INTENSIVE BEHAVIORAL THERAPY FOR AUTISM SPECTRUM DISORDERS

Policy Number: 2014T0202K
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Related Policies:
- Chelation Therapy for Non-Overload Conditions
- Cognitive Rehabilitation
- Neuropsychological Testing Under the Medical Benefit
- Sensory Integration Therapy and Auditory Integration Training
- Vagus Nerve Stimulation
- Applied Behavioral Analysis for Autistic Spectrum Disorder
- Early Start Denver Model (ESDM)/Denver Model as Treatment for Autism Spectrum Disorders

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee’s specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit 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.

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BENEFIT CONSIDERATIONS

Some states mandate benefit coverage for applied behavioral analysis for treatment of autism. In those states, the applicable mandate must be followed. Under the Affordable Care Act, habilitative and rehabilitative services are classified as Essential Health Services. Some requirements are state-specific. In those states, the applicable rules must be followed.
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 (such as maternity benefits), 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 guideline, it is important to refer to the enrollee’s specific 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 disorders (i.e., autistic disorder, Asperger’s disorder, Rett syndrome, pervasive development 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. Additional studies are required to define optimal treatment approaches for autistic children at different intelligence quotient (IQ) levels and to identify which treatment variables are responsible for significant effect. 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 Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit 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 claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

<table>
<thead>
<tr>
<th>CPT® Code</th>
<th>Description</th>
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<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>
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<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>
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<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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<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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<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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<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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<tr>
<th>HCPCS Code</th>
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<td>H0031</td>
<td>Mental health assessment, by non-physician</td>
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<td>H0032</td>
<td>Mental health service plan development by non-physician</td>
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<tr>
<td>H2012</td>
<td>Behavioral Health Day Treatment, per hour</td>
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<td>H2014</td>
<td>Skills Training and Development, per 15 minutes</td>
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<td>H2019</td>
<td>Therapeutic Behavioral Services, per 15 minutes</td>
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<tr>
<td>T1025</td>
<td>Intensive, extended multidisciplinary services provided in a clinic setting to children with complex medical, physical, mental and psychosocial impairments, per diem</td>
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<tr>
<td>T1026</td>
<td>Intensive, extended multidisciplinary services provided in a clinic setting to children with complex medical, physical, mental and psychosocial impairments, per hour</td>
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<tr>
<td>T1027</td>
<td>Family training and counseling for child development, per 15 minutes</td>
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**DESCRIPTION OF SERVICES**

Autism is a developmental disorder of brain function classified as one of the pervasive developmental disorders. These disorders can vary widely in severity and symptoms; classical autism is characterized by impaired social function, problems with verbal and nonverbal communication and imagination, and unusual or severely limited activities and interests.

Behavioral therapy programs used to treat autism spectrum disorders are referred to as Intensive Behavioral Intervention (IBI), Early Intensive Behavioral Intervention (EIBI), or Applied Behavior Analysis (ABA) including Lovaas therapy. 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, 2011).

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).

Other behavioral therapy programs, such as the TEACCH (Treatment and Education of Autistic and related Communication-handicapped Children) program and Early Start Denver Model (ESDM) programs, involve relatively intensive interaction; however, the number of hours of therapy per day and the duration of treatment in these programs are generally less than those in Lovaas therapy (Hayes, 2011).

Relationship Development Intervention (RDI) is a program designed to guide parents of children with autism spectrum disorders (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).

**CLINICAL EVIDENCE**

**Summary of Clinical Evidence**

Conclusions from several meta-analyses and large-scale assessments have suggested that the evidence to support the use of Intensive Behavioral Therapy (IBT) for the treatment of autism 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. 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.

**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 long term follow up does establish 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.

