UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

DEC - 3 2021

The Honorable Jack Reed
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The Department's response to the Senate Report 114-49, pages 157-158, accompanying S. 1376, the National Defense Authorization Act for Fiscal Year (FY) 2016, which requests the Secretary of Defense provide an annual report on the Autism Care Demonstration Program (ACD), is enclosed.

The ACD offers Applied Behavior Analysis (ABA) services for all TRICARE-eligible beneficiaries diagnosed with Autism Spectrum Disorder. ABA services are not limited by the beneficiary's age, dollar amount spent, or number of services provided. The ACD began July 25, 2014 and was originally set to expire on December 31, 2018. The Department extended the demonstration until December 31, 2023 to determine the appropriate characterization of ABA services as a medical treatment or other modality under the TRICARE program coverage requirements.

ACD participation increased 41 percent from 11,461 beneficiaries in FY 2015 to 16,160 beneficiaries in FY 2020. Program costs increased 139 percent from $161.5M in FY 2015 to $385.6M in FY 2020. The annual report for FY 2020 provides information on the current state of the ACD, including enrollment and costs, clinical outcomes, lessons learned, and steps for the future to improve the care and support for beneficiaries and families.

Thank you for your continued strong support for our Service members, veterans, and families. I am sending a similar letter to the Committee on Armed Services of the House of Representatives.

Sincerely,

Gilbert R. Cisneros, Jr.

Enclosure:
As stated

cc:
The Honorable James M. Inhofe
Ranking Member

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

DEC - 3 2021

The Honorable Adam Smith
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

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Sincerely,

Gilbert R. Cisneros, Jr.

Enclosure:
As stated

cc:
The Honorable Mike D. Rogers
Ranking Member

Report to the Committees on Armed Services of the Senate and House of Representatives

The Department of Defense

Comprehensive Autism Care Demonstration

Annual Report

2021

In Response to: Senate Report 114-49, pages 157-158, accompanying S. 1376, the National Defense Authorization Act for Fiscal Year 2016

The estimated cost of this report or study for the Department of Defense is approximately $14,000 in Fiscal Years 2021. This includes $0 in expenses and $14,000 in DoD labor.
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REPORT ON EFFORTS BEING CONDUCTED BY THE DEPARTMENT OF DEFENSE ON APPLIED BEHAVIOR ANALYSIS SERVICES

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INTRODUCTION

This report is in response to the Senate Report 114-49, pages 157-158, accompanying S. 1376, the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2016, which requests a report to the Committees on Armed Services of the Senate and House of Representatives on the results of the Comprehensive Autism Care Demonstration (ACD). An interim report was sent to Congress on March 1, 2021, stating that the final report would be submitted by June 30, 2021. This report is delayed due to claims data mining and analysis, as well as the impact of the Coronavirus Disease 2019 (COVID-19) pandemic. This report is based on FY 2020 claims data, and is the sixth of these annual reports.

> "The annual report should include a discussion of the evidence regarding clinical improvement of children with Autism Spectrum Disorder (ASD) receiving Applied Behavior Analysis (ABA) therapy and a description of lessons learned to improve administration of the demonstration program. In the report, the Department should also identify any new legislative authorities required to improve the provision of autism services to beneficiaries with ASD."

BACKGROUND

ABA services are one of many TRICARE covered services available to mitigate the symptoms of ASD. Other services include, but are not limited to: speech and language pathology (SLP); occupational therapy (OT); physical therapy (PT); medication management; psychological testing; and psychotherapy. ABA services are based on clinical necessity that address the core symptoms of ASD and are not limited by the beneficiary's age, dollar amount spent, number of years of services received, or number of sessions provided. Generally, all ABA services continue to be provided through the private sector care system.

The ACD began July 25, 2014, and consolidated three previous programs.[1] The goal of the ACD is to strike a balance between maximizing access while ensuring the highest level of quality and appropriateness of services for beneficiaries. The consolidated demonstration ensures consistent ABA service coverage for all TRICARE-eligible beneficiaries, including Active Duty family members (ADFMs) and non-ADFMs (NADFMs) diagnosed with ASD. The ACD was originally set to expire on December 31, 2018. The Department extended the demonstration, via a Federal Register Notice[2] that was published on December 11, 2017, until December 31, 2023. The Notice stated that additional analysis and experience is required in order to determine the appropriate characterization of ABA services as a medical treatment, or other modality, under the TRICARE program coverage requirements. The Department will obtain additional information about which services TRICARE beneficiaries are receiving under the ACD and how to most effectively target services providing the most benefit. The Department will then collect more

[1] Notice. "Comprehensive Autism Care Demonstration." *Federal Register* 79, no. 115 (June 16, 2014) 34291-34296. www.govinfo.gov/content/pkg/FR-2014-06-16/pdf/2014-14023.pdf

[2] Notice. "Extension of the Comprehensive Autism Care Demonstration for TRICARE Eligible Beneficiaries Diagnosed With Autism Spectrum Disorder." *Federal Register* 82, no. 236 (December 11, 2017) 58186-58187. www.govinfo.gov/content/pkg/FR-2017-12-11/pdf/2017-26567.pdf

comprehensive outcomes data to gain greater insight and understanding of the diagnosis of ASD in the TRICARE population.

DESCRIPTION OF THE ACD

Through this reporting period, the ACD offers only ABA services for all TRICARE-eligible beneficiaries diagnosed with ASD by an approved provider. ABA services under the ACD are authorized for the purpose of ameliorating the core symptoms of ASD (deficits in social communication and restrictive, repetitive behaviors). Under the ACD, a Board Certified Behavior Analyst (BCBA), BCBA-Doctorate, or other TRICARE-authorized provider who practices within the scope of his or her state licensure or state certification, referred to as an "authorized ABA supervisor," plans, delivers, and supervises an ABA program. The authorized ABA supervisor can deliver ABA services under either the sole provider model or tiered-delivery model.

The TRICARE Operations Manual (TOM) Chapter 18, Section 4 "Department Of Defense (DoD) Comprehensive Autism Care Demonstration" provides guidance to all TRICARE contractors on how to execute the benefit under the demonstration authority. The TOM describes: beneficiary eligibility, referral, and authorization requirements; provider eligibility requirements; outcome measure requirements; covered services and reimbursement rates; documentation requirements; exclusions; and contractor responsibilities.

The Defense Health Agency (DHA) acknowledges the ACD has been largely focused on the implementation of ABA services; however, since the ACD is a comprehensive demonstration, DHA is directing efforts toward incorporating all available medically or psychologically necessary and appropriate services for children diagnosed with ASD and supporting the family.

The DHA recently published a comprehensive revision to the demonstration (March 23, 2021), that focuses on providing enhanced beneficiary and family support, improving outcomes, encouraging parental involvement, and improving utilization management controls. These updates also include expanded coverage of certain Adaptive Behavior Services (ABS) for the delivery of ABA services to TRICARE-eligible beneficiaries diagnosed with ASD. These revisions will also improve the quality of, and access to, care and services, and will also improve management and accountability of both the contractors and the ABA providers. The revisions will have a 270-day phased implementation plan. These improvements are discussed below.

UTILIZATION TRENDS

The following information was generated using TRICARE private sector care claims incurred during the last six FYs (FY 2015 – FY 2020) for which full year data is available for the ACD. All claims data examined in this report were extracted from the Military Health System (MHS) Data Repository (MDR) on January 5, 2021 and our results are based upon data entered into the MDR by that date.

TRICARE ACD Program Participants Per FY

At the end of FY 2020, there was a total of 16,160 beneficiaries with a diagnosis of ASD participating in the ACD: 12,049 ADFMs and 4,111 NADFMs (Table 1). This number reflects a 41 percent increase in total participants from the FY 2015 level (11,461): a 31 percent increase for ADFMs (9,178) and 80 percent increase for NADFMs (2,283).

Table 1 – Historical Number of TRICARE ADFM/NADFM ACD Program Participants per FY

Year	Number of Participants	% Growth in Participants from Prior FY
ADFM Participants		
FY 2015	9,178	--
FY 2016	10,321	12%
FY 2017	10,596	3%
FY 2018	11,098	5%
FY 2019	11,994	8%
FY 2020	12,049	0%
NADFM Participants		
FY 2015	2,283	--
FY 2016	3,070	34%
FY 2017	3,431	12%
FY 2018	3,850	12%
FY 2019	4,038	5%
FY 2020	4,111	2%
Total Participants		
FY 2015	11,461	--
FY 2016	13,391	17%
FY 2017	14,027	5%
FY 2018	14,948	7%
FY 2019	16,032	7%
FY 2020	16,160	1%
Source: MDR Data as of January 5, 2021		

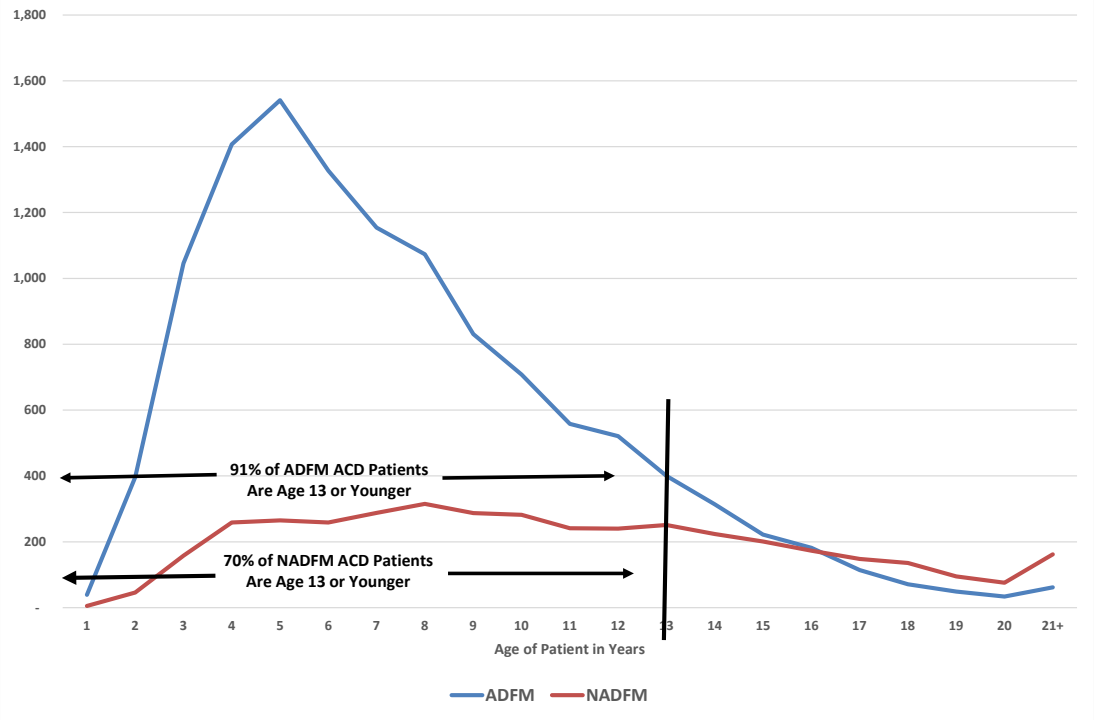
Age Distribution of ACD Program Users FY 2020

Table 2 presents a distribution by beneficiary age and category (ADFMs and NADFMs) using TRICARE ACD services during FY 2020. Across both beneficiary categories, 98.6 percent of ACD beneficiaries are younger than age 21 and 86.0 percent are age 13 and younger (see Table 2); 91 percent of ADFMs and 70 percent of NADFMs are age 13 or younger (see Figure 1). The median participant age is 7 years, the average age is 8.4 years, and the most common age (mode) of participating beneficiaries is 5 years. Roughly 4 out of 5 beneficiaries diagnosed with ASD and participating in the ACD are male. ADFM beneficiaries tend to be younger than NADFMs, with a median age of 7 years (mean of 7.5) versus 10 years (mean of 10.7) for NADFMs.

