UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND READINESS

The Honorable John McCain
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

AUG 28 2015

Dear Mr. Chairman:

The enclosed report is in response to Senate Report 113-176, page 133, to accompany S. 2410, the National Defense Authorization Act for Fiscal Year (FY) 2015, which requests the Secretary of Defense submit a report explaining why funding was not included in the FY 2016 defense budget to provide health care, including behavioral health treatment and applied behavior analysis (ABA) when prescribed by a physician or psychologist, for the treatment of developmental disabilities, including Autism Spectrum Disorder (ASD).

The Department currently covers ABA services for ASD through the Comprehensive Autism Care Demonstration. Currently, the cost of ABA for TRICARE beneficiaries with ASD diagnoses alone has more than quadrupled between FY 2009 and FY 2014 (from $31.0 to $136.7 million).

The report reflects an independent, external health technology assessment (HTA) consisting of an objective review of the research completed by Hayes, Inc. The FY 2016 budget does not include coverage of ABA for all developmental disabilities, because, as summarized in this report, the HTA determined in their review of the research that the provision of ABA for developmental disabilities does not meet the reliable evidence criteria standard for TRICARE coverage at this time.

Extending ABA for an undefined number of medical diagnoses contributing to developmental disabilities, for a service that is not an evidence-based clinically indicated treatment, will exponentially accelerate the growth in Government expenditures for ABA.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter is being sent to the House Committee on Armed Services.

Sincerely,

Brad Carson
Acting

Enclosure:
As stated

cc:
The Honorable Jack Reed
Ranking Member

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND READINESS

The Honorable William M. "Mac" Thornberry
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

AUG 28 2015

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Sincerely,

Brad Carson
Acting

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member

Report to the Congressional Armed Services Committees in Response to Senate Report 113-176, page 133, to accompany S. 2410, the National Defense Authorization Act for Fiscal Year 2016

Behavioral Health Treatment of Developmental Disabilities under TRICARE

The estimated cost of report for the Department of Defense is approximately $52,310 for the 2015 Fiscal Year. This includes $50,000 in expenses and $2,310 in DoD labor.

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Behavioral Health Treatment of Developmental Disabilities under TRICARE

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BEHAVIORAL HEALTH TREATMENT OF DEVELOPMENTAL DISABILITIES UNDER TRICARE

INTRODUCTION

This report to the Armed Services Committees fulfills the request in Senate Report 113-176, page 133, to accompany S. 2410, the National Defense Authorization Act for Fiscal Year (FY) 2015. The Committee on Armed Services of the Senate requests the Department of Defense (DoD) submit a report to the Committees on the Armed Services of the Senate and the House of Representatives explaining, if funding in the defense budget for FY 2016 required to provide developmental disabilities health care is not included, why funding was not included in the FY 2016 budget for certain forms of behavioral health treatment, specifically applied behavior analysis (ABA), when prescribed by a physician or psychologist, (as defined by title 42, United States Code (U.S.C.), section 15002(8)) for the treatment of developmental disabilities including autism spectrum disorder (ASD).

EXECUTIVE SUMMARY

All TRICARE eligible beneficiaries with a developmental disability currently are eligible to receive robust medical benefits, such as physician services, pharmacotherapy, speech therapy, occupational therapy; as well as behavioral interventions when indicated, including psychotherapy and neuropsychological testing.

The *TRICARE Management Activity Assessment of ABA for ASD* (April 2013 and 2014 update), reviewed the available research on ABA for ASD and concluded that the efficacy of ABA as an intensive behavioral intervention has not been proven as medically or psychologically necessary for the treatment of ASD, and therefore cannot be covered under the TRICARE Basic Program (the medical benefits) as the 32 Code of Federal Regulations (CFR) Sec. 199.4(g)(15) requirements for "proven" medical care are not met. The meta-analyses, technical reports, and other literature reviews consistently indicate that while there is some evidence that ABA therapy may improve certain behaviors in some young children, the evidence overall is weak, and there have been no comparative effectiveness studies of ABA to other interventions such as speech and language pathology and occupational therapy. However, TRICARE covered ABA for ASD for Active Duty family members (ADFMs) for many years under the non-medical Extended Care Health Option (ECHO) Enhanced Access to Autism Services Demonstration, and since 2014, TRICARE has covered ABA for all beneficiaries with ASD under the Comprehensive Autism Care Demonstration (ACD). TRICARE currently is evaluating ABA as a safe and effective treatment for ASD under the ACD. Although ABA does

not meet TRICARE Basic Program coverage standards as a proven medical treatment, it can cover ABA as part of an approved temporary demonstration because requirements for coverage under the Department's demonstration authority are less stringent.