The studies by Lovaas (1987) and McEachin et al. (1993) reported that young autistic children treated with intensive behavioral therapy experienced substantial, durable improvements in behavior, social interaction, and cognitive function, with some able to attend regular classes at school. These investigators also suggested that some of the intensively treated children were essentially cured of autistic symptoms. At the time they were published, these reports had a tremendous impact on the field of behavioral therapy, and generated much enthusiasm for intensive behavioral therapy for autistic children. However, over the past decade, a number of questions have been raised regarding the Lovaas study, including potential selection bias due to inclusion/exclusion criteria and lack of randomization, the sensitivity of measurement instruments, and the relevance of study endpoints. Similar methodological weaknesses are present in other studies that have reported positive effects of Lovaas therapy (Sheinkopf, 1998; Smith, 1997).

A randomized controlled trial by Smith et al. (2000) used IQ selection criteria similar to those of the Lovaas study but with a less intensive therapy schedule that averaged about 25 hours per week with professional therapists. Compared with a control group that had special education and 10 hours per week of parent-administered therapy, the intensive therapy group demonstrated greater improvements in IQ, visual-spatial skills, and language skills. However, the posttherapy mean IQ score of the intensive therapy group still fell within the developmentally disabled range, and there was no significant change in posttherapy behavior or socialization. Moreover, children in the control group also showed some gains in visual-spatial skills and language.

Sallows and Graupner (2005) completed a randomized controlled trial of 24 children assigned to a clinic sponsored intensive behavior therapy or a parent directed group that received intensive hours with less supervision. Outcomes after four years showed that the cognitive, language, adaptive, social and academic measures were similar for both age groups. The authors concluded that treatment outcome was best predicted by pretreatment imitation, language and social responsiveness. Although this study does show that parent directed therapy is as good as therapist led therapy, it does not establish the supremacy of this treatment over other methods.

Rogers et al. (2012) conducted a randomized controlled trial involving 98 children (aged 14 to 24 months) and families investigating the efficacy of a parent delivery of the Early Start Denver model (P-ESDM) compared to community treatment as usual. The P-ESDM consisted of 12 consecutive sessions (1-hour/wk of therapist contact). Assessments were completed at baseline and 12 weeks later, immediately after the end of parent coaching sessions. There was no significant difference between the two groups in terms of parent-child interaction characteristics or on any child outcomes. Both the P-ESDM parents and those in the treatment as usual group improved interaction skills, and both groups of children demonstrated improvement in developmental skills and a reduction in core symptoms. Children in the treatment as usual group received significantly more intervention hours than those in the P-ESDM group. Both younger child age when the intervention was initiated and a greater number of intervention hours were significantly positively related to the degree of improvement in children's behavior for most variables when the group was analyzed as a whole (P-ESDM and treatment as usual combined). The authors concluded that parent-implemented intervention studies for early ASD thus far have not demonstrated the large effects seen in intensive-treatment studies. According to the authors, their findings that both younger age at the beginning of the intervention and more intervention hours were positively related to developmental gains has implications for when treatment should
begin and the intensity level of that treatment. This study was limited by the short study duration, as well as problems in study design, including differences in the intervention hours the two groups received, similar content in the usual care group to that of the P-ESDM group, and the parental learning curve required in the P-ESDM group, which meant that children did not receive the full intervention until several weeks into the study period.

Dawson et al. (2010) conducted a randomized, controlled trial to evaluate the efficacy of the Early Start Denver Model (ESDM), a comprehensive developmental behavioral intervention, for improving outcomes of toddlers diagnosed with autism spectrum disorder (ASD). Forty-eight children diagnosed with ASD between 18 and 30 months of age were randomly assigned to 1 of 2 groups: (1) ESDM intervention, which is based on developmental and applied behavioral analytic principles and delivered by trained therapists and parents for 2 years; or (2) referral to community providers for intervention commonly available in the community. Compared with children who received community-intervention, children who received ESDM showed significant improvements in IQ, adaptive behavior, and autism diagnosis. Two years after entering intervention, the ESDM group on average improved 17.6 standard score points compared with 7.0 points in the comparison group relative to baseline scores. The ESDM group maintained its rate of growth in adaptive behavior compared with a normative sample of typically developing children. In contrast, over the 2-year span, the comparison group showed greater delays in adaptive behavior.