Table 2 – FY 2020 Distribution of ADFM/NADFM TRICARE ACD Participants by Age

	Number of ACD Participants			Cumulative Percent Distribution
Age	ADFM	NADFM	Total	Total
1	39	5	44	0.3%
2	396	46	442	3.0%
3	1,046	158	1,204	10.5%
4	1,407	259	1,666	20.8%
5	1,541	265	1,806	31.9%
6	1,327	259	1,586	41.8%
7	1,154	288	1,442	50.7%
8	1,073	315	1,388	59.3%
9	831	287	1,118	66.7%
10	708	282	990	72.3%
11	558	241	799	77.3%
12	521	240	761	82.0%
13	400	251	651	86.0%
14	314	224	538	89.3%
15	222	201	423	91.9%
16	182	173	355	94.1%
17	114	148	262	95.8%
18	71	135	207	97.0%
19	49	95	144	97.9%
20	34	76	110	98.6%
21+	62	162	224	100.0%
Total	12,049	4,111	16,160	
Median Age	7	10	8	
Mean Age	7.5	10.7	8.5	
Mode Age	5	8	5	
% males	78%	78%	80%	
Source: MDR Data as of January 5, 2021				

Figure 1 – ACD Age Distribution FY 2020



ABA Program Costs Per FY

Total government costs for the ACD increased 139 percent from the FY 2015 level to FY 2020 ($161.5 million (M) in FY 2015 and $385.6M in FY 2020) (Table 3 – Historical Government Expenditures for TRICARE ADFM/NADFM ACD Program Participants). Government costs for ADFMs increased 124 percent from the FY 2015 level to FY 2020 ($132.1M in FY 2015 and $296.0M in FY 2020) and 205 percent for NADFMs ($29.4M in FY 2015 to $89.6M in FY 2020). Of note, effective October 1, 2015, the maximum Government payment or annual cap for ABA services of $36,000.00 was lifted, and all beneficiary cost-sharing and deductibles and enrollment fees were aligned with the TRICARE Basic Program. Additionally, effective January 1, 2019, all ABA services rendered on the same day became subject to only one copayment for ABA services per day. That change protects beneficiary costs when multiple ABA services are rendered per day. The annual catastrophic cap protections apply to all ABA services for beneficiaries participating in the ACD.

The annual average growth rate was nearly 14 percent from FY 2016-2019. This annual growth rate decreased to roughly 2 percent between FY 2019 and FY 2020, most likely reflecting the effects of COVID-19 social distancing orders. A subsequent section will discuss the findings to date regarding the impact of COVID-19 on the delivery of ABA services.

Table 3 – Historical Government Expenditures for TRICARE ADFM/NADFM ACD Program Participants

FY	Dollars in Millions	% Growth in Dollars from Prior FY
ADFM		
FY 2015	$132.1	--
FY 2016	$185.6	41%
FY 2017	$210.1	13%
FY 2018	$246.9	17%
FY 2019	$289.6	17%
FY 2020	$296.0	2%
NADFM		
FY 2015	$29.4	--
FY 2016	$46.5	58%
FY 2017	$58.2	25%
FY 2018	$73.4	26%
FY 2019	$85.7	19%
FY 2020	$89.6	3%
Total		
FY 2015	$161.5	--
FY 2016	$232.1	44%
FY 2017	$268.3	16%
FY 2018	$320.2	19%
FY 2019	$376.9	18%
FY 2020	$385.6	2%
Source: MDR Data as of January 5, 2021		

The average cost per participant has increased a total of 69 percent from FY 2015 to FY 2020. Average ADFM cost per ACD participant (Table 4 – Historical Government Expenditures per Participant for TRICARE ADFM/NADFM ACD Program per FY) increased 71 percent from $14,393.00 in FY 2015 to $24,569.00 in FY 2020. The average cost per ADFM user increased at an average annual rate of 8 percent. Average NADFM expenditures per ACD participant increased 69 percent from $12,878.00 in FY 2015 to $21,786.00 in FY 2020. The average annual cost per NADFM user increased at an average rate of 10 percent.

Table 4 – Historical Government Expenditures per Participant for TRICARE ADFM/NADFM ACD Program per FY

FY	Dollars per Participant	% Growth in Dollars from Prior FY
ADFM Participant Expenditures		
FY 2015	$14,393	--
FY 2016	$17,986	25%
FY 2017	$19,829	10%
FY 2018	$22,243	12%
FY 2019	$24,142	9%
FY 2020	$24,569	2%
NADFM Participant Expenditures		
FY 2015	$12,878	--
FY 2016	$15,143	18%
FY 2017	$16,951	12%
FY 2018	$19,075	13%
FY 2019	$21,625	12%
FY 2020	$21,786	1%
Total Participant Expenditures		
FY 2015	$14,091	--
FY 2016	$17,335	23%
FY 2017	$19,125	10%
FY 2018	$21,427	12%
FY 2019	$23,508	10%
FY 2020	$23,861	2%
Source: MDR Data as of January 5, 2021		

Annual Expenditure Ranges in FY 2020

In the past, there has been interest in the share of ABA users that are near or reaching the historical $36,000 fiscal year cap on expenditures. While the ACD no longer has annual expenditure limits, the $36,000 expenditure level can serve as a historical benchmark to evaluate the distribution of annual expenditures by ACD program beneficiaries.

In FY 2020, 22.9 percent of ACD users (3,708 of 16,160) had expenditures exceeding $36,000; including 23.8 percent of ADFMs (2,864 of 12,049 users) and 20.5 percent of NADFMs (844 of 4,111 users) (see Table 5). These values have increased significantly from FY 2015 when 9.9 percent of ADFMs and 10.0 percent of NADFMs had annual expenditures that exceeded $36,000.00.

Table 5 – Number of ACD Participants by Annual Expenditure Ranges in FY 2020

Beneficiary Category	<$30K	$30-34.99K	$35-35.99K	$36K Exactly	$36.01-$99.99K	$100K+	Total
ADFM	8,466	603	116	0	2,633	231	12,049
NADFM	3,070	161	36	0	750	94	4,111
Total	11,536	764	152	0	3,383	325	16,160
Source: MDR Data as of January 5, 2021							

Additional analyses were conducted to examine more detailed information regarding the ACD users who exceeded $36,000 in expenditures in FY 2020. Specifically, additional data is presented in Table 6 regarding users by age and beneficiary category. Of the 3,708 users with these large expenditures, 77.2 percent were ADFMs and 22.8 percent were NADFMs. These large expenditure users represent 23.8 percent of all ADFMs and 20.5 percent of NADFMs in the ACD during FY 2020. While two-thirds of these high expenditure users were ages 4 to 9, users in this age cohort represent only 56 percent of ACD users overall. Total paid amounts for users with expenditures exceeding $36,000 annually amounted to $233.8 million in FY 2020, representing 61 percent of the total ACD paid expenditures (but only 22.9 percent of ACD users). For these ACD program users ($36,000+), the total average paid expenditure was $63,060, which is 264% more than the average paid expenditure per ACD program user ($23,861).

Table 6 – FY 2020 ACD Users, Paid Expenditures, & Expenditures Per User for Beneficiaries with Annual Paid Expenditures Exceeding $36,000 by Age and Beneficiary Category (Percent of Total)

Age Group	ADFM	NADFM	Total
Number of ACD Users (% of Total Users)			
Age 3 or Younger	338 (22.8)	29 (13.9)	367 (21.7)
Age 4	512 (36.4)	73 (28.2)	585 (35.1)
Age 5	556 (36.1)	77 (29.1)	633 (35.0)
Ages 6-7	606 (24.4)	148 (27.1)	754 (24.9)
Ages 8-9	380 (20.0)	131 (21.8)	511 (20.4)
Ages 10-12	272 (15.2)	146 (19.1)	418 (16.4)
Ages 13+	200 (13.8)	240 (16.4)	440 (15.1)
Total	2,864 (23.8)	844 (20.5)	3,708 (22.9)
ACD Paid Expenditures-$ Millions (% of Total Paid Amounts)			
Age 3 or Younger	$20.7 (61.8)	$1.9 (53.6)	$22.6 (61.0)
Age 4	$32.0 (71.6)	$5.1 (70.5)	$37.1 (71.5)
Age 5	$36.5 (71.5)	$5.2 (70.5)	$41.7 (71.4)
Ages 6-7	$37.7 (59.7)	$10.3 (68.0)	$48.0 (61.3)
Ages 8-9	$23.6 (55.5)	$8.5 (62.7)	$32.1 (57.3)
Ages 10-12	$16.1 (46.1)	$8.8 (57.7)	$24.8 (49.6)
Ages 13+	$12.2 (46.3)	$15.3 (55.7)	$27.8 (51.1)
Total	$178.7 (60.4)	$55.1 (61.5)	$233.8 (60.6)
Average ACD Participant Expenditures per Patient			
Age 3 or Younger	$61,213	$65,818	$61,577
Age 4	$62,445	$69,917	$63,377
Age 5	$65,706	$67,025	$65,867
Ages 6-7	$62,205	$69,542	$63,645
Ages 8-9	$62,002	$65,021	$62,776
Ages 10-12	$59,077	$59,991	$59,397
Ages 13+	$61,071	$63,948	$62,640
Total	$62,408	$65,272	$63,060
Source: MDR Data as of January 5, 2021			

To further analyze ACD users with large expenditures who exceeded $100,000 in expenditures during FY 2020, Table 7 presents users by age and beneficiary category. Of the 325 ACD users with very large expenditures, ADFMs represent 71.1 percent and NADFMs represented 28.9 percent. These users represent only 1.9 percent of all ADFMs and 2.3 percent of all NADFMs in the ACD. While more than 70 percent of these high expenditures were associated with children between the ages of 4 and 9, users in this age cohort represent only 56 percent of all ACD users. Total paid amounts for users with expenditures exceeding $100,000 in FY 2020 totaled to $40.2 million representing about 10 percent of total ACD paid expenditures (but only 2 percent of ACD users). For these ACD program users ($100,000+), the total average ACD expenditure was $123,744, which is 519% more than the average paid expenditure per ACD program user ($23,861).

Table 7 – FY 2020 ACD Users, Paid Expenditures, & Expenditures Per User for Beneficiaries with Annual Paid Expenditures Exceeding $100,000 by Age and Beneficiary Category (Percent of Total)

Age Group	ADFM	NADFM	Total
Number of ACD Users (% of Total Users)			
Age 3 or Younger	21 (1.4)	3 (1.4)	24 (1.4)
Age 4	39 (2.8)	10 (3.9)	49 (2.9)
Age 5	59 (3.8)	9 (3.4)	68 (3.8)
Ages 6-7	47 (1.9)	23 (4.2)	70 (2.3)
Ages 8-9	31 (1.6)	14 (2.3)	45 (1.8)
Ages 10-12	18 (1.0)	9 (1.2)	27 (1.1)
Ages 13+	16 (1.1)	26 (1.8)	42 (1.4)
Total	231 (1.9)	94 (2.3)	325 (2.0)
ACD Paid Expenditures-$ Millions (% of Total Paid Amounts)			
Age 3 or Younger	$2.6 (61.8)	$0.4 (53.6)	$3.0 (8.1)
Age 4	$4.5 (71.6)	$1.3 (70.5)	$5.8 (11.2)
Age 5	$7.2 (71.5)	$1.0 (70.5)	$8.3 (14.1)
Ages 6-7	$5.7 (59.7)	$2.9 (68.0)	$8.6 (11.0)
Ages 8-9	$3.9 (55.5)	$1.7 (62.7)	$5.6 (10.0)
Ages 10-12	$2.4 (46.1)	$1.0 (57.7)	$3.4 (6.7)
Ages 13+	$2.2 (46.3)	$3.4 (55.7)	$5.6 (10.3)
Total	$28.4 (60.4)	$11.8 (61.5)	$40.2 (10.4)
Average ACD Participant Expenditures per Patient			
Age 3 or Younger	$123,519	$134,101	$124,842
Age 4	$115,193	$129,949	$118,205
Age 5	$122.152	$116,345	$121,384
Ages 6-7	$121,706	$127,110	$123,482
Ages 8-9	$123,292	$124,678	$124,412
Ages 10-12	$130,703	$113,853	$125,087
Ages 13+	$135,674	$130,152	$132,256
Total	$122,901	$125,814	$123,744
Source: MDR Data as of January 5, 2021			

Potential for Future Growth

One approach to understanding the potential for growth in the ACD is to examine the proportion of current beneficiaries diagnosed with ASD who are currently receiving ABA services as a percentage of those beneficiaries diagnosed with ASD under TRICARE. To estimate the total number of beneficiaries diagnosed with ASD in a given year, we queried both direct and private sector care claims to determine the number of beneficiaries ages 2 to 17 who had two or more separate claims with a diagnosis of ASD in any position (i.e., primary or secondary position).[3] Based on this analysis, DHA estimates the number of ADFMs and NADFMs diagnosed with ASD in FY 2020 was 35,473.