In response to the Senate report, the Department commissioned Hayes, Inc., to complete a health technology assessment (HTA) for ABA for all developmental disabilities other than ASD. Hayes, Inc., scanned the research on developmental disabilities that includes over 800 unique disorders (discussed on page six of this report). Subsequently, four neurodevelopmental disabilities were identified for study inclusion: (1) Intellectual Disabilities (ID) (regardless of etiology); (2) Communication Disorders, comprised of Language Disorder, Speech Sound Disorder, Childhood-Onset Fluency Disorder (stuttering), Social (Pragmatic) Communication Disorder, and Unspecified Communication Disorder; (3) Attention-Deficit/Hyperactivity Disorder (ADHD); and (4) Motor Disorders, to include Developmental Coordination Disorder, Stereotypic Movement Disorder, Tic Disorder (Tourette's disorder, Persistent Motor of Vocal Tics, or Provisional Tic Disorder), other Specified Tic Disorder, and Unspecified Tic Disorder.

Findings from this HTA identified the current research evidence to be of very low to fair quality. There is not sufficient reliable evidence to support the provision of comprehensive ABA (comparable to that provided for ASD) for neurodevelopmental disabilities, including intellectual disabilities, communication disorders, ADHD, or motor disorders. Only one specific ABA-related behavioral technique, habit reversal training (HRT) for Tic disorder, demonstrated moderate quality evidence of effectiveness based on research studies. Currently, HRT is already reimbursed as a covered benefit under the TRICARE Basic program when billed as outpatient psychotherapy. Concurrent with the findings of the Hayes, Inc., technology assessment, published reports from national professional medical associations do not identify ABA as a recommended treatment for any developmental disability other than ASD.

According to the most recent Autism Services Utilization Report, Government costs of ABA for TRICARE beneficiaries with ASD diagnoses alone more than quadrupled between FY 2009 and FY 2014 (from $31.0 to $136.7 million). Increases in autism costs are responsible for over 50 percent of the increase in Active Duty dependent outpatient mental health costs since FY 2008, and, in FY 2014, autism costs for Active Duty dependents accounted for over one-quarter of all Active Duty dependent mental health costs. Using the average FY 2014 health care costs for ABA for ASD under TRICARE, the initial estimated cost of an additional $38.2 million would be required to cover comprehensive ABA for the treatment of challenging behaviors alone for those with a developmental disability other than ASD.

The Department will continue to review the clinical literature every three years to determine if new research evidence supports the provision of ABA or other behavioral treatments not currently covered under the TRICARE Basic Program as interventions for specific developmental disabilities.

BACKGROUND

TRICARE already covers all medically necessary evidence-based treatments for all developmental disabilities under the TRICARE Basic Program. Medically necessary treatments include occupational therapy (OT) to improve self-management skills such as dressing oneself, physical therapy (PT) to improve balance and coordination, and speech and language pathology (SLP) to improve swallowing and communication. All medically necessary primary and specialty care physician services, pharmacology, and behavioral health services to include psychotherapy, psychological testing, and psychopharmacology are also covered for TRICARE eligible beneficiaries with developmental disabilities. TRICARE currently covers ABA specifically for the one developmental disability of ASD under the ACD. ABA for ASD is covered under the Department's demonstration authority and not under the TRICARE Basic Program's medical benefit because ABA does not yet meet TRICARE's reliable evidence standard under 32 CFR 199.4 as "proven medical care" for the treatment of ASD (see discussion of TRICARE reliable evidence criteria for proven medical care on page seven). Rather, the state of the current research evidence for ABA for ASD only meets TRICARE standards as a promising, emerging treatment. The overarching goal of the ACD is to analyze, evaluate, and compare the quality, efficiency, convenience, and cost effectiveness of those autism-related services that do not constitute proven medical care provided under the medical benefit coverage requirements that govern the TRICARE Basic Program.

The purpose of this report is to meet the requirement of Senate Report 114-102 to provide Congress with a report on why ABA is not covered in the FY 2016 budget for the TRICARE Basic Program as a behavioral health treatment for developmental disabilities other than ASD. The Department commissioned Hayes, Inc., to conduct a technology assessment in order to obtain an independent expert assessment of the current state of the research from an impartial scientific review body outside of the DoD.

Developmental disabilities are defined under federal law as "a severe, chronic disability of an individual that (i) is attributable to a mental or physical impairment or combination of mental and physical impairments; (ii) is manifested before an individual attains age 22; (iii) is likely to continue indefinitely; (iv) results in substantial functional limitations in three or more major life activities; and (v) reflects an individual's need for a combination and sequence of special, interdisciplinary, or generic services, individualized supports, or other forms of assistance that are of lifelong or extended duration and are individually planned and coordinated" (title 42, U.S.C., section 15002 (8)). According to the Centers for Disease Control and Prevention, "developmental disability refers to a group of conditions that cause impairment in physical, learning, language, or behavioral areas." Over 800 unique disorders fall under this broad category that are then grouped according to the underlying affected body system (i.e.,

nervous system disorders, sensory-related disorder, metabolic disorders, and degenerative disorders).