Children who received ESDM also were more likely to experience a change in diagnosis from autism to pervasive developmental disorder, not otherwise specified, than the comparison group. This study is limited by the small sample size.

Data from a controlled but incompletely randomized study of autistic children who had initial IQ scores of 50 or higher suggest that intensive behavioral therapy based on the intensive behavioral treatment/applied behavioral analysis (IBT/ABA) model may provide greater gains in cognitive and language function than some other forms of therapy, particularly in high-functioning autistic children (Eikseth, 2002). In this study, 25 autistic children between 4 and 7 years of age were assigned by an independent clinician to either intensive behavioral therapy based on the Lovas model or to eclectic therapy based on a variety of different commonly used methods for treating autistic children. All subjects received at least 20 hours of therapy per week, and were evaluated after 1 year. The mean gains in IQ scores, language skills, and composite scores on adaptive behavior scales were significantly greater for children who received intensive behavioral therapy than for those who received eclectic therapy. However, this study focused primarily on measures of cognitive function rather than social development and included only children with a high level of cognitive function (IQ>50) on intake. Other limitations include small sample size; no power analysis; and lack of randomization. Eikeseth et al. (2007) continued to follow the children's progress and evaluated them at 8 years of age. Once the children entered elementary school, the amount of hours of therapy decreased. A total of 5 children in the intensive behavioral intervention (IBI) group and 1 child in the eclectic group were in mainstreamed classes and no longer received one-to-one therapy. Children in the IBI group had greater improvement in IQ score, Vineland Adaptive Behavior Scales scores, social skills, and aggressive behavior than those in the eclectic group. Most gains in communication skills and IQ scores were achieved in the first year of therapy, whereas significant improvements in behavior and socialization occurred between the first year and the long-term follow-up.

Fernell et al. (2011) assessed ASD outcome in a study that included 208 children, aged 20-54 months, with a clinical diagnosis of ASD. The children were given intervention and monitored prospectively in a naturalistic fashion over a period of 2 years. Data on intervention type and intensity were gathered prospectively in a systematic fashion. Intervention was classified into intensive applied behavior analysis (ABA) and non-intensive, targeted interventions, also based on ABA principles. Children were comprehensively assessed by a research team before the onset of intervention, and 2 years later. The research team remained blind to the type and intensity of interventions provided. One hundred and ninety-eight (95%) of the original samples stayed in the study throughout the whole 2-year period and 192 children had a complete Vineland composite score results both at intake and when leaving the study. Vineland composite scores
increased over the 2-year period. This increase was accounted for by the subgroup with normal cognitive functioning. There was no significant difference between the intensive and non-intensive groups. According to the authors, this data does not support that children with ASD generally benefit more from the most intensive ABA intervention programs than from less intensive interventions or targeted interventions based on ABA.

Cohen et al. (2006) completed a three year prospective outcome study that compared 21 children who received 35-40 hours per week of intensive behavioral therapy to 21 age and IQ matched children who attended special education classes in a local school. Outcomes were conducted by independent examiners using tests for IQ, adaptive behavior, language and nonverbal skills. The children were placed in the groups by parental preference. At the end of three years, the IBI group obtained significantly higher IQ and adaptive behavior scores than the control group. No difference was noted in the language and nonverbal skills between the two groups. This study was limited by the non-random assignment and the potential selection bias as parents chose the group placement for their child.