Subsequently, the DHA compared the total number of beneficiaries with a diagnosis of ASD to those with a diagnosis of ASD who are receiving ABA services under the ACD. The DHA found that of all MHS beneficiares with a diagnosis of ASD, 43.1 percent of ADFMs and 71.2 percent of NADFMs are not currently receiving any ABA services under the ACD (see Table 8). With 54.4 percent of the total MHS population of beneficiaries diagnosed with ASD not receving ABA services under the ACD, there is potential room for growth in this program. It is undetermined why 54.4 percent of the TRICARE beneficiary population does not use ABA services; these beneficiaries may be using other clinical services (such as PT, OT, SLP, psychotherapy, psychotropic medication, etc.) or non-clinical services (such as academic supports, respite, other community resources, etc.), school-based or private pay ABA services, their diagnosis does not warrant clinical ABA services, they have previously used ABA services and no longer require these services, or other reasons.

Table 8 – Percent of Users Diagnosed with ASD Participating in the ACD during FY 2020

Beneficiary Category	Number of TRICARE Beneficiaries Diagnosed with ASD	Number of TRICARE ACD Program Users	Percent of TRICARE Beneficiaries Diagnosed with ASD Using the TRICARE ACD Program
ADFM	21,192	12,049	56.9%
NADFM	14,281	4,111	28.8%
Total	35,473	16,160	45.6%
Source: MDR Data as of January 5, 2021			

[3] DHA used this operational definition of two or more claims to estimate the number of beneficiaries diagnosed with ASD. Beneficiaries with only one claim are excluded because they likely would have been diagnosed with a non-ASD diagnosis as a result of additional testing.

It is also important to note that ABA utilization rates have plateaued over the years for both ADFM and NADFM (see Figures 2 and 3). Additionally, there is no expectation of equivalent utilization rates between the two groups due to demographic differences; most notable is the average age of the participants. In general, NADFMs tend to be older children, and the utilization of ABA services tends to decrease significantly over time as noted in Figure 1 (see above).

Figure 2 – ADFM Beneficiaries Diagnosed with ASD in FY 2020: ACD Users/Non-Users

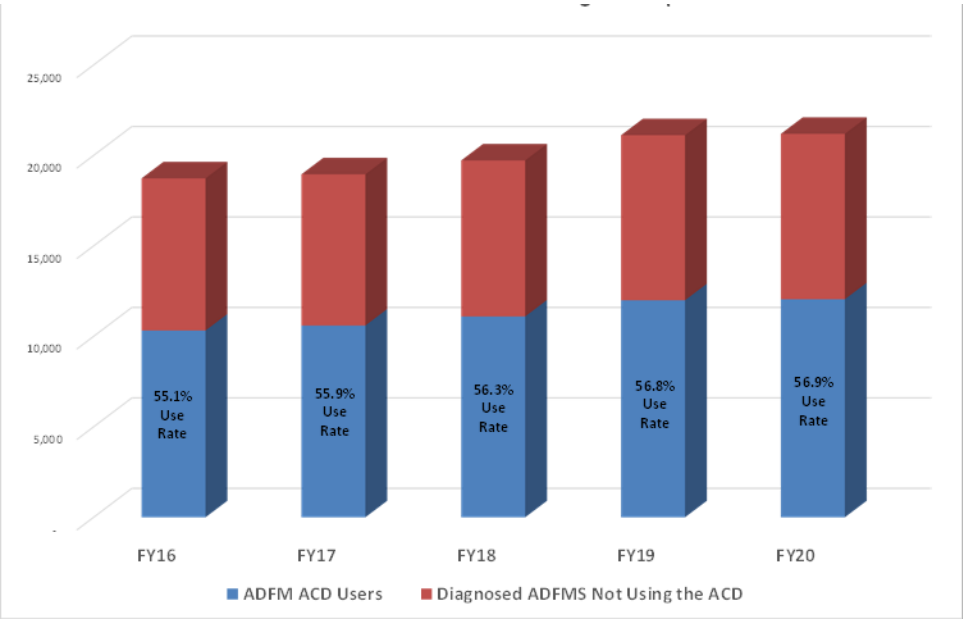
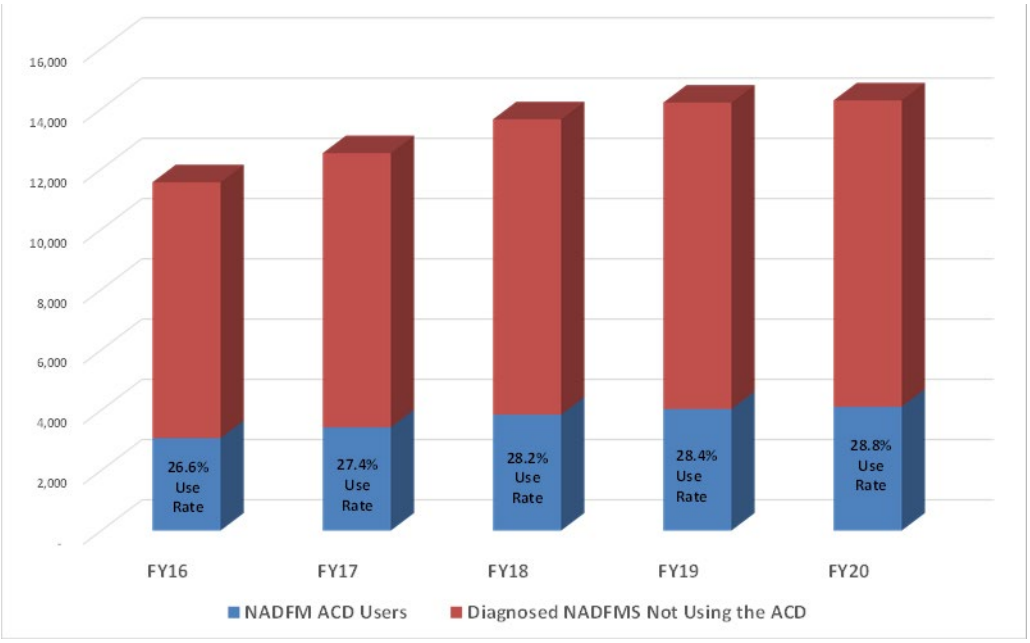


Figure 3 – NADFM Beneficiaries Diagnosed with ASD in FY 2020: Uses/Non-Users



Expenditures for Physical/Speech/Occupational Therapy and Prescription Drugs

In addition to the $385.6M in FY 2020 expenditures in the ACD, beneficiaries diagnosed with ASD participating in the ACD also utilized relatively large amounts of TRICARE medical services for PT, SLP, and OT in both the private sector care and direct care systems. Further, beneficiaries diagnosed with ASD in the ACD also used the retail pharmacy, TRICARE Mail Order Pharmacy, and direct care pharmacy for prescription medications to treat behaviors impacting the symptoms of ASD, Attention Deficit Hyperactivity Disorder (ADHD), and related medical and mental health conditions. The 16,160 TRICARE beneficiaries who participated in the ACD during FY 2020 also utilized $49.1M in PT, SLP, and OT services (private sector care paid amounts and direct care full cost amounts) and $17.2M in prescription medications.

Table 9 – Historical Government Expenditures for PT/OT/SLP and Prescription Medication for TRICARE ADFM/NADFM ACD Program Participants

Year	PT/SLP/OT Services	Prescription Medications[1]	Total
ADFM Participant Expenditures			
FY 2015	$28,028,408	$13,852,350	$41,880,758
FY 2016	$31,516,590	$12,222,371	$43,738,961
FY 2017	$33,203,356	$10,427,384	$43,630,740
FY 2018	$37,982,102	$11,016,239	$48,998,341
FY 2019	$43,801.496	$11,947,119	$55,748,615
FY 2020	$42,388,393	$11,506,747	$53,895,140
NADFM Participant Expenditures			
FY 2015	$3,775,274	$4,674,041	$8,449,315
FY 2016	$5,018,476	$4,297,492	$9,315,968
FY 2017	$5,877,184	$4,497,166	$10,374,350
FY 2018	$6,783,759	$4,483,788	$11,267,547
FY 2019	$7,515,353	$4,438,281	$11,953,634
FY 2020	$6,737,811	$5,721,878	$12,459,680
Total Participant Expenditures			
FY 2015	$31,803,682	$18,526,391	$50,330,073
FY 2016	$36,535,066	$16,519,863	$53,054,929
FY 2017	$39,080,540	$14,924,550	$54,005,090
FY 2018	$44,765,861	$15,500,027	$60,265,888
FY 2019	$51,316,849	$16,385,400	$67,702,249
FY 2020	$49,126,204	$17,228,625	$66,354,829

Source: MDR Data as of January 5, 2021
Note: Include paid Government amounts for private sector care and full costs for the direct care.
[1/]Includes medication for ASD, ADHD, and other types of mental health diagnoses.

ACD Participating ABA Providers

Under the ACD, an authorized ABA supervisor plans, delivers, and supervises an ABA program subject to approval by the contractors. Based on reports submitted by the managed care

support contractors (MCSCs), as of September 31, 2020, there were 15,189 TRICARE-authorized ABA supervisors across both TRICARE regions (East and West), and there were 1,339 assistants and 38,010 BTs supporting authorized ABA supervisors. This totals 53,538 certified providers delivering ABA services to TRICARE beneficiaries.[4]

Impact of COVID-19 on ABA Services under the ACD

In response to the COVID-19 pandemic, TRICARE authorized an exception to the ACD policy regarding the use of telehealth (TH) capabilities for ABA services specifically during the pandemic period. Effective March 31, 2020, TRICARE authorized the unlimited use of Current Procedural Terminology (CPT) code 97156, "Family Adaptive Behavior Treatment Guidance" via only synchronous (real-time Health Insurance Portability and Accountability Act [HIPAA]-compliant two-way audio and video) TH services to beneficiaries with an authorization from the TRICARE contractors. The initial period of the exception to policy was authorized through May 31, 2020, but was subsequently extended through the end of the public health emergency.

For the fourth quarter report for FY 2020, DHA reported the monthly total number of hours rendered, as well as the average number of hours utilized per beneficiary. While overall parent engagement/participation and average number of hours increased initially during the pandemic period (25 percent in March to 46 percent in April), utilization both in beneficiary count and number of rendered hours per month for both in-person and via TH was low. The highest average utilization of the unlimited provision for parent training via TH was 4.41 hours for the month of April (approximately one hour per week). Additionally, after the initial peak utilization (April 2020), parent engagement consistently declined month after month for both in-person and TH-rendered services.

