the following:
 - o Mitigate the core features of ASD, such as persistent deficits in social communication (e.g., social-emotional reciprocity, nonverbal communicative behaviors), and restricted, repetitive patterns of behavior, interests, or activities (American Psychiatric Association, 2013).
 - o Target specific deficits related to imitation, attention, motivation, compliance and initiation of interaction, and the specific behaviors that are to be incrementally taught and positively reinforced.
 - o Tie to objective and quantifiable treatment goals that have projected timeframes for completion.
 - As clinically indicated, include the member's parents in parent training and the acquisition of skills in behavior modification to promote management of skills within the home (Myers & Johnson, reaffirmed 2014). Training family members and other caregivers to manage problem behavior and interact with the individual with ASD in a therapeutic manner is considered a critical component of this treatment model (Behavior Analyst Certification Board, 2014)
 - o As indicated, include psychotherapy (e.g., cognitive behavioral therapy) for higher functioning members to treat anxiety, anger management, etc (American Academy of Child and Adolescent Psychiatry, 2014).
 - o Have an appropriate level of intensity and duration driven by factors such as:
 - Treatment goals;
 - Changes in the targeted behavior(s) / response to treatment;
 - The demonstration and maintenance of management skills by the parents/guardians;
 - Whether specific issues are being treated in a less intensive group format (e.g., social skills groups);
 - The member's ability to participate in IBT given attendance at school, daycare or other treatment settings; and
 - The impact of co-occurring behavioral or medical conditions on skill attainment.
- Services are intensive and may be provided daily, but ordinarily will not exceed 8 hours per day or 40 hours per week inclusive of other interventions. These hours of service also take into account other non-behavioral services such as school, speech, and occupational therapies, generally covered by other entities.

Continued Service Criteria

 See "Common Criteria and Best Practices for All Levels of Care", available at: https://www.providerexpress.com/content/ope-provexpr/us/en/clinical-resources/guidelines-policies/locg.html
 AND

- The member's current condition can be safely, efficiently, and effectively assessed and/or treated. Examples include:
 - o Reducing problem behavior such as aggression or self-injury;
 - o Increasing socially appropriate behavior;
 - o The acquisition of communication and social skills;
 - Learning to tolerate changes in the environment and activities.

Evaluation & Treatment Planning:

- Outcome-oriented interventions targeting specific baseline behaviors are updated in a treatment plan describing the frequency, intensity, duration and progress.
 - o Treatment planning a minimum of 1 hour per month up to 8 hours per month (not to exceed 1 hour for every 10 hours of direct service).
 - o As clinically indicated, the treatment plan addresses how the parents/guardians will be trained in management skills that can be generalized to the home.
 - o The treatment plan is in sync with the member's Individual Family Service Plan (IFSP) / Individualized Education Plan (IEP).
 - Treatment plan updates reflect that active treatment is being delivered by documentation of changes in the type, amount, frequency, and duration of the treatment services rendered as the member moves toward expected outcomes.
 - The treatment plan is updated frequently enough to address changes in the member's condition. Lack
 of progress and its relationship to active treatment and reasonable expectation of improvement should
 also be noted.
- All components of the member's care are tracked and updated throughout the duration of services to include:
 - o Updated treatment plans for members with an ASD that include the following:
 - Changes in treatment hours and level of care;
 - The member's progress, new goals, and visual representations of skills and behavioral gains;
 - A transition plan detailing how the member will be transitioned out of services or to a lower level of care; the transition plan should also include how the member will titrate from current level of service to lower hours of service as he or she moves towards discharge. As member progresses, it may be clinically indicated to titrate hours prior to discharge.
 - If the member is an older child or adolescent, the treatment plan addresses the plan to transition members out of ASD treatment into adult care.
 - o A separate transition plan for children who are moving into or out of the school system.

Treatment

- The IBT interventions continue to address all of the following:
 - Mitigate the core features of ASD, such as persistent deficits in social communication (e.g., socialemotional reciprocity, nonverbal communicative behaviors), and restricted, repetitive patterns of behavior, interests, or activities (American Psychiatric Association, 2013).
 - o Target specific deficits related to imitation, attention, motivation, compliance and initiation of interaction, and the specific behaviors that are to be incrementally taught and positively reinforced.
 - o Tie to objective and quantifiable treatment goals that have projected timeframes for completion.
 - As clinically indicated, include the member's parents in parent training and the acquisition of skills in behavior modification to promote management of skills within the home (Myers & Johnson, reaffirmed 2014). Training family members and other caregivers to manage problem behavior and interact with the individual with ASD in a therapeutic manner is considered a critical component of this treatment model (Behavior Analyst Certification Board, 2014)
 - As indicated, include psychotherapy (e.g., cognitive behavioral therapy) for higher functioning members to treat anxiety, anger management, etc (American Academy of Child and Adolescent Psychiatry, 2014).
 - Have an appropriate level of intensity and duration driven by factors such as:
 - Treatment goals;
 - Changes in the targeted behavior(s) / response to treatment;
 - The demonstration and maintenance of management skills by the parents/guardians;
 - Whether specific issues are being treated in a less intensive group format (e.g., social skills groups);
 - The member's ability to participate in IBT given attendance at school, daycare or other treatment settings; and
 - The impact of co-occurring behavioral or medical conditions on skill attainment.
- Services are intensive and may be provided daily, but ordinarily will not exceed 8 hours per day or 40 hours per week inclusive of other interventions. These hours of service also take into account other non-behavioral services such as school, speech, and occupational therapies, generally covered by other entities.