Eldevik et al. (2012) evaluated outcomes for 31 children with autism (2-6 years of age at intake) who received behavioral intervention in mainstream pre-school settings and a comparison group of 12 children receiving treatment as usual. After 2 years, children receiving behavioral intervention had higher IQ scores and adaptive behavior composite scores, and these group level outcomes were comparable to studies providing more intensive intervention. Individual child data also showed positive results with 19.4% achieving change at a reliable level for IQ; but a lower percentage than found in recent meta-analysis research. Limitations included non-random assignment to study groups and only IQ and adaptive behavior outcome data were available. Future evaluations of this mainstream pre-school model and other service delivery models should examine a wider range of outcomes.

Zachor et al. (2007) compared two intervention approaches, Eclectic-Developmental (ED) and Applied Behavioral Analysis in very young children with autism/autism spectrum disorder (ASD). Nineteen children received ED intervention, using combination of methods. Twenty children received Applied Behavioral Analysis intervention. Children in both groups were not significantly different in their autism severity, cognitive abilities and in socio-economic background at pre-intervention time. Change in the severity of autism symptoms was assessed by the Autism Diagnosis Observation Schedule (ADOS). The ABA group showed significantly greater improvements than the ED group at post-intervention time. Pre-post intervention differences in language and communication domain were significant only for the ABA group. Both groups showed significant improvement in reciprocal social interaction domain. However, the effect size was greater for the ABA group. Changes in diagnostic classification were noted in both groups but were more pronounced for the ABA group. Pre-treatment IQ scores were positively related to ADOS scores at pre- and post-intervention times, but not to progress over time. The investigators concluded that behavioral intervention is more effective than eclectic approach in improving autism core symptoms in young children with autism. This study is limited by the small sample size.

Zachor and Itzchak (2010) found that IBI therapy and eclectic treatment both improved Vineland Adaptive Behavior Scale (VABS) socialization and communication skills, with no significant differences between the groups in a study that included 78 children with autism. However, neither group exhibited improvement in daily living skills or motor skills scores from intake to follow-up. Study limitations include small sample size, no power analysis, and no randomization.

In a study comparing IBI with eclectic treatment for ASD in 22 children, Fava et al. (2011) reported that both IBI and eclectic groups showed significant improvement on Vineland Adaptive Behavior Scale (VABS) (communication, daily living skills, motor, composite), but only the eclectic group showed significant improvement on the socialization measure. The eclectic group had significantly greater improvement on VABS socialization than the group receiving IBI therapy.
Hayward et al. (2009) examined progress after 1 year of treatment for children with autism who received a mean of 36 hours per week one-to-one University of California at Los Angeles Applied Behavior Analysis (UCLA ABA) treatment. Two types of service provision were compared: an intensive clinic based treatment model with all treatment personnel (N = 23), and an intensive parent managed treatment model with intensive supervision only (N = 21). A non-concurrent multiple baseline design across participants (N = 13) examined whether progress was associated with ABA treatment or confounders. Between intake and follow-up, children in both groups improved significantly on IQ, visual-spatial IQ, language comprehension, expressive language, social skills, motor skills and adaptive behavior. There were no significant differences between the two groups on any of the measures at follow-up. Mean IQ for participants in both groups increased by 16 points between intake and follow-up. This study is limited by small sample size.

Howard et al. (2005) reported that children who received IBI therapy made more gains in cognitive and verbal skills than did children who received either intensive “eclectic” therapy or who participated in non-intensive early intervention programs. These findings were supported by a study comparing IBI with school-based care (Remington et al., 2007). In this nonrandomized study, children who received home-based IBI had significantly greater improvement in measures of intelligence, language, daily living skills, and social behavior compared with those who received standard school-based care for autism, although there was substantial individual variation, with some children making large gains and others showing minimal improvement. However, a similar study by Magiati et al. (2007) reported that both home-based IBI therapy and an autism-specific nursery program provided similar improvements in cognitive and language skills and in severity of autism symptoms at the 2-year follow up. Both of these latter studies were limited by parent selection of treatment, differences in primary outcome measures, and small sample size (n=44 in each study). Kovshoff et al. (2011) conducted a follow-up 2 years after the end of the Remington et al. (2007) study. Twenty-three children in the intervention group (100% of original sample) and 18 in the treatment-as-usual comparison group (86% of original sample) were located and retested. Group differences favoring intervention substantially diluted in this period but varied significantly between subgroups who had received university-supervised and parent-commissioned interventions, favoring the latter. At the 2-year follow-up, significantly more children in the IBI group were still able to achieve a standard score than in the comparison group on the Reynell Developmental Language Scales (RDLS) receptive (or comprehension) scale. However, these differences did not reach statistical significance for the RDLS expressive language scale.