This Annual report describes ongoing analyses regarding ABA services utilization during the COVID-19 period. A total of 11,664 of 16,160 ACD users (72 percent) had parents or guardians who received family treatment guidance services (CPT 97156) during FY 2020. The use rate was slightly higher for ADFMs at 73 percent (8,855 of 12,049 users) versus 68 percent for NADFMs (2,809 of 4,111 users). Average family treatment guidance services use rates did not vary substantially across age categories but nonetheless were the lowest for children age 3 and younger (66 percent), increased to the highest level at age 5 (78 percent), and then declined to 68 percent for children age 13 and older. Family treatment guidance services represented roughly 4 percent of total ACD expenditures for FY 2020 ($15.8 million/$385.6 million). Of significance is that while 72 percent of ACD participant families had a claim filed for parent/family treatment guidance, the average annual hours utilized per beneficiary was 10.83 hours which translates to less than 1 hour per month of parent/family engagement. This low level of parent participation is concerning.

In April and May 2020, the total cost for family treatment guidance services (CPT Code 97156) increased by 173 percent and 112 percent respectively, relative to costs in 2019. In June, July, August, and September, these family treatment guidance costs were up against the baseline by 74, 63, 50, and 38 percent, respectively. For the nine-month period between January and

[4] DHA used this operational definition of two or more claims to estimate the number of beneficiaries diagnosed with ASD. Beneficiaries with only one claim are excluded because they likely would have been diagnosed w

September of 2020, family treatment guidance costs were up by 61 percent over the same nine-month period in 2019. While these are significant increases, at its peak, family treatment guidance only accounted for about 10 percent of total ACD costs in April of 2020 at $2.5M. On the other hand, costs for all other services declined in April and May of 2020. For example, one-to-one ABA services (CPT code 97153) usually accounts for roughly 80 percent or more of ACD costs ($37.3 million in January and $34.8 million in February of 2020). These costs fell by 32 percent in April and 24 percent in May relative to 2019, rebounding to a 3 percent increase in June, then declining by 6 percent in July, and 5 percent increase in both August and September. For the nine-month period of January through September of 2020, one-to-one treatment services costs decreased by 3 percent compared with 2019.

TRICARE ACD Program – Trends Since 2015-2020

The annual report provides utilization data on ACD participants on a FY basis (e.g., number of participants, annual costs, per beneficiary costs, etc.). However, this report has never reported on the entire duration of the ACD participants to date. While the ACD began July 25, 2014, the previous programs transitioned all beneficiaries to the ACD by January 1, 2015. Therefore, Tables 10 and 11 represent data on unique ACD users and their associated program costs only over the 69-month period from January 1, 2015 through September 30, 2020.

In order to analyze the data consistently, all references to age in this section refer to the age of the beneficiary at the time of their first ACD paid claim. All references to beneficiary category are also the beneficiary category at the time of their first ACD paid claim. ACD user and utilization data is presented by age, gender, beneficiary category (ADFMs and NADFMs), and whether or not the beneficiary's sponsor retired over the 69-month period examined. In total, there were 29,861 unique ACD participant users with one or more claims over the period of January 2015 through September 2020 with a total cost for all claims totaling $1,752,010,979. More than 50 percent of these users were between ages 1 and 5 at the time of their first claim and only 8 percent were ages 14 and older. More than 21 percent of the users were female and nearly 78 percent were ADFMs at the time of their first claim. More than 10 percent of beneficiary sponsors transitioned from active duty to retiree status over the 69-month period (see Table 10).

Table 10 – Distribution of the Number of ACD Beneficiary Users with Paid claims over the 69-Month Period (January 2015-September 2020)

	Unique ACD Beneficiary Users	Percentage Distribution
	All Users	
All Users	29,861	100%
Total Cost	$1,752,010,979	100%
	Ages at Time for First ACD Claim	
Ages 1-5 Years	14,953	50%
Ages 6-10 Years	9,245	31%
Ages 11-13 Years	3,213	11%
Ages 14+ Years	2,449	8%
	Gender	
Females	6,355	21%
Males	23,506	79%
	Beneficiary Category	
ADFM	23,175	78%
NADFM	6,886	23%
	Did the Beneficiary's Sponsor Retire over the Period	
Yes	3,103	10%
Did Not Retire	26,758	90%

Table 11 describes the distribution of the 29,861 ACD beneficiaries by calendar year of their first month of paid claims and the total number of months of paid claims during the 69-month period. Because new ACD beneficiaries enter the program every year, it would not be possible for all 29,861 patients to have claims for all 69 months that we examined. To date, a large portion of the ACD participants (40 percent) had claims filed for 12 months or less of ABA services. Nearly 36 percent of the users had paid claims for 25 or more months (more than 2 years), and more than 21 percent had claims for 37 or more months (more than 3 years). Nearly 12 percent of beneficiaries had claims for more than 49 months (more than 4 years), and more than 5 percent had claims for more than 61 months (more than 5 years). Only slightly more than one percent of beneficiaries had paid claims for 69 of 69 months.

Table 11 – Distribution of 29,861 Unique ACD Beneficiaries by CY of First Month of Paid Claims and Number of Months of Paid Claims over the 69-Month Period

Year of First Claim	Number of Months of Paid ACD Claims over the 69 Months							
	1-12	13-24	25-36	37-48	49-60	61-68	69	Total
	Number of Unique ACD Beneficiary Users							
CY 2015	3,107	2,348	1,768	1,486	1,545	1,254	321	11,829
CY 2016	1,195	856	685	794	387			3,917
CY 2017	1,070	823	1,033	547				3,473
CY 2018	1,431	1,571	894					3,896
CY 2019	2,646	1,562						4,208
CY 2020	2,538							2,538
All Years	11,987	7,160	4,380	2,827	1,932	1,254	321	29,861
	Percent Distribution of Unique ACD Beneficiary Users							
CY 2015	10%	8%	6%	5%	5%	4%	1%	40%
CY 2016	4%	3%	2%	3%	1%			13%
CY 2017	4%	3%	3%	2%				12%
CY 2018	5%	5%	3%					13%
CY 2019	9%	5%						14%
CY 2020	8%							8%
All Years	40%	24%	15%	9%	6%	4%	1%	100%

This data is important when considering the average number of months of rendered ABA services per beneficiary (22 months) in relation to outcome measures. Specifically, a significant number of beneficiaries do not stay in the ACD for more than 24 months; 64 percent terminated by the 2-year mark. Prior to March 23, 2021, the publication date of the revised ACD manual, two-thirds of the participants did not complete their 2-year outcome measures because they were no longer enrolled in the program. While the annual number of beneficiaries participating in the ACD continues to grow, the year-over-year retention rate is low, meaning that new beneficiaries are enrolling in the ACD while many are dropping out. This data does not account for why any beneficiary terminated services.

DISCUSSION OF THE EVIDENCE REGARDING CLINICAL IMPROVEMENT OF CHILDREN DIAGNOSED WITH ASD

While there is limited research suggesting early behavioral and developmental interventions (based on the principles of ABA services delivered in intensive and comprehensive programs) can significantly affect the development of some children diagnosed with ASD, not all children diagnosed with ASD receiving ABA services show improvements. Two well-respected medical literature review services (external to DHA) continue to find the evidence for ABA services (Intensive Behavior Intervention) for the diagnosis of ASD is weak, noting, "[a]n overall low-quality body of evidence mainly from poor-quality studies suggests that Intensive Behavior Intervention (IBI) improves intelligence or cognitive skills, visual-spatial skills, language skills, and adaptive behavior compared with baseline levels or other treatments." Six years after the DHA's extensive June 2013 ABA coverage review, the published reliable "evidence does not reflect any consensus as to whether the reported improvements are clinically significant; very few studies reported on the clinical significance of findings. A paucity of evidence regarding the durability of treatment following treatment cessation, as well as uncertainty regarding optimal therapy parameters, preclude firm conclusions regarding the efficacy of IBI for ASD"[5]. The 2020 Hayes, Inc. update reported no change in the current rating. Another study noted, "The strength of the evidence in this review is limited because it mostly comes from small studies that are not of the optimum design. Due to the inclusion of nonrandomized studies, there is a high risk of bias and we rated the overall quality of evidence as 'low' or 'very low' using the GRADE system, meaning further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. [6]"

The research literature available regarding ABA services predominantly consists of single-case design studies, which does not meet criteria for "reliable evidence" under TRICARE standards.[7] There are still methodological concerns limiting the strength of the research such as identified characteristics of children (including symptom severity), rendering providers, and types of treatment for positive outcomes. These limitations include: "dose-response" (frequency, intensity, and duration), treatment fidelity, few studies which use a control group, few longitudinal studies which demonstrate long-term effectiveness, and no replication of similar results in well-designed studies.

Currently, there are no defined ASD treatment Standards of Care (SoC). Practice parameters have been developed by various interest groups, to include the clinical report from the American Academy of Pediatrics (2020)[8], to guide the assessment, diagnosis, and treatment of

[5] Hayes, Inc. (2019) Comparative Effectiveness Review: Intensive Behavioral Intervention for Treatment of Autism Spectrum Disorder

[6] Reichow B, Hume K, Barton EE, Boyd BA. Early intensive behavioral intervention (EIBI) for young children with autism spectrum disorders (ASD). *Cochrane Database of Systematic Reviews* 2018, Issue 5. Art. No.: CD009260. DOI:10.1002/14651858.CD009260.pub3

[7] Title 32, Code of Federal Regulations, part 199.2 (32 CFR 199.2) Definitions: "Reliable Evidence"

[8] Hyman, S., Levy, S., and Myers, S. (2020). Identification, Evaluation, and Management of Children with Autism Spectrum Disorder, PEDIATRICS Volume 145, number 1.

ASD. However, research has not been able to demonstrate effective and consistent results to identify a clear SoC for the treatment of ASD. No single intervention has been proven beneficial across all core symptoms of ASD. Consensus among recognized national organizations endorses the use of a comprehensive program that includes PT, OT, SLP, as well as ABA services, all targeted at deficits in the areas of: social communication, language, play skills, maladaptive function/behaviors, and ongoing parent education. Research demonstrates that ABA services produce the best results for targeted maladaptive behavior, and the strongest intervention evidence appears to be for parent training and support, noting that parental involvement is a fundamental component of effective ASD intervention.[9]

The Department continues to support evaluations into the nature and effectiveness of ABA services under the TRICARE program. The TOM Change 199, [10] implemented norm-referenced, valid, and reliable outcome measures; the data collection began on January 1, 2017. That change added three outcome measures as required under the ACD that are collecting data: the Vineland Adaptive Behavior Scale – Third Edition (Vineland-3) which is a measure of adaptive behavior functioning; the Social Responsiveness Scale, Second Edition (SRS-2) which is a measure of social impairment associated with ASD; and the Pervasive Developmental Disorder Behavior Inventory (PDDBI), which is a measure designed to assist in the assessment of various domains related to ASD. Additionally, the PDDBI is a measure designed to assess the effectiveness of treatments for children with pervasive developmental disorders, including ASD, in terms of Response to Interventions. The outcome measure scores are completed and submitted to the MCSCs by eligible providers authorized under the ACD. As of the time of this report, data collected for the Vineland-3 and SRS-2 are required at baseline and every two years, and the PDDBI is required at baseline and every six months. In order to not impede access to ABA services, the Vineland-3 and the SRS-2 were given a one-year period to be completed.