Discharge Criteria

- see "Common Criteria and Best Practices for All Levels of Care", available at: https://www.providerexpress.com/content/ope-provexpr/us/en/clinical-resources/guidelines-policies/locg.html
- The desired outcomes for discharge should be specified at the initiation of services and refined throughout the treatment process (Behavior Analyst Certification Board, 2014)

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.

CPT Code		Description
0359T*	Assessment	Behavior identification assessment (may be followed by 0360T, 0361T or 0362T, 0363T)
0360T*	Assessment	Observational behavioral follow-up assessment (first 30 minutes)
0361T*	Assessment	Observational behavioral follow-up assessment (each additional 30 minutes)
0362T*	Assessment	Exposure Behavioral Follow-up Assessment
+0363T*	Assessment	Each <u>additional 30 minutes</u> of technician time, face-to-face with patient (list separately in addition to code for primary service).
0364T*	Treatment	Adaptive Behavior Treatment by protocol, administered by technician, face-to-face with <u>one patient;</u> first 30 minutes of technician time
+0365T*	Treatment	Adaptive Behavior Treatment by protocol, administered by technician, face-to-face with <u>one patient</u> ; each additional 30 minutes of technician time (List separately in addition to code for primary procedure)
0366T*	Treatment	<u>Group</u> Adaptive Behavior Treatment by protocol, administered by technician, faceto-face with <u>two or more patients</u> ; first 30 minutes of technician time
+0367T*	Treatment	<u>Group</u> Adaptive Behavior Treatment by protocol, administered by technician, faceto-face with <u>two or more patients</u> ; <u>each additional 30 minutes</u> of technician time (List separately in addition to code for primary procedure)
0368T*	Treatment	Adaptive Behavior Treatment with protocol modification administered by physician or other qualified health care professional with <u>one patient</u> ; first 30 minutes of patient face-to- face time
+0369T*	Treatment	Adaptive behavior treatment with protocol modification administered by physician or other qualified health care professional with <u>one patient; each additional 30 minutes</u> of patient face-to-face time (List separately in addition to code for primary procedure)
0370T*	Treatment	Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present)
0371T*	Treatment	Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present)
0372T*	Treatment	Adaptive behavior treatment social skills group, administered by physician or other qualified health care professional face-to-face with multiple patients
0373T*	Treatment	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
+0374T*	Treatment	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)

 $\textit{CPT} \textit{\&} \ \textit{is a registered trademark of the American Medical Association}$

^{*}Category III Codes (codes ending in T) are not reimbursable when IBT/ABA is clinically managed (prior authorization / notification is required), except where mandated.

HCPCS Code	Description
H0031	Mental health assessment, by non-physician

HCPCS Code	Description
H0032	Mental health service plan development by non-physician
H2012	Behavioral Health Day Treatment, per hour
H2014	Skills Training and Development, per 15 minutes
H2019	Therapeutic Behavioral Services, per 15 minutes
H2021 (Pennsylvania only)	Community-Based Wrap-Around Services, per 15 minutes
H2027 (Pennsylvania only)	Psychoeducational Service, per 15 minutes

DSM-5 Diagnosis Code	ICD-10 Diagnosis Code	Diagnostic Description
299.0	F84.0	Autism Spectrum Disorder (DSM-5)
		Autistic Disorder (ICD-10)