"Developmental disabilities" is a broad term that encompasses many different medical conditions. This expansive term led Hayes, Inc., to adopt a narrow definition of developmental disabilities in order to be able to draw meaningful conclusions about the current state of the research for ABA as a behavioral health treatment for developmental disabilities other than ASD. The most common developmental disabilities under the nervous system developmental disorders classification are those that cause intellectual disability. This category includes conditions such as Down syndrome, Fragile X syndrome, and cerebral palsy. Sensory related developmental disorders are impairments in the sensory system where there is an inability to sense the surrounding world. Vision and hearing problems fall under this category. Likewise, children with Fragile X may also have sensitivities to sights and sounds. Metabolic related developmental disorders affect a person's metabolism, which is the way the body builds up and breaks down materials it needs to function. A common metabolic developmental disability is phenylketonuria (PKU). PKU is treated with a special diet. Another condition in this category is hypothyroidism.

The last category is degenerative developmental disorders. Rett's syndrome is one such disorder. Rett's syndrome is of interest because it was previously included as a diagnosis under the Diagnostic and Statistical Manual of Mental Disorders (DSM), Fourth Edition, Text Revision under the Pervasive Developmental Disorders (PDD) chapter that also included ASD, and subsequently was a qualifying condition for ABA prior to the ACD. Ongoing research revealed that Rett's syndrome is no longer a part of the PDD spectrum, and that ABA is not an effective treatment for this disorder. Therefore, under the Fifth edition of the DSM (DSM-5), Rett's syndrome was removed from the neurodevelopmental chapter. Of note, this evolution of a diagnosis indicates that ongoing medical research is important for identifying effective treatments for specific disorders, and that research evidence can and does change over time.

Developmental disabilities generally cause lifelong functional impairments that cannot be cured, but may be mitigated by appropriate treatments tailored to specific symptoms. For example, an individual born with the metabolic disorder of hypothyroidism needs lifelong treatment with replacement thyroid medication. With early identification of and treatment for hypothyroidism, the individual may not progress to a developmental disorder due to the hypothyroidism. Persons with cerebral palsy, a nervous system developmental disorder, commonly have lifelong problems with muscle coordination and balance, swallowing, and drooling. Ongoing OT, PT, and SLP services are needed. Individuals born with a sensory-related developmental disorder such as vision or hearing impairments, require treatments tailored to compensating for the visual or auditory impairment. TRICARE covers all required treatments for the above described developmental disabilities. Additionally, ECHO covers additional

services for these conditions, such as durable equipment, (which may include adaptive, non-medical devices) and additional OT, PT, and SLP services for ADFMs.

Another key concept is "applied behavior analysis." In general, ABA is a broad term that consists of multiple types of behavioral techniques. For the purposes of this report, Hayes, Inc., defines ABA as: "a form of therapy that applies the principles of behavior modification in real world settings that consists of processes such as operant and respondent conditioning, to socially significant behavior in real world settings." Hayes, Inc., uses the term "ABA-related approaches" to mean any approach that encompasses objective measurement of behavior, techniques based on scientifically established principles of behavior, and control of the environment to allow objective measurement of outcomes.

Some individuals with certain developmental disabilities may, at times, exhibit challenging behaviors such as self-injurious behavior, aggressive behavior, inappropriate sexualized behavior, behavior directed at property, and stereotyped behaviors. These challenging behaviors may be caused by a number of factors to include biological, social, environmental, psychological, and/or communication factors. Advocacy groups maintain the position that challenging behaviors for all developmental disabilities can be addressed and modified through behavioral interventions, specifically ABA. Subsequently there has been significant attention and pressure that TRICARE cover ABA as a medical benefit for all developmental disabilities.

RELIABLE EVIDENCE HIERARCHY FOR PROVEN MEDICAL CARE

Title 32 CFR Part 199.2 provides the TRICARE hierarchy of reliable evidence used in making determinations when a drug, device, medical treatment, or procedure has moved from the status of unproven to the position of nationally accepted medical practice.

The reliable evidence standards (1) as used in Sec. 199.4(g)(15) require:

(i) Well-controlled studies of clinically meaningful endpoints, published in refereed medical literature.

(ii) Published formal technology assessments.

(iii) Published reports of national professional medical associations.

(iv) Published national medical policy organization positions; and

(v) Published reports of national expert opinion organizations.