ACD Outcome Measures

This report includes a comprehensive analysis of all beneficiaries who participated in the ACD during the period from January 1, 2018 to December 31, 2020. The Department has published several previous reports with findings from the available records of PDDBI scores. Initial findings demonstrate that overall, the majority of beneficiaries experienced little to no change in symptom presentation based on parent/guardian report. Additionally, a small percentage of beneficiaries were noted as having worsening symptoms and a similar small percentage demonstrated symptom improvement. The DHA also noted that these findings should be interpreted with caution as the PDDBI is just one metric of several collected and reported. Caution should be used in those initial reports as there were no other factors considered in those summaries such as age, symptom severity, number of hours of services, total duration of ABA services, other services, academic placement, etc. While the Department continues to receive criticisms on the use and analysis of the PDDBI, the DHA is confident that the data and its analyses accurately represent the ACD data. This report will address many of the recently highlighted concerns.

[9] National Research Council. (2001). Educating Children with Autism. Washington, DC: The National Academies Press. https://doi.org/10.17226/10017

[10] https://manuals.health.mil/pages/DisplayManualFile.aspx?Manual=TO08&Date=2016-11-29&Type=AsOf&Filename=C18S18.pdf

Additionally, this Annual report presents, for the first time, findings from the Vineland-3 and SRS-2 administrations.

It is important to begin with an understanding of the TRICARE population reported in these analyses, to include how the data is collected and submitted to the DHA, and who is included/excluded in this analysis. Every TRICARE beneficiary participating in the ACD is required to complete outcome measures. Applicable age ranges vary for each measure, so not all beneficiaries are required to complete all measures at their respective intervals (Vineland-3 = birth to 90 years; SRS-2 = 2.5 to 99 years; the PDDBI = 1.5 to 18.5 years). These outcome measures may be administered by a variety of TRICARE-authorized providers, i.e., an ASD diagnosing provider or a BCBA, who are responsible for scoring and submitting valid assessments to the MCSCs. The MCSCs consolidate the provider-submitted data and then submit the consolidated data to DHA for analysis. Neither the MCSCs nor the DHA administers, scores, or interprets the data for each beneficiary. Rather, the DHA completes an observational analysis on the population sample in attempts to answer the question: "is ABA effective for the DoD beneficiary population diagnosed with ASD participating in the ACD as a whole."

Data submitted to DHA by the MCSCs includes data on every unique beneficiary who participated in the ACD during this three-year period (January 2018 – December 2020). A total of 21,934 unique beneficiaries participated in the ACD during this time. In reviewing the submitted composite scores, DHA found that 97.4 percent of beneficiaries in the data set had at least one PDDBI Parent Autism Composite score (PACS), 60.7 percent had at least one Vineland-3 Adaptive Behavior Composite (ABC) score, and 51.4 percent had at least one SRS-2 Total score. The composite scores selected for reporting as ABA services authorized under the ACD are for the clinically-necessary and appropriate services related to the core symptoms of ASD (i.e., impairments in social communication and restrictive, repetitive behaviors). Goals that target non-core symptoms of ASD, e.g., the use of mass transit, job interview skills, or folding laundry, are not authorized under the ACD, as those skills are not clinically/medically appropriate.

In defining a sample population, the DHA identified the following inclusion criteria for this analysis:

1. Beneficiaries who had all three outcome measures at baseline and following two years (24 consecutive months) of rendered ABA services;
2. Scores for beneficiaries within the age ranges for the respective measures (narrowed to the most conservative range to include a consistent population: 2.5-18.5 years); and
3. Valid composite scores were submitted (scores that were excluded fell outside of the possible score range, i.e., 6560 on the PDDBI, 710 on the Vineland-3, and 7473 on the SRS-2)

Additionally, beneficiaries were eliminated based on beneficiary identifying information that changed during the review period, e.g., name change (n=52) or beneficiary identifying number change (n=13). As a result, only 341 beneficiaries met the narrow inclusion criteria. Since this number represents 1.5 percent of the total possible beneficiary data submitted, analyses and conclusions would be limited. Subsequently, the DHA expanded the criteria to include all beneficiaries with at least two administrations of each outcome measure where the PDDBI had a

PACS baseline score and a score after two consecutive years of rendered ABA services, while the Vineland-3 and the SRS-2 had two scores at any point over the two year period. This modification resulted in a sample size of 1,214 (females = 251; males = 963). This means that the Vineland-3 and the SRS-2 had two scores where analyses could be conducted. However, since these measures were not administered at the same time during the period, subsequent analyses were limited.

The following histograms (Figures 4-6) represent each measure's initial point score distribution for the sample of 1,214 beneficiaries. These histograms describe initial point scores of the TRICARE population of beneficiaries diagnosed with ASD participating in the ACD. Specifically, these histograms display a normal distribution of scores with 68 percent of the population falling between one standard deviation above and below the mean for each measure. For example, for the PDDBI PACS (Figure 4), 68 percent of the scores fall between 43.02 and 67.87; for the Vineland-3 ABC score (Figure 5), 68 percent of the scores fall between 53.28 and 82.81; and for the SRS-2 Total score (Figure 6), 68 percent of the scores fall between 64.83 and 89.17.

Figure 4 – PDDBI: Initial PACS Point Score Distribution (n=1,214)

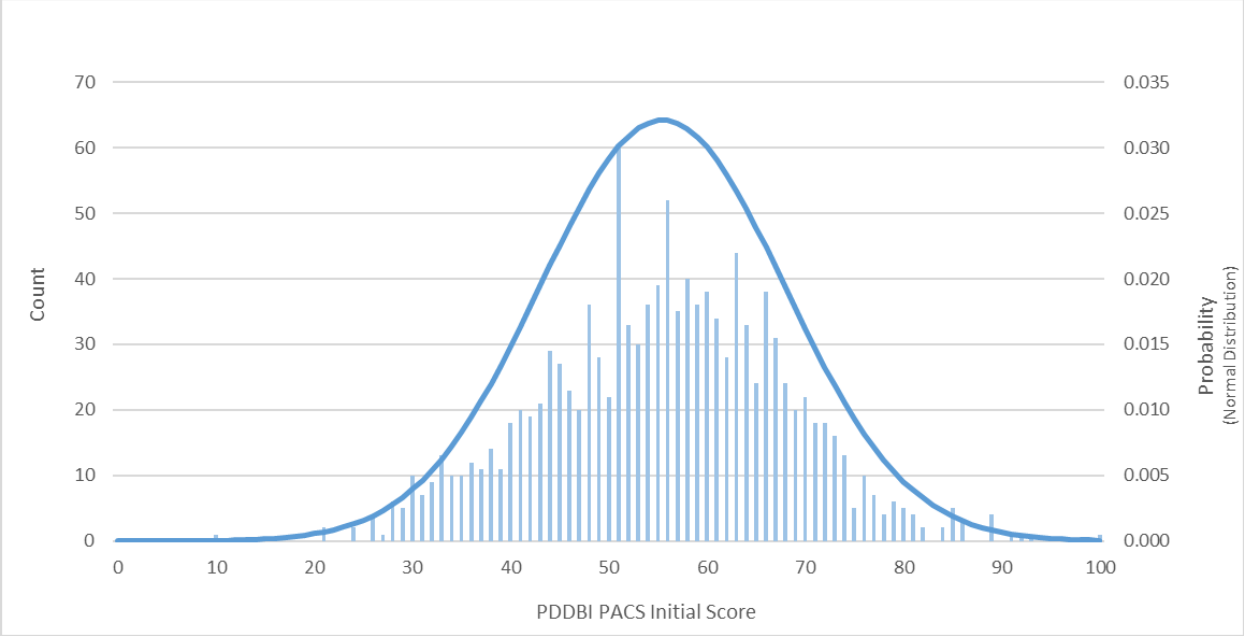


Figure 5 – Vineland-3: Initial ABC Point Score Distribution (n=1,214)