REFERENCES

- 1. American Psychiatric Association. Practice guidelines for the psychiatric evaluation of adults (3rd ed.). Arlington, VA: American Psychiatric Publishing; 2016.
- 2. American Psychiatric Association. Diagnostic and statistical manual of mental disorders (5th ed.). Arlington, VA: American Psychiatric Publishing; 2013.
- 3. Behavior Analyst Certification Board. *Applied behavior analysis treatment of autism spectrum disorder: Practice quidelines for healthcare funders and managers* (2nd ed.) 2014.
- 4. Bishop-Fitzpatrick L, Minshew NJ, & Eack SM. A systematic review of psychosocial interventions for adults with autism spectrum disorders. Journal of Autism and Developmental Disorders 2013; 43(3): 687-694.
- 5. Brugha TS, Doos L, Tempier A, Einfield S, & Howlin P. Outcome measures in intervention trials for adults with autism spectrum disorders: A systematic review of assessments of core autism features and associated emotional and behavioral problems. International Journal of Methods in Psychiatric Research 2015; 24(2): 99-115.
- 6. Department of Health & Human Services: Centers for Medicare & Medicaid Services. CMCS Informational Bulletin: Clarification of Medicaid Coverage of Services to Children with Autism; July 7, 2014. Available at: http://www.medicaid.gov/Federal-Policy-Guidance/Downloads/CIB-07-07-14.pdf
- 7. Department of Health & Human Services: Centers for Medicare & Medicaid Services. Medicaid and CHIP FAQs: Services to Address Autism; September 24, 2014. Available at: https://www.medicaid.gov/federal-policy-quidance/downloads/faq-09-24-2014.pdf
- 8. Eldevik S, Hastings RP, Hughes JC, Jahr E, Eikeseth S, & Cross S. Using participant data to extend the evidence base for intensive behavioral intervention for children with autism. Am J Intellect Dev Disabil 2010; 115(5): 381-405.
- 9. Eldevik S, Hastings RP, Hughes JC, Jahr E, Eikeseth, S, & Cross S. Meta-analysis of early intensive behavioral intervention for children with autism. Journal of Clinical Child and Adolescent Psychology 2009; 38(3): 439-450.
- 10. Hayes, Inc. Hayes medical technology directory report: Applied behavior analysis-based interventions for Autism Spectrum Disorder 2014; Lansdale, PA: Hayes, Inc.
- 11. Lounds Taylor J, Dove D, Veenstra-VanderWeele J, Sathe NA, McPheeters ML, Jerome RN, & Warren Z. Interventions for Adolescents and Young Adults with Autism Spectrum Disorders. *Comparative Effectiveness Review No. 65* (Prepared by the Vanderbilt Evidence-based Practice Center under Contract No. 290-2008-10065-I.) AHRQ Publication No. 12-EHC063-EF. Rockville, MD: Agency for Healthcare Research and Quality; August 2012.
- 12. Maglione MA, Gans D, Das L, Timbie K, & Kasari C. (2012). Nonmedical interventions for children with ASD: Recommended guidelines and further research needs. Pediatrics 2012; 130(2): S169-S178.
- 13. Makrygianni MK, & Reed P. A meta-analytic review of the effectiveness of behavioral early intervention programs for children with autism spectrum disorders. Research in Autism Spectrum Disorders 2010; 4(4): 577-593.
- 14. McDonald TA, & Machalicek W. Systematic review of intervention research with adolescents with autism spectrum disorders. Research in Autism Spectrum Disorders 2013; 7(11): 1439-1460.
- 15. Myers SM, Johnson CP and the American Academy of Pediatrics Council on Children with Disabilities. Management of children with autism spectrum disorders. Pediatrics 2007, reaffirmed 2014; 120(5): 1162-1182.