(2) The hierarchy of reliable evidence of proven medical effectiveness, established by (i) through (v) of this paragraph, is the order of the relative weight to be given to any particular source. With respect to clinical studies, only those reports and articles containing scientifically valid data and published in the refereed medical and scientific literature shall be considered as meeting the requirements of reliable evidence. Specifically not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence, or personal professional opinions. Also not included in the meaning of reliable evidence is the fact that a provider or a number of providers have elected to adopt a drug, device, or medical treatment or procedure as their personal treatment or procedure of choice or standard of practice.

Title 32 CFR Part 199.4(g)(15)(i) provides that "any device, medical treatment or procedure whose safety and efficacy has not been established is unproven and excluded from coverage."

> (i) A drug, device, or medical treatment or procedure is unproven:
>
> (C) Unless reliable evidence shows that any medical treatment or procedure has been the subject of well-controlled studies of clinically meaningful endpoints, which have determined its maximum tolerated dose, its toxicity, its safety, and its efficacy as compared with standard means of treatment or diagnosis. (See the definition of *reliable evidence* in Sec. 199.2 of this part for the procedures used in determining if a medical treatment or procedure is unproven.)
>
> (D) If reliable evidence shows that the consensus among experts regarding the medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated doses, its toxicity, its safety, or its effectiveness as compared with the standard means of treatment or diagnosis (see the definition of reliable evidence in Sec. 199.2 for the procedures used in determining if a medical treatment or procedure is unproven).

METHOD

As discussed above, "developmental disabilities" encompass many physical disabilities for which ABA is never an indicated intervention. The Department is committed to providing effective evidence-based treatments to all beneficiaries with developmental disabilities. However, it was impractical to review all literature regarding the potential of ABA as an effective treatment for the entire category of over 800 developmental disabilities. For example, ABA would not be an appropriate treatment for PKU, as a special diet is the indicated treatment, nor would ABA be the appropriate treatment for hypothyroidism, blindness, or deafness, even

though all are developmental disabilities. Therefore, the focus of this HTA was to become informed about the state of the research evidence for ABA as an effective treatment for specific neurodevelopmental disabilities for which ABA may be beneficial. The Hayes, Inc., technology assessment evaluated the available research evidence for each neurodevelopmental disorder listed in the DSM-5 (other than ASD) against TRICARE's regulation and policy governing the reliable evidence standards for medical benefit coverage under the TRICARE Basic program. Specifically, the Hayes, Inc., *Technology Assessment on Applied Behavior Analysis for Developmental Disorders Other than Autism Spectrum Disorder* (May 13, 2015), evaluated the currently available research evidence for ABA for the DSM-5 (May 2013) Neurodevelopmental Disorders categories of :

1. ID, regardless of etiology;
2. Communication Disorders, comprised of Language Disorder, Speech Sound Disorder, Childhood-Onset Fluency Disorder (stuttering), Social (Pragmatic) Communication Disorder, and Unspecified Communication Disorder;
3. ADHD; and
4. Motor disorders, to include Developmental Coordination Disorder, Stereotypic Movement Disorder, Tic Disorders (Tourette's Disorder, Persistent Motor of Vocal Tics or Provisional Tic Disorder), Other Specified Tic Disorder, and Unspecified Tic Disorder.

Randomized control trials (RCTs) and systematic reviews were selected for inclusion as these study designs represent the best available evidence (Hayes, Inc., 2015). Six RCTs and five systematic reviews (475 studies and 900 total participants) were found for ID; two RCTs were found for ADHD; one systematic review (of eight RCTs) was found for Tourette's disorder; and one systematic review (of eight RCTs plus one quasi-experimental design) was found for stuttering. None of the systematic reviews analyzed data specific to other developmental disabilities such as cerebral palsy, Fragile X syndrome, hearing loss, kernicterus (a condition caused by jaundice) muscular dystrophy, vision impairment, or hearing impairment (Hayes Inc., 2015).

The strength of the evidence was evaluated according to the following categories: very low quality, low quality, fair quality, moderate quality, and high quality. Hayes, Inc., relied on the general principles of research evaluation applicable to any type of clinical research, rather than adopting a specific classification of quality such as that of the American Psychological Association, or other organizations. Hayes, Inc., selected this course of action to take into account the potential strength of single-subject design (SSD) studies that are common in the developmental disorder research literature (Hayes, Inc., 2015). SSDs are typically not acceptable for inclusion in the hierarchy of reliable evidence according to standard sources of guidance such

as those provided by the Grading of Recommendations Assessments, Development and Evaluation Working Group (Guyatt et al., 2011), the Center for Evidence-Based Medicine (CEBM, 2014), the Cochrane Collaboration Handbook (Cochrane Collaboration, 2011), and the Agency for Healthcare Research and Quality (AHRQ, 2015). These hierarchies place RCTs at the top of the list, followed by meta-analyses of RCTs, and rank other study designs in descending order according to each design's increasing risk of bias and lack of internal validity. While well designed SSDs may have good internal validity, experts in ABA acknowledge that external validity, the applicability of results to other patients (generalizability), may be poor (Hayes, Inc., 2015). TRICARE's reliable evidence standards, 32 CFR Sec. 199.4(g)(15), follow the same general hierarchy of the evidence standards.