A study conducted by Gutstein et al. (2007) examined the effectiveness of Relationship Development Intervention (RDI) in 16 children with autism. Changes in the Autism Diagnostic Observation Schedule (ADOS) and Autism Diagnostic Interview-Revised (ADI-R), flexibility, and school placement were compared prior to treatment and at a minimum 30 month follow-up period. While all children met ADOS/ADI-R criteria for autism prior to treatment, no child met criteria at follow-up. Similar positive results were found in relation to flexibility and educational placement. These are remarkable observations. However, generalizability of current findings is limited by the lack of a control or comparison group, constraints on age and IQ of treated children, parent self-selection, and parent education conducted through a single clinic setting.

**Systematic Reviews with Meta-Analyses**

Two reviews concluded that the evidence was weak and/or inadequate regarding the efficacy of IBI therapy for treatment of autism (Ospina et al., 2008; Spreckley and Boyd, 2009). One review concluded that IBI is an effective therapy for a subpopulation of children with autism (Reichow and Wolery, 2009). Five reviews concluded that IBI therapy results in beneficial improvement in outcomes and suggested that the treatment should be considered a therapy of choice for children with autism (Eldevik et al., 2009; Eldevik et al., 2010; Makrygianni and Reed, 2010; Virués-Ortega, 2010; Peters-Scheffer et al., 2011).

Reichow (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 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.

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. For more information see the following Web site: [http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=12010007347 Accessed April 2014.](http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=12010007347)

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-dependant 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 (2008) 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 Lovaaas 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.

**Technology Assessments**

In April 2011, the AHRQ published a comparative effectiveness review of the evidence on therapies for children aged 2 to 12 years with ASDs. Therapies evaluated included 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., 2011a; Warren et al., 2011b).

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).

An evidence report published by ECRI Institute evaluated the comprehensive educational and behavioral interventions for autism spectrum disorders (ASD) (ECRI, 2011). The report included 10 controlled studies involving 431 children. The review included the following results regarding...
whether comprehensive educational or behavioral intervention improved outcomes for children with ASD when compared to no treatment, wait-list control, or standard care:

- After one year of treatment, children with ASD who received early intervention based primarily on applied behavior analysis (ABA) scored higher on IQ tests than children who received standard care. Strength of Evidence: Moderate. Stability of Evidence: Unstable.
- At later follow-up times (greater than one year), children in the ABA group continued to demonstrate improvement in scores on IQ tests compared to children in the standard care group. Strength of Evidence: Low. Stability of Evidence: Unstable.
- Children with ASD who received early intervention based primarily on ABA were more likely to achieve an IQ score within normal range for typically developing children (85 or higher) than children who received standard care. Strength of Evidence: Low. Stability of Evidence: Unstable.
- After one year of treatment, children with ASD who received early intervention based primarily on ABA score higher on tests of expressive and receptive language than children who received standard care. Strength and of evidence: Moderate. Stability of Evidence: Unstable.
- After one year of treatment, children with ASD who received early intervention based primarily on ABA performed more adaptive behaviors as indicated by higher scores on the Vineland Adaptive Behavior Composite Score than children who received standard care. Strength of Evidence: Moderate. Stability of Evidence: Unstable.
- At later follow-up times (greater than one year), children in the ABA group continued to demonstrate improvement in adaptive behaviors compared to children in the standard care group. Strength of Evidence: Low. Stability of Evidence: Unstable.