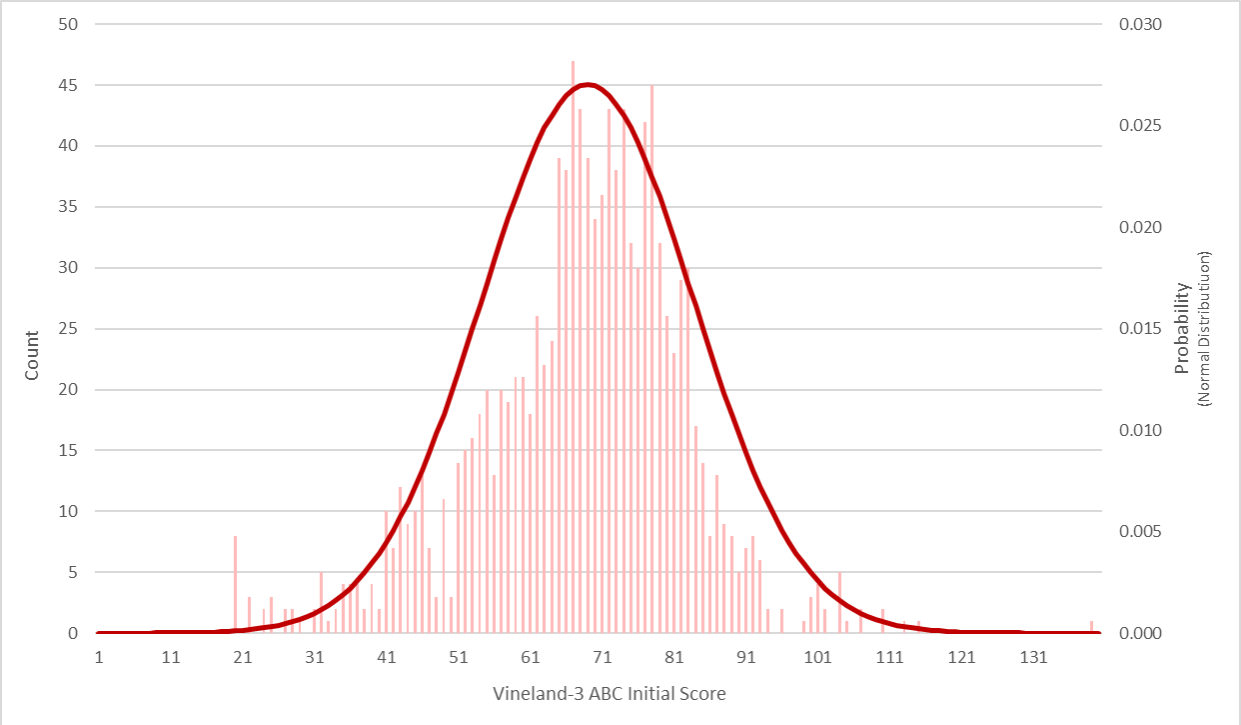
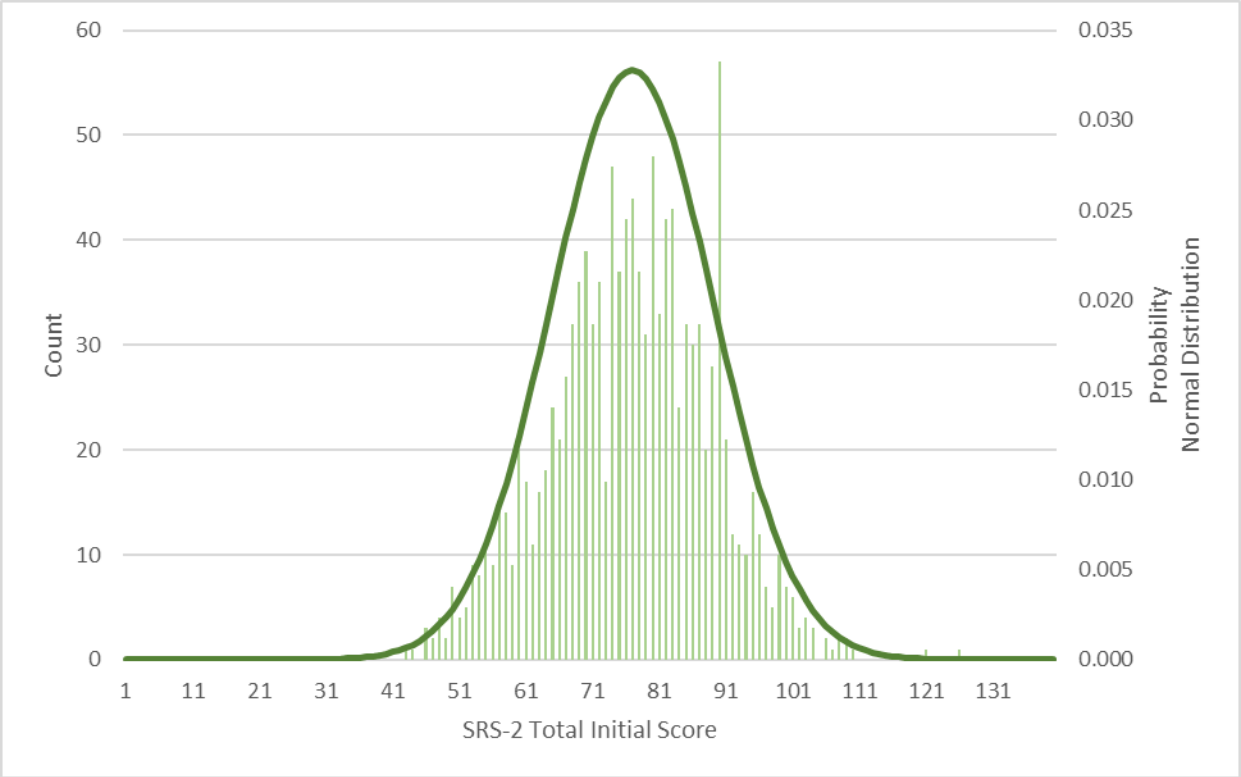
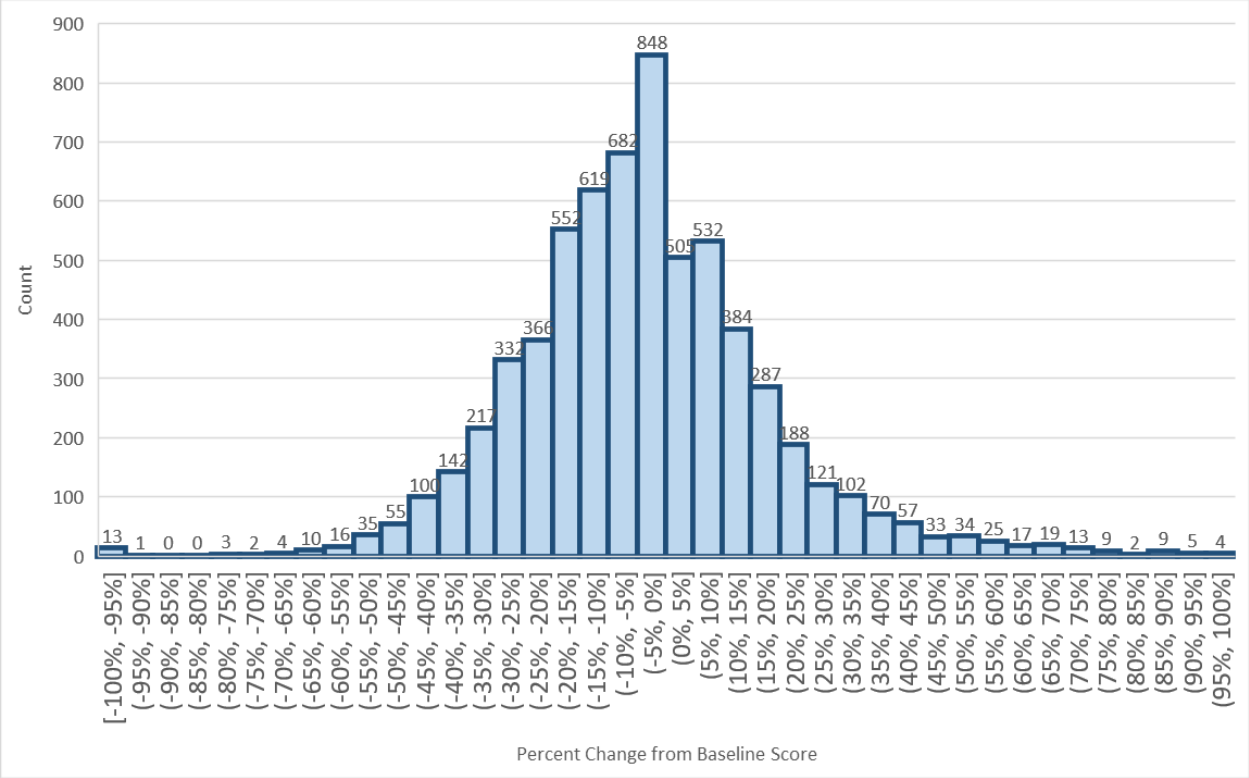


Figure 6 – SRS-2 Initial Total Score Point Score Distribution (n=1,214)



Since the PDDBI PACS administrations met the original inclusion criteria (baseline and following two years of ABA services), additional analyses were completed for a sample size of 6,413 (females = 1,353; males = 5,060), excluding the criteria for two Vineland-3 and SRS-2 scores. Figure 7 depicts the PDDBI percent change in PACS distribution. A one-tailed paired sample t test was applied to the data. This test determined whether there is a statistical difference in means for PDDBI point scores, before and after two years of ABA services, which is less than zero. The "p value" of the paired t test for the percent difference in PDDBI PACS is zero (p=0.00). The evidence suggests that the true change is less than zero, which indicates overall improvement. Said another way, there is statistical evidence to suggest that the true difference between the mean PDDBI PACS point scores is less than zero, indicating improvements in the PACS. However, statistical significance does not equate to clinical significance. Additional analyses would be required to address that question.

Figure 7– PDDBI Percent Change (PACS) Score Distribution (n=6,413)



The DHA also conducted a one-way Analysis of Variance (ANOVA) test to evaluate differences in the percent change in PDDBI PACS between age groups. This ANOVA test determines whether there is a statistically significant difference in the average percent change in PDDBI PACS between age groups. Because the analyses obtained a p value (p=0.16) that was greater than the alpha value of 0.05, the results did not indicate enough evidence to reject the null hypothesis; none of the age groups had a statistically significant difference in percent change scores in the PDDBI PACS. However, from the analysis results, it is important to note that the age group of 2 to 5 years had the largest mean percent change scores in the PDDBI PACS than the other 3 age groups (6-9, 10-13, and 14-18) with a mean value of -7.53 percent compared to -3.34 percent, -2.97 percent, and 3.86 percent.

The next analysis completed was a Multiple Linear Regression (MLR) model that considers the effects of more than one explanatory variable on an outcome of interest. This analysis considers the effects of age and hours of rendered ABA services on the percent change from baseline PDDBI PACS. Specifically, the model evaluates whether there is an association between the response variable (the percent change score), and the explanatory variables in the model (age and total hours rendered). The assumptions of an MLR are: the true relationship is linear, the errors are normally distributed, there is homoscedasticity of errors, and each observation is independent. A plot of the residuals for the hours rendered variable indicated minor heteroscedasticity. This heteroscedasticity will result in smaller p-values in the regression model results for the influence of the hours rendered variable on percent change in PDDBI PACS. However, it will not affect the coefficients produced in the model for the impact of the hours rendered variable on the outcome. Future analyses should be conducted to evaluate the true impact of the hours rendered variable and to determine a more accurate picture of the statistical association of hours rendered on the PDDBI PACS outcome. For the time being, the preliminary results are as follows:

The regression equation in this MLR is: $Y_i = -0.097 + 0.005*x_i1 + 0.00005*x_i2$. The p-values corresponding to the explanatory variables "age and hours rendered" indicate that there is a statistically significant association between percent change in PDDBI PACS and each of these explanatory variables. Because the coefficients of both explanatory variables are positive, this indicates that a higher age or higher number of hours rendered will predict worse PDDBI PACS percent change outcomes. Said another way, the younger beneficiaries are more likely to have a negative percent PACS change (meaning more improvement), compared to older ages if they received the same number of rendered ABA services hours. Additionally, more hours does not yield better outcomes.

For example, if a 2-year-old and an 18-year-old receive 1,000 hours of ABA services (over the two-year period), it is predicted that the 2-year-old will obtain a -3.7 percent change in PDDBI PACS indicating symptom improvement, while the 18-year-old will obtain a 4.3 percent change in PDDBI PACS indicating worsening of symptoms. In summary, this model indicated that the younger beneficiary is likely to experience improvement while the older beneficiary is likely to experience worsening of symptoms for the same number of hours. For example, if a 2-year-old received 1,000 hours versus 4,000 hours of ABA services over the two-year period, it is predicted that the beneficiary who receives 1,000 hours will obtain a percent change score of -3.7 percent (symptom improvement) while the beneficiary who receives 4,000 hours will obtain a percent change score of 11.3 percent (symptom worsening). In this example, more hours did not predict better outcomes. Further analysis is required to support this hypothesis.

The following box plot (Figure 8) displays the average percent change in PDDBI PACS by initial severity group (all age groups combined). All severity groups with scores of 50 and above demonstrated statistically significant change on the PDDBI PACS. However, those beneficiaries with the most severe baseline scores (80-100) demonstrated the greatest change in PDDBI score after 2 years of ABA services. Additionally, scores 49 and below demonstrated worsening of symptoms compared to baseline scores. While slight percent differences occurred between age groups, the general trend remained constant. Although the PDDBI is not a diagnostic tool, the

research findings suggest that scores lower than 40 may indicate very mild features of ASD or may not be indicative of a diagnosis of ASD. It is unclear if ABA services were the change agent impacting these percent score changes or if another variable, or combination of variables, created the change. Additionally, it is unclear if any of the changes observed are of clinical significance.

Figure 8 – Average Percent Change in PDDBI PACS by Initial Severity Group after 2 Years of ABA Services