Studies selected for inclusion met the following criteria:

1. RCTs or systematic reviews with a formal meta-analysis
2. Selection of studies or participants to a specific developmental disorder
3. Any form of therapy applying principles of ABA
4. Compliance with the Populations-Interventions-Comparator-Outcomes-Setting schema of research (Hayes Inc., 2015)

The Hayes, Inc., HTA considered ABA to include any form of therapy applying the principles of ABA regardless of whether the term ABA was used or not. Any interventions that include objective measurement of behavior, techniques based on scientifically established principles of behavior, and control of the environment to allow objective measurement of outcomes were included (Hayes Inc., 2015). Since the definition of ABA is broad, Hayes, Inc. used the term "ABA-related approaches" to address the fact that ABA-related approaches differ based on the therapeutic need of the patient. Treatment of problem behaviors may include punishment procedures such as aversive stimuli (i.e., slapping a patient, spraying the patient with lemon juice, physically restraining a patient in a padded room in certain circumstances) or imposing a task requirement. Presently, the field of ABA emphasizes environmental rewards whenever possible. One specific ABA-related technique, HRT, which focuses on awareness training, has been specifically studied as an intervention for Tourette syndrome. HRT for Tourette's disorder involves training an individual to detect early recognition that a tic is developing and then to substitute the tic with another, incompatible behavior.

The Hayes, Inc., HTA highlighted the distinction between *comprehensive ABA* as versus *focused ABA*. Comprehensive ABA refers to intensive ABA that addresses multiple targets and requires many hours of ABA per week (up to 25-40 hours per week) for up to several years of continuous treatment. The goal of comprehensive ABA is to attempt to teach skills in the areas of attention, language/communication, socialization, and sometimes to improve academic skills over an extended period of time (Hayes, Inc., 2015). Comprehensive ABA may take place in the

home or educational setting. Comprehensive ABA is also called *Early Intensive Behavioral Intervention* or *Intensive Behavioral Intervention* in the research literature. Comprehensive ABA is increasingly recommended for the treatment of ASD. Success is often measured according to global measures of intelligence, adaptive behavior, and social functioning. Focused ABA refers to a time-limited and targeted approach for a specific problematic behavior. Treatment intensity and duration are relatively brief.

HEALTH TECHNOLOGY ASSESSMENT FINDINGS

Intellectual Disability

Six RCTs and five systematic reviews (475 studies and 900 total participants) were found on ID. The studies evaluated behavior therapy for skills training, sleep problems, or challenging behaviors. Most of the 252 participants in the six RCTs were adults with ID, ranging from mild to severe ID, who were institutionalized. One of the six RCTs studied children with severe learning disabilities where approximately one third of the children had an underlying primary diagnosis of ASD. Approximately 475 SSD studies with 900 participants were represented in the five remaining systematic reviews. Furthermore, in two of the five systematic reviews, 39-48 percent of the subjects had an autism diagnosis as the underlying primary diagnosis. The other three systematic reviews did not report what proportion of subjects had an underlying ASD as their primary diagnosis. None of the reviews provided information on treatment intensity or duration. The RCTs were rated as being of poor or fair quality. Weaknesses include a lack of blinding subject assignment to treatment or control groups and small sample sizes. A weakness for two of the systematic reviews is the fact that such a high percentage of participants had a primary underlying diagnosis of ASD and that the reported effectiveness of the intervention could have been due to the fact that ABA was an effective intervention for the ASD, rather than for the ID. The systematic reviews were assessed to be of very low to low quality. None of these studies had control groups; therefore, it is not possible to conclude that the results would be generalizable to other similar individuals (Hayes, Inc., 2015).

Hayes, Inc., concluded that for individuals with ID with challenging behaviors, the evidence for ABA-related therapies is as follows:

1. Group skills training for adults (four small RCTs): Low quality of the evidence. Low quantity of data reported. Limitations included: small magnitude or non-significant effects. The programs represented by these studies involved nine to 20 sessions.

2. Parent-delivered treatment of sleep problems in children (one small RCT): Very low quality of the evidence. Low quantity of data. Treatment was six weeks of parent-delivered behavior modification strategies. Parents received 90-180 minutes of therapist training.