The authors stated that the meta-analytic results for measures of intellectual functioning, language, and adaptive behavior should be interpreted with caution due to the small size of the evidence base, moderate quality of studies, and variability in performance of children on these outcomes.

The ECRI Institute also completed a systematic review on focal educational and behavioral interventions for autism spectrum disorders. ECRI concluded that parent-training interventions to reduce or eliminate problem behaviors, as measured by the Eyberg Child Behavior Inventory, were effective compared to a wait-list control condition. However, the studies used a variety of different techniques in their parent-training programs, and the treatment components responsible for improving behavior could not be isolated. Several studies compared imitation to contingent responsiveness, but the evidence was insufficient to determine whether imitation improves outcomes for children with ASD as compared to no treatment or routine care. ECRI considered the evidence insufficient to determine whether one focal intervention is more effective than another in improving outcomes for children with ASD (ECRI, May 2010).

According to a 2011 Hayes report, “There is some evidence that suggests that treatment of young autistic children with intensive behavioral intervention (IBI) therapy, also called Lovaas or applied behavior analysis (ABA) therapy, may promote gains in cognitive function, language skills, and adaptive behavior. However, although almost all studies suggested improvements in children treated with IBI compared with other treatments, most studies had major limitations in design and methodology, including lack of randomization procedures, small sample sizes, and a lack of blinded assessments to determine treatment effects. Although the initial work by Lovaas suggested that some high-functioning autistic children who undergo IBI therapy can achieve normal school performance and behavior, these findings have not been replicated by other investigators” (Hayes Directory, Intensive Behavioral Intervention Therapy for Autism 2011).

The National Autism Center conducted a complex multifaceted review of educational/behavioral treatments for individuals under the age of 22 with a diagnosis of Autismic Disorder, Asperger's Syndrome, or PDD-NOS, and reported results in the National Standards Project (NSP). 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).

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 (Maglione, 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).

A report by the National Research Council (NRC) on educational intervention for children with autism included a review of comprehensive programs for the treatment of ASD. The NRC indicates that although there are limitations in outcome research, it is likely that many children benefit substantially from the programs. The report states that while substantial evidence exists that treatments can reach short-term specific goals in many areas, gaps remain in addressing larger questions of the relationships between particular techniques, child characteristics, and outcomes (NRC, 2001).

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 Lovaas 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).

**Professional Societies**

**American Academy of Pediatrics (AAP):** The AAP published clinical guidelines for the management of autism in 2007 (Myers and Johnson, 2007). The AAP stated that children who receive early intensive behavioral treatment have been shown to make substantial, sustained gains in IQ (intelligence quotient), language, academic performance, and adaptive behavior as well as some measures of social behavior, and their outcomes have been significantly better than those of children in control groups. 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; reaffirmed September 2010).

**American Academy of Child and Adolescent Psychiatry (AACAP):** The AACAP published practice parameter 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 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 trials referenced 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.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for intensive behavioral therapy for autism spectrum disorders. Local Coverage Determinations (LCDs) do not exist at this time. (Accessed April 11, 2014)

REFERENCES


POLICY HISTORY/REVISION INFORMATION

<table>
<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>07/01/2014</td>
<td>• Reorganized policy content</td>
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<td>• Updated benefit considerations; added language for Essential</td>
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Health Benefits for Individual and Small Group plans to indicate:
- 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 (such as maternity benefits), 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 guideline, it is important to refer to the enrollee’s specific plan document to determine benefit coverage
  - Updated coverage rationale; added language to indicate the unproven service is “not medically necessary”
  - Added list of applicable CPT codes: 0364T, 0365T, 0366T, 0367T, 0368T, 0369T, 0370T, 0371T, 0372T, 0373T and 0374T
  - Updated supporting information to reflect the most current description of services, clinical evidence, CMS information and references
  - Archived previous policy version 2013T0202J