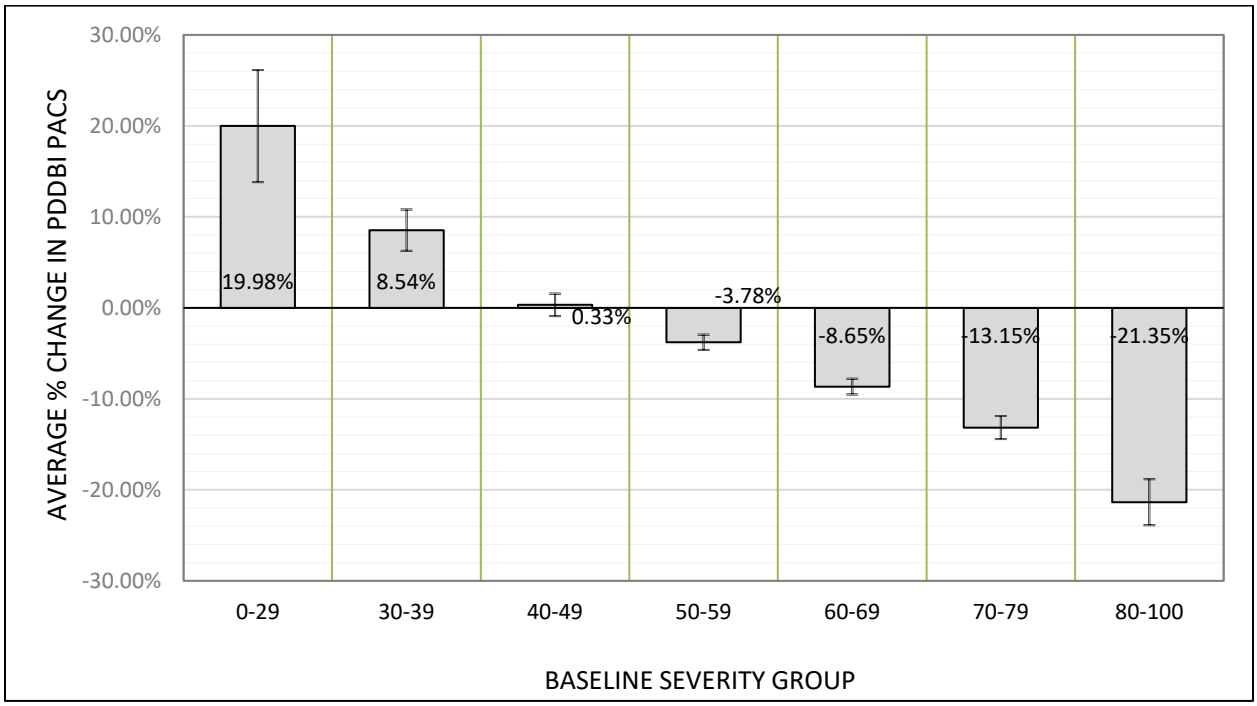


Figure 9 depicts the percent change in baseline PDDBI PACS compared to the total number of hours of rendered ABA services over the two-year (24 Month) period. This number is the total number of direct one-to-one hours of paid claims for Category I CPT code 97153 (Adaptive Behavior Treatment by Protocol). While the trend lines remain relatively flat for all age groups, only the trend line for the youngest age group (2-5 year olds) stayed below zero, suggesting that the youngest group saw more improvement compared to the other age groups. An increase in the number of ABA hours rendered did not appear to positively impact the average outcome scores over the two-year period. In other words, increasing the number of hours rendered to a participant does not appear to create improvements in outcomes. Additionally, despite there being a small change in PDDBI PACS, this analysis cannot directly attribute hours of ABA services provided under the ACD to the improvement, as this is not a research study but rather an observational analysis of a population sample. All other age and severity groups had trend lines that were above or crossed the line of zero suggesting no improvement or worsening of symptoms.

Table 12 displays a summary table of age groups by severity that demonstrated overall improvement in the entire group. All ages for the severity groups of 70 or higher had trend lines that stayed below zero suggesting that on average, participants in each group demonstrated improvements in PDDBI PACS. Additionally, for the youngest age group (2-5 year olds), severity groups of 50-59 and 60-69 also had trend lines that stayed below zero.

Figure 9 – PDDBI PACS Percent Change by Age Group vs Total Hours of Rendered ABA Services after 24 Months (All Age Groups)

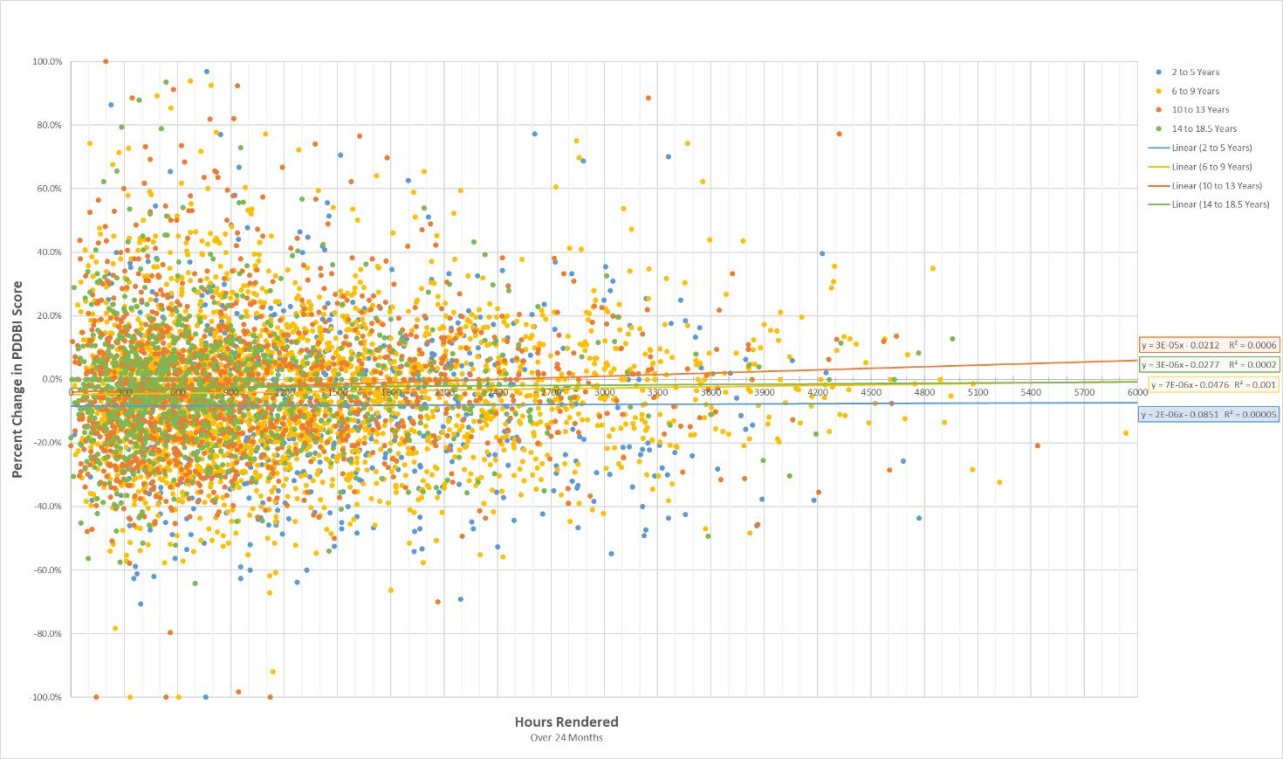


Table 12 - Percent Change in PDDBI PACS Based on Age Group and Baseline Severity after 24 Months of ABA Services

		Age Groups			
		2-5 Years	6-9 Years	10-13 Years	14-18 Years
Severity Groups	0-29				
	30-39				
	40-49				
	50-59	X			
	60-69	X			
	70-79	X	X	X	X
	80-100	X	X	X	X

Summary of ACD Outcome Measures Analysis

Overall, the findings from this analysis demonstrate that some beneficiaries demonstrate some improvement of symptoms associated with ASD as indicated by statistical significance; however, clinical significance is yet to be determined. Alternatively, other beneficiaries show no improvement or even worsening of symptoms over the two-year period. Based on the PDDBI PACS (n=6,413), 57 percent of the beneficiaries saw improvement while 43 percent saw no improvement or worsening of symptoms. Additionally, based on Table 12, those 10 groups (age

and severity) make up approximately 18 percent of the beneficiary population who as a group overall made improvements. Their consistent improvement in these groups is important to note. While younger children and beneficiaries with more severe symptoms make greater gains than older beneficiaries or beneficiaries with mild or no symptoms of ASD, there is still much to learn about which groups of beneficiaries are most likely to demonstrate improvements, and under what circumstances. Although this group was small in number (n=60), it is promising that even though gains were small, all 2-5 year old beneficiaries with baseline severity in the 80-100 range demonstrated symptom improvement. The MLR also provides an indication that younger beneficiaries are more likely to see greater gains than older beneficiaries, and that an increase in the number of rendered hours did not result in greater symptom improvement. However, further analysis is required to support whether or not increasing hours has a positive treatment effect.

There is still the question of whether the changes are clinically significant. In addition, there is no comparison group (no treatment or another type of treatment) to determine whether the change score is associated with ABA services or other treatments received. As a result, there is no way to know if the relatively small change observed is the result of ABA services or another variable. Additionally, it is important to note that there is still no industry standards for "dose-response" regarding expected changes for any group of beneficiaries receiving ABA services.

There were several challenges and limitations with the available data set. While there were over 21,000 beneficiaries who had claims filed during this three-year period, only 30 percent of beneficiaries continued in the program for at least 24 months, and completed all three outcome measures as expected. The provision to allow a one-year period from initial diagnosis in order to obtain a Vineland-3 and SRS-2 score was intended to not delay the initiation of ABA services. However, this provision resulted in significant impairments in the ability to capture accurate initial data. As noted above, a possible 6,413 beneficiaries completed 24 months of ABA services and completed PDDBI PACS at baseline and after two years of services. Ideally, there should have also been as many administrations of the Vineland-3 and SRS-2. However, the MCSCs provided two Vineland-3 ABC scores for only 3,159 and two SRS-2 Total scores for only 1,889 beneficiaries. Additionally, these scores were not administered with any consistency at baseline or within the one-year period. Therefore, these administrations pose challenges for comparison analyses. This limitation has been corrected in the recently published TRICARE policy update (TOM Change 85)[11] that will require the measures to be completed at baseline, prior to initiating treatment, and also completing the measures annually vice every two years. The TRICARE policy update also revised the requirement to allow specific authorized providers, who possess the competency to administer the measure, to complete the outcome measure without delays in completion as well as without delays in access to ABA services.

As mentioned above, the composite scores were selected as comprehensive measures that assess the core symptoms of ASD. Treatment under the ACD is authorized for only clinically necessary and appropriate services targeting the core symptoms of ASD. As noted in recent critiques regarding DHA's reporting of the analyses of outcome measures, some beneficiaries' treatment plans may not be targeting core symptoms of ASD, therefore their scores may not reflect their individual progress. However, those targets are not appropriate for the ACD. Additionally,

[11] https://manuals.health.mil/pages/DisplayManualHtmlFile/2021-03-23/AsOf/TO15/C18S4.html

while domain scores may provide additional information regarding specific areas relating to the core symptoms of ASD, those domain scores do not present an entire picture of the beneficiary's functioning. While the DHA will conduct sample analyses of domain scores in the future, ABA providers should incorporate that data into the beneficiary's treatment plans. Lastly, while this data set did not account for which parent completed both administrations, there is no requirement in the literature, nor in the PDDBI manual that mandates that the same parent respond to both administrations. In efforts to address the possibility that different respondents report their observations differently, the recently published TRICARE policy update will now facilitate collection of respondent data.

With the newly published policy update, the DHA has already taken steps to improve data collection and reporting as well as treatment plan oversight and engagement. These improvements to the manual engage beneficiaries and providers earlier and more consistently to address any lack of progress or issues in the overall treatment. With this update, the DHA will be able to conduct more thorough analyses of TRICARE beneficiaries' clinical longitudinal improvement, or lack thereof. While recognizing the limitations of the existing data, the Department remains very concerned about the findings that a) almost half of the participants are experiencing no change or worsening symptoms after two years of ABA services, and b) for any beneficiary who saw improvement, was the improvement clinically significant. The DHA is committed to ensuring that all beneficiaries in the ACD reach their maximum potential through the most appropriate and effective services.

Congressionally Directed Medical Research Program (CDMRP) Study

To acquire additional information on ABA services under TRICARE, DHA worked with the CDMRP to award a contract to a research group to study ABA service delivery models. The CDMRP study was awarded to a research group from the University of Rochester in September 2018. Results from their second annual report noted that this study, titled "Comparative Effectiveness of Early Intensive Behavioral Intervention and Adaptive ABA for Children with Autism in TRICARE", was impacted by COVID-19 and had significant challenges specifically related to recruitment of eligible beneficiaries. Despite these challenges, the researchers have expanded recruitment efforts to include expanding locations for participant access. Additional information is available at: https://clinicaltrials.gov/ct2/show/study/NCT04078061. It is anticipated that the results of the CDMRP study will not only further DHA's understanding of the impact of ABA services delivered to ACD participants, but that findings from this study may also benefit the larger community of individuals diagnosed with ASD and their families in several ways, including but not limited to, offering more choices to families, potentially identifying response to treatment through predictive factors, and lowering cost while increasing access.