3. Individual treatment of challenging behaviors in adults and children (one small RCT, five systematic reviews of SSD studies): RCT and systematic reviews were of low quality of the evidence. The RCT consisted of nine sessions of behavior therapy as an add-on treatment to standard treatment. SSD studies showed ABA therapy to be delivered in multiple short sessions per day over a period of approximately 10 to 85 days. Limitations included: small sample size of 66, no control group, and possible publication bias. The five systematic reviews had consistently positive conclusions. The five systematic reviews had very low to low quality of the evidence.

ADHD

Only two of 30 RCTs on the non-pharmacological treatment of ADHD met inclusion criteria for this review. Most studies were excluded because multiple interventions were identified that did not allow for the identification of ABA-related behavior therapy. One RCT studied behavioral interventions for improving school organization and other school-related skills. The second RCT examined ABA-related principals for improving sleep. The two studies (402 evaluable participants) either compared treatment based on ABA-related principals with no treatment or treatment as usual. In one study, approximately one-third of the children were using ADHD medications, and in the other study, 91 percent of the children in the behavior therapy group were using ADHD medication, while 68 percent of the control group received ADHD medications. The first RCT (158 subjects) examined school-related behavior therapy for organizational skills and other school-related measures, to improve the child's ability to function in the school setting. The study compared two programs involving either a limited reward system or a more structured contingency system, and this study included a waitlist control group. The treatment was delivered twice a week for 20 sessions over 10 weeks. The main limitations of this study were missing data (poor quality and quantity), and the possibility that the treatment effect was partially due to the increased attention the students received in the RCT. This RCT was determined to be a poor quality study with very low quality of the evidence.

The second RCT studied sleep problems in children with ADHD (244 subjects). The sleep RCT was of fair quality. The study design was a brief intervention to train parents in an individualized sleep treatment plan for their children versus usual care. The training included two telephone calls and two meetings with the parents. For some children, the intervention involved a cognitive therapy and not behavioral therapy. The results showed a small positive effect on sleep problems. The quality of the evidence was low.

Tourette's disorder

A systematic review and meta-analysis of eight RCTs (438 participants) of a behavior therapy called HRT were reviewed. HRT uses a competing response technique whereby the individual with Tourette's disorder is taught to recognize when a tic is about to manifest and to intervene before onset by using a competing response, thereby preventing the tic from appearing.

Treatment consisted of seven to 14 sessions. In seven of the studies, 25-48 percent of the subjects were on medication for tics but this did not influence the treatment effect. Moderate quality evidence showed that HRT was efficacious but not superior to other treatments that include a behavioral component. Greater effect was associated with a co-morbid ADHD diagnosis and older age.

Stuttering

A systematic review of eight RCTs and one study using a quasi-experimental design were reviewed. The review was intended to evaluate different forms of behavior therapy for children who stutter. A program called the Lidcombe program was identified as being effective in reducing stuttering in preschoolers. The Hayes, Inc., HTA concluded that the data from the systematic reviews provided low quality evidence that 12-16 weeks of the Lidcombe program reduces stuttering. The Lidcombe program teaches parents to deliver verbal contingencies to their child who stutters. Very low quality evidence from the other studies suggested that behavioral approaches other than the Lidcombe program were not effective in reducing stuttering.

PUBLISHED REPORTS FROM NATIONAL PROFESSIONAL MEDICAL ASSOCIATIONS

National organizations with published guidelines on ABA do not include recommendations for ABA for developmental disorders other than ASD. The following table identifies current publications and recommendations for ID, ADHD, and Tourette's disorder.

ABA			
	Organization	**Publication**	**Findings**
ID	AHRQ	Comparative Effectiveness Review No. 137: Therapies for Children With Autism Spectrum Disorders (August 2014)	There are no AHRQ technology assessments for ABA for other developmental disabilities.
	American Academy of Pediatrics (AAP)	Management of Children With Autism Spectrum Disorders (2007) and November 2014 Affirmation	ABA is identified for the management of children with autism only.
	American Academy of Child and Adolescent Psychiatry (AACAP)	Practice parameters on the assessment and treatment of children, adolescents, and adults with autism and pervasive developmental disorders (2014)	No specific recommendations for ABA therapies for ID.

ADHD	AAP	ADHD: Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents (2011)	Evidence-based parent and teacher administrated behavior therapy is a first line treatment for 4-5 year olds.
	AACAP	Practice parameters on the assessment and treatment of children, adolescents, and adults with autism and pervasive developmental disorders (2014)	Behavior therapy may be a first line treatment for mild symptoms of ADHD.
	National Collaborating Centre for Mental Health	Attention deficit hyperactivity disorder. Diagnosis and management of ADHD in children, young people and adults (2008)	Recommends parents or caregivers be referred to training and education programs.
Tourette's disorder	AACAP	Practice parameters for the Assessment and Treatment of Children and Adolescents with Tic Disorders (2013)	HRT as a behavior therapy for Tourette's disorder has the strongest empirical support.