- 16. National Autism Center. The National Standards Project, Phase II: Addressing the need for evidence based practice guidelines for autism spectrum disorders 2015. National Autism Center, Randolph, MA.
- 17. National Autism Center. The National Standards Project: Addressing the need for evidence based practice guidelines for autism spectrum disorders 2009. National Autism Center, Randolph, MA.
- 18. Peters-Scheffer N, Didden R, Korzilius H, & Sturmey P. A meta-analytic study on the effectiveness of comprehensive ABA-based early intervention programs for children with autism spectrum disorder. Research in Autism Spectrum Disorders 2011; 5: 60-69.
- 19. Reichow B, Barton EE, Boyd BA, & Hume K. Early intensive behavioral intervention (EIBI) for young children with autism spectrum disorders (ASD). Cochrane Database of Systematic Reviews 2012; Issue 10. Article No.: CD0009260. DOI: 10.10002/13651858.CD0009260.pub2.
- 20. Reichow, B. Overview of meta-analyses on early intensive behavioral intervention for young children with autism spectrum disorders. J Autism Dev Disord 2012; 42(4): 512-520.
- 21. Reichow B, & Worlery M. Comprehensive synthesis of early intensive behavioral interventions for young children with autism based on the UCLA young autism project model. J Autism Dev Disord 2009; 39: 23-41.
- 22. Roth ME, Gillis JM, & DiGennaro Reed FD. A meta-analysis of behavioral interventions for adolescents and adults with autism spectrum disorders. Journal of Behavioral Education 2014; 23(2): 258-286.
- 23. Spreckley M, & Boyd R. Efficacy of applied behavioral intervention in preschool children with autism for improving cognitive, language, and adaptive behavior: A systematic review and meta-analysis. Journal of Pediatrics 2009; 154: 338-344.
- 24. Strauss K, Mancini F, the SPC Group, & Fava L. Parent inclusion in early intensive behavior interventions for young children with ASD: A synthesis of meta-analyses from 2009 to 2011. Research in Developmental Disabilities 2013; 34: 2967-2985.
- 25. Virues-Ortega J, Julio FM, & Pastor-Barriuso R. The TEACCH program for children and adults with autism: A meta-analysis of intervention studies. Clinical Psychology Review 2013; 33: 940-953.
- 26. Virues-Ortega J. Applied behavior analytic intervention for autism in early childhood: Meta-analysis, meta-regression, and dose-response meta-analysis of multiple outcomes. Clin Psychol Rev 2010; 30(4): 387-399.
- 27. Volkmar F, Siegel M, Woodbury-Smith M, King B, McCracken J, State M, and the American Academy of Children and Adolescent Psychiatry (AACAP) Committee on Quality Issues (CQI). Practice parameter for the assessment and treatment of children and adolescents with autism spectrum disorder. Journal of the American Academy of Child and Adolescent Psychiatry 2014; 53(2): 237-257.
- 28. Walton KM, & Ingersoll BR. Improving social skills in adolescents and adults with autism and severe to profound intellectual disability: A review of the literature. Journal of Autism and Developmental Disorders 2013; 43: 594-615
- 29. Warren Z, McPheeters ML, Sathe N, Foss-Feig JH, Glasser A, & Veenstra-VanderWeele J. A systematic review of early intensive intervention for autism spectrum disorders. Pediatrics 2011a; 127(5): e1303-e1311.
- 30. Warren Z, Veenstra-VanderWeele J, Stone W, Bruzek JL, Nahmias AS, Foss-Feig JH, Jerome RN, Krishnaswami S, Sathe NA, Glasser AM, Surawicz T, & McPheeters ML. Therapies for Children with Autism Disorder. *Comparative Effectiveness Review No. 26* (Prepared by the Vanderbilt Evidence-based Practice Center under Contract No. 290-2007-10065-I.) AHRQ Publication No. 11-EHC029-EF. Rockville, MD: Agency for Healthcare Research and Quality; April 2011b.
- 31. Weitlauf AS, McPheeters ML, Peters B, Sathe N, Travis R, Aiello R, Williamson E, Veenstra-VanderWeele, J, Krishnaswami S, Jerome R, & Warren Z. Therapies for Children with Autism Spectrum Disorder: Behavioral Interventions Update. *Comparative Effectiveness Review No. 137* (Prepared by the Vanderbilt Evidence-based Practice Center under Contract No. 290-2012-00009-I.) AHRQ Publication No. 14-EHC036-EF. Rockville, MD: Agency for Healthcare Research and Quality; August 2014.
- 32. Wong C, Odom SL, Hume K, Cox A, Fettig W, Kurcharczyk S, . . . Schultz TR. Evidence-based practices for children, youth, and young adults with Autism Spectrum Disorder 2013; Chapel Hill: The Univ. of North Carolina, Frank Porter Graham Child Development Institute, Autism Evidence-Based Practice Review Group.
- 33. Zwaigenbaum L, Bauman ML, Choueiri R, Kassari C, Carter A, Granpeesheh D, Mailloux Z, . . . Natowicz MR. Early intervention for children with autism spectrum disorder under 3 years of age: Recommendations for practice and research. Pediatrics 2015, 136(1): S60-S81.

ADDITIONAL RESOURCES

Clinical Protocols

Optum maintains clinical protocols that include the Level of Care Guidelines and Best Practice Guidelines which describe the scientific evidence, prevailing medical standards, and clinical guidelines supporting our determinations regarding treatment. These clinical protocols are available to Covered Persons upon request, and to Physicians and other behavioral health care professionals on www.providerexpress.com.

Peer Review

Optum will offer a peer review to the provider when services do not appear to conform to this policy. The purpose of a peer review is to allow the provider the opportunity to share additional or new information about the case to assist the Peer Reviewer in making a determination including, when necessary, to clarify a diagnosis.

Second Opinion Evaluations

Optum facilitates obtaining a second opinion evaluation when requested by an member, provider, or when Optum otherwise determines that a second opinion is necessary to make a determination, clarify a diagnosis or improve treatment planning and care for the member.

Referral Assistance

Optum provides assistance with accessing care when then provider and/or member determine that there is not an appropriate match with the member's clinical needs and goals, or if additional providers should be involved in delivering treatment.

HISTORY/REVISION INFORMATION

Date	Action/Description		
04/27/2016	Behavioral Clinical Policy version 1 created (Approved by BPAC)		
07/06/2016	Behavioral Clinical Policy version 1 revised (Reviewed by UMC)		
08/09/2016	Behavioral Clinical Policy version 1 revised (Reviewed by UMC)		