LESSONS LEARNED

Since implementation of the ACD in July 2014, the Department has conducted 20+ ACD round table and provider information session events. These events were well attended, and senior Department officials listened to concerns, answered questions, and noted key issues for further analysis and action. The most recent ABA stakeholder webinars focused on the recently published TRICARE policy updates, providing focused reviews and summaries of the revisions and how

they impact beneficiaries, their families, and providers. The DHA representatives have also presented at several behavior analytic annual conferences on medical records documentation and other issues related to the ACD, and have met with numerous experts in the field of autism care. The DHA received constructive feedback from each event from interested stakeholders. The DHA appreciates the participation of all interested parties and, through this process, gained additional insights about how to further refine and implement an optimum care delivery and reimbursement system for TRICARE beneficiaries diagnosed with ASD. Communication continues with stakeholders and is crucial to the successful implementation of the policy revisions underway.

Continuous Improvement

The DHA is committed to ensuring all TRICARE-eligible beneficiaries diagnosed with ASD reach their maximum potential, and that all treatment and services provided support this goal. TRICARE continues to have one of the most robust ABA benefits nationwide, which is one component of comprehensive treatment for ASD. However, currently there are no clear guidelines or industry standards of care available with regards to "dose-response" or expected outcomes for an individual beneficiary as a result of ABA services.

Since the beginning of the ACD, the DHA has made significant improvements to the program, such as increased access, implementation of audits in response to the Department of Defense Office of Inspector General audits, and collection and evaluation of outcomes measures. Additionally, the DHA has worked with experts in the field of autism care, within and external to the MHS, including ABA providers, advocates, MHS providers, commercial and Medicaid plans, and leading researchers to develop a comprehensive revision of the ACD.

The comprehensive review of the ACD, published March 23, 2021, evolves the program to a more beneficiary- and family-centric model. These revisions focus on not only improving the quality, value, and access to care and services for beneficiaries diagnosed with ASD and their families, but also improving the management and accountability of both the MCSCs and the ABA providers. These revisions have been informed by a review of the data collected in the program, ongoing reviews of research evidence into the treatment of ASD, and discussions with experts in the field of autism care. These revisions focus on providing enhanced beneficiary and family support, improving outcomes, encouraging parental involvement, improving utilization management controls, and revising coverage of ABS for the delivery of ABA services to TRICARE eligible beneficiaries diagnosed with ASD. Major areas of improvement and program revisions include:

- Specialized care managers/coordinators, or Autism Services Navigator (ASN), are assigned to each new beneficiary and family enrolling in the ACD. This ASN will ensure families receive accurate, timely information about treatment and service options, and will work with the family and providers to manage the beneficiary's care.
- Increased parental involvement and support. Available research notes that outcomes are better when parents are actively involved. Evidence suggests that family support is the

most effective modality for the treatment of ASD. Additionally, more supports by way of resources and services will be provided to all families in the ACD.

- Increased utilization management (UM). The TRICARE policy update implements UM solutions that consistently review impairments, level of functioning, and treatment goals and protocols using standardized outcomes measures when possible/appropriate to ensure the needs of the beneficiary and family are being met.
- Revision of coverage of ABS CPT Codes.
- Other revisions include improvements to the diagnosing requirements, inclusion of a parent stress measure, improved audit requirements, and ABA provider education and training of the ACD and the TRICARE benefit.

Department of Defense Ongoing Efforts to Eliminate Fraud, Waste, and Abuse in the ACD

The Department continues to be concerned regarding the improper billing and improper payments for ABA services, which undermine the integrity of the ACD program. The Program Integrity offices and the Department of Justice continue to identify ABA providers/practices in their reviews. DoD has seen an increase in the number of ABA cases being investigated (see Table 13 for the number of cases).

Table 13 – Number of ABA Cases under DoD Investigation by Calendar Year

Calendar Year	Number of ABA Cases
2008	1
2009	2
2010	0
2011	1
2012	4
2013	8
2014	7
2015	4
2016	5
2017	16
2018	8
2019	16
2020	41
Total	113*
* To date as of 3/15/2021	

For the period of 2008 to 2020, the total value in civil settlements for ABA services to the DHA during this period is $9,014,038. In addition to the amounts above, the DHA has recouped $2,011,874 for improperly billed ABA services for this same period. Some of the findings that led to these actions include: services billed to TRICARE that were never rendered to a beneficiary, falsification of medical records, and falsification of non-medical care as medical care (e.g., day care, transportation).

The Department continues to evaluate the oversight and monitoring of billing and payment activities of the ABA providers/practices via the contractor audit requirements. The recently published policy update revised the audit requirements to increase compliance and to reduce potential fraud, waste, and abuse via more comprehensive oversight prior to treatment plan authorization, as well as improved post claims payment audits.

LEGISLATIVE AUTHORITIES REQUIRED TO IMPROVE THE PROVISION OF ABA SERVICES

There continues to be advocacy from TRICARE beneficiaries and their families, advocacy groups, legislators, and others, for the Department to expand coverage of ABA services. Such TRICARE coverage expansions, however, are not discretionary. TRICARE Basic Program benefit coverage determinations must be based solely on the hierarchy of "reliable evidence" defined in federal regulation.[12]

As of now, ABA services do not meet the TRICARE hierarchy of evidence standard for medical and proven care. The Department continues to review the latest evidence in published literature regarding the effectiveness of ABA services for the diagnosis of ASD. At this time, no significant additions to the evidence-based literature have been published since the last annual report regarding the "dose-response" (including intensity, frequency, or duration), treatment effectiveness, most effective use of ABA with other services, use of tiered model compared to BCBAs only, benchmarks for outcomes, or anticipated/expected changes in ASD symptom presentation.

CONCLUSION

The ACD provides TRICARE reimbursement for ABA services delivered to TRICARE-eligible beneficiaries diagnosed with ASD. At the end of FY 2020, there was a total of 16,160 beneficiaries with a diagnosis of ASD participating in the ACD with a cost of $385.6M and with an additional $66M in other medical services. Of the total ACD participants, 3,708 beneficiaries (22.9 percent) exceeded the $36,000 threshold for annual expenditures with 325 beneficiaries (2 percent) exceeding $100,000 in annual expenditures. ACD participation by beneficiary demographics reveal that 86.0 percent of ACD participants are age 13 years and younger, that the median age is 7 years, and that roughly 4 out of 5 ACD participants are male. There were 53,538 ABA providers rendering ABA services to TRICARE beneficiaries for approximately a 3:1 ratio of ABA providers to ACD beneficiaries.

Also included in this report is an initial review of the entire ACD enrollment since its inception. During the 69-month period, 29,861 beneficiaries diagnosed with ASD have claims filed for ABA services with a total cost of $1,752,010,979. Fifty percent of the participants first enrolled in the ACD when they were between the ages of 1 and 5 years. While the average number of months of rendered ABA services was 22 months, 40 percent of participants obtained ABA services for 12 months or less, and 20 percent have received ABA service for more than three years.

[12] Title 32, Code of Federal Regulations, part 199.2 (32 CFR 199.2) Definitions: "Reliable Evidence"

The COVID-19 pandemic began during this FY and had significant implications for health care delivery nationally and as it relates to the TRICARE benefit. Among the many revisions that the TRICARE benefit implemented during this period, included was the exception to policy provision to authorize the unlimited use of parent/caregiver training and guidance. While there was an increase in the utilization of this specific CPT code compared to other months in 2020 and compared to other years, utilization (or parent engagement) remains low overall. During the peak month of utilization, 46 percent of families used 4.41 hours on average of parent/caregiver training. This number is unexpectedly low as the DHA anticipated that parents and caregivers would require additional support during the peak period when social distancing orders were in place. The DHA does not expect parents to take on the role of the sole treating provider, but rather use the provision to gain knowledge and skills about how to help beneficiaries maintain and generalize skills during this period and for the future.

The COVID-19 pandemic also impacted recruitment efforts for the ongoing CDMRP contract award. Nonetheless, researchers continue to make progress and have expanded recruitment to include additional locations for participant access. Ongoing updates will be provided in the next ACD Annual Report.

Previous analyses yielded concerning results regarding treatment outcomes based on the scores reported in the Parent Form of the PDDBI. As a result of those findings and feedback from stakeholders about the analysis of the PDDBI, this report included initial observational findings from additional outcome measures, the Vineland-3 and the SRS-2, and further analyses on the PDDBI. Due to data collection limitations, this report was able to analyze only initial outcomes data for the Vineland-3 and the SRS-2 for 1,214 beneficiaries. An analysis of the impact of treatment was not conducted due to not having two consistent time periods of reported scores. However, the reported data provides an initial picture of symptom presentation of the TRICARE beneficiary population participating in the ACD as seen by their initial composite scores (indicating severity). While the ability to make conclusions are limited, the DHA now has three outcome measures providing information on the ACD population . The limitations experienced in this analysis have been addressed with the recently published TRICARE policy update that revised the outcome measures requirements for administration and submission. Future reports will further explore the three measures in light of those revisions.

Since there were limitations in analyzing three outcome measures, the DHA conducted more detailed analyses with the PDDBI PACS data. Out of the 21,934 unique beneficiaries that had claims filed during the three-year period, only 6,413 had baseline and post-two years of ABA services PACS data submitted. As noted above, the composite scores were selected as comprehensive measures that assess the response to treatment for the core symptoms of ASD. Treatment under the ACD is authorized for only clinically necessary and appropriate services targeting the core symptoms of ASD. While domain scores may provide additional information regarding specific areas, those scores may be most beneficial when incorporated into decision making for treatment plan goals. The DHA's analysis is targeted at understanding effective treatment for the population served under the ACD. As ABA services are currently considered not to be proven medical care, the DHA is attempting to glean information about beneficiaries most likely to benefit from ABA services as well as the most effective delivery method because the ABA research literature has yet to define dose-response recommendations for best outcomes.

The findings from this analysis demonstrate that some beneficiaries have made some statistically significant improvements (57 percent), while other beneficiaries show no improvement or even worsening of symptoms (43 percent) over the two-year period. However, clinical significance is still unknown. Specifically, as evidenced by the MLR, younger beneficiaries are more likely to see greater gains than older beneficiaries and that an increase in the number of rendered hours did not result in greater symptom improvement. However, further analysis is required to support this hypothesis. It is promising to note that even though gains were small, that all 2-5 year old beneficiaries with baseline severity in the 80-100 range had greater and consistent percentage gains in symptom improvement. However, this sample size (n=60) is small and therefore further analysis is required.

The DHA's report of the findings based on the three outcomes measures does not constitute experimental research, but rather an observational analysis of the TRICARE population. This data analysis does not control for all possible variables (i.e., treatment techniques, treatment goals, treatment fidelity, parent characteristics, etc.), as this is not a research study. However, this analysis included variables such as age, baseline severity, and number of treatment hours over the course of two years. Data to date does not describe an entire population that is improving as a whole. Additional analyses will be required to further explore additional details of which beneficiaries make the most change as well as what might be considered clinically significant changes.

A continued concern with this program is the ongoing fraud, waste, and abuse by ABA providers and the improper billing and payments for ABA services. Government offices continue to identify improper activities by TRICARE ABA providers and practices that has resulted in millions of dollars of restitution, settlements, and recoupments. The revisions to the manual implement improved oversight and auditing systems with the goal of reducing the number of fraud, waste, and abuse activities, and improve the integrity of the ACD.

Recently published revisions to the ACD policy aim to provide enhanced beneficiary and family support, improve outcomes, encourage parental involvement, and improve utilization management controls. These updates include the expansion of coverage of certain ABS CPT Codes for the delivery of ABA services to TRICARE eligible beneficiaries diagnosed with ASD. These comprehensive revisions move the program to a more beneficiary- and