Behavior therapy is already covered under the TRICARE outpatient psychotherapy benefit. TRICARE outpatient mental health providers are encouraged to follow clinical practice guidelines when selecting a specific therapy for a specific condition. Behavior therapy is cited as an evidence-based therapy identified by the AAP for the first line treatment of ADHD in 4-5 year olds. TRICARE-authorized child therapists commonly provide behavior therapy for young children with ADHD and their parents in accordance with this AAP guidance. Similarly, HRT is a specific behavior therapy for the treatment of Tourette's disorder. Therapists trained in HRT already provide this behavior technique to TRICARE eligible beneficiaries during covered outpatient psychotherapy visits

COST-ESTIMATE FOR ABA FOR DEVELOPMENTAL DISABILITIES OTHER THAN ASD

The Department conducted a cost-estimate analysis for TRICARE to add coverage of comprehensive ABA for all developmental disabilities other than ASD. The cost-estimate report (May 29, 2015) highlighted that other than requiring ABA coverage for all "developmental disabilities," there are no specific qualifying criteria for ABA services that have been identified. This led the report to base the analysis on the assumption that TRICARE coverage of ABA would be limited to those patients who have both developmental disabilities and severe problem behaviors. This assumption was determined by information available from a 2012 literature review by Kennedy Krieger Institute and Johns Hopkins University School of Medicine, and the definition of "severe problem behaviors" from the Behavior Analyst Certification Board. This

cost-estimate report omits ABA for all other treatment targets and goals other than those for improving severe problem behaviors.

The severe problem behaviors identified by the cost-estimate analysis report included the following diagnosed conditions in FY 2014: self-injury, aggression, Pica, disturbance of conduct, Oppositional Defiant Disorder, and Unspecified Emotional Disturbance. The age ranges examined were children and adolescents ages 2-15 years. The number of children/adolescents with a diagnosis of a developmental disorder that also had FY 2014 claims for treatment of severe behavior disturbance was 13,406. Of these, roughly 90 percent were diagnosed with ADHD and 9 percent were diagnosed with a specific developmental delay.

Using the average FY 2014 health care costs for ABA for ASD under TRICARE ($16,855 per ADFM beneficiary and $12,229 per NADFM beneficiary), the report concluded an estimated cost of an additional $38.2 million would be required to cover comprehensive ABA for the treatment of challenging behaviors alone for those with a developmental disability other than ASD. However, this cost-estimate is likely an underestimate because it does not factor in the cost of providing ABA to those with developmental disabilities other than ASD for treatment targets and goals other than severe problem behaviors.

According to the most recent *Autism Services Utilization Report*, Government costs of ABA for TRICARE beneficiaries with ASD diagnoses alone more than quadrupled between FY 2009 and FY 2014 (from $31.0 to $136.7 million). Increases in autism costs are responsible for over 50 percent of the increase in Active Duty Dependent outpatient mental health costs since FY 2008, and in FY 2014, autism costs for Active Duty Dependents accounted for over one-quarter of all Active Duty Dependent mental health costs. Extending ABA for an undefined number of medical diagnoses contributing to developmental disabilities will exponentially accelerate the growth in government expenditures for ABA.

CONCLUSIONS

According to the Hayes, Inc., HTA, the only ABA-related approach that is supported by at least moderate quality research evidence is HRT for Tourette's disorder. The AACAP also identifies HRT as having the strongest evidence-based support as treatment for Tourette's disorder. HRT, as a focused behavioral intervention for the treatment of tics related to Tourette's disorder, is already a covered benefit under the TRICARE Basic Program's outpatient psychotherapy benefit.

The outpatient psychotherapy benefit is a comprehensive benefit based entirely on medical necessity. Outpatient psychotherapy offers up to two 90-minute outpatient sessions per week for as long as medically necessary. Evidence-based approaches are covered as outpatient

psychotherapy and promoted through initiatives that encourage the use of published clinical practice guidelines for each condition. For example, cognitive behavioral therapy is encouraged for the treatment of depression; exposure-based psychotherapy (such as Cognitive Processing Therapy and Prolonged Exposure Therapy) is encouraged for the treatment of Post-Traumatic Stress Disorder. Likewise, the Department covers, and will continue to promote HRT, as an evidence-based treatment for Tourette's disorder.

For ID, the Hayes, Inc., HTA found that most of the studies implemented ABA-related approaches that were expressly labeled ABA, based on a functional behavior assessment, were designed to address specific challenging behaviors. However, Hayes, Inc., was able to draw only very tentative conclusions about the effectiveness of ABA for challenging behaviors in the ID population due to the very low to fair quality of the studies. Likewise, the evidence for ABA for ADHD and stuttering was also found to be of very low to fair quality. Therefore, ABA-related approaches for ID, ADHD, and stuttering cannot be recommended as evidence-based therapies under the TRICARE Basic Program (medical benefit) at this time. Behavioral approaches are commonly used by mental health providers for challenging behaviors in ID, and for ADHD in pre-school children and early school age children for whom medication is not yet a desired option. Behavioral therapies are already delivered to TRICARE beneficiaries with these conditions during outpatient psychotherapy sessions.

The cost-estimate for providing ABA for the treatment of only challenging behaviors for those with a developmental disorder other than ASD is $38.2 million. This is likely an underestimate because it does not account for the costs of providing ABA to those with developmental disorders other than ASD for other treatment targets and goals. Of the research evidence reviewed by Hayes, Inc., none of the studies identified researched the effectiveness of comprehensive ABA such as that provided under the ACD for those with ASD (e.g., 25-40 hours a week for continuous years of treatment). Rather, the existing research literature is limited to ABA-related behavior therapy approaches that are delivered during brief sessions over relatively brief periods of time for the treatment of DSM-5 neurodevelopmental disorders reviewed (ID, ADHD, Tourette's disorder, and Stuttering). Many behavior therapy techniques can be delivered to TRICARE eligible beneficiaries now through the covered outpatient psychotherapy benefit under the TRICARE Basic Program at no additional costs to TRICARE.

Based on a thorough review of the literature, the Department cannot support the provision of ABA, especially such as that provided under the ACD for ASD, to those beneficiaries with a developmental disability other than ASD. While the research literature supports an endorsement of HRT for Tourette's disorder based on the moderate strength of evidence in support of its effectiveness in decreasing tics, HRT is already provided in covered outpatient psychotherapy sessions under the TRICARE Basic Program when rendered by TRICARE-authorized providers. Providing TRICARE coverage of ABA for a host of developmental disabilities that would not benefit from it diverts costly health care resources away from provision of effective evidence-

based treatments for all developmental disabilities. Furthermore, extending ABA for an undefined number of medical diagnoses contributing to developmental disability will exponentially accelerate the growth in government expenditures for ABA. TRICARE cannot endorse spending, at minimum, an extra $38.2 million on comprehensive ABA for all developmental disabilities for which there is poor quality evidence.

Finally, an unintended consequence of expanding coverage would create false hope in the parents of a disabled child for whom ABA would not help. This would inflict a great injustice to our military families that surely they do not deserve.

The Department supports continued research on ABA-related interventions for specific developmental disabilities and will conduct another review of the literature in three years to determine if research evidence evolves to the point where ABA for specific developmental disabilities can, in the future, meet the criteria for coverage as proven medical care under 32 CFR 199.4 for coverage under the TRICARE Basic Program.

Behavioral health treatment of developmental disabilities under TRICARE

The committee directs the Secretary of Defense to either: (1) Include in the defense budget for FY 2016 the funding required to provide health care, including behavioral health treatment and applied behavior analysis when prescribed by a physician or psychologist, under title 10, U.S.C., section 1077, for treatment of developmental disabilities (as defined by section 102(8) of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (title 42, U.S.C., section 15002(8)), including autism spectrum disorder; or (2) Submit a report to the Committees on Armed Services of the Senate and the House of Representatives explaining why such funding is not included in the budget for FY 2016.

The health care described above should be provided by licensed or board-certified professionals. However, applied behavior analysis or other behavioral health treatment may be provided by authorized employees, contractors, or trainees under the supervision of the licensed or board-certified professionals when the employee, contractor, or trainee meets minimum qualifications, training, or supervision requirements established by State law, an accredited national certification board, or by the Secretary.

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ACRONYM LIST

AACAP – American Academy of Child and Adolescent Psychiatry

AAP – American Academy of Pediatrics

ABA – Applied behavior analysis

ACD – Autism Care Demonstration

ADFM – Active Duty family member

ADHD – Attention Deficit/Hyperactivity Disorder

AHRQ – Agency for Healthcare Research and Quality

ASD – Autism spectrum disorder

CFR – Code of Federal Regulations

DoD – Department of Defense

DSM – Diagnostic and Statistical Manual of Mental Disorders

ECHO – Extended Care Health Option

FY – Fiscal Year

HRT – Habit reversal training

HTA – health technology assessment

ID – Intellectual disability

OT – Occupational therapy

PDD – Pervasive Developmental Disorders

PKU – Phenylketonuria

PT – Physical therapy

RCT – Randomized control trial

SLP – Speech and language pathology

SSD – Single subject design

U.S.C. – United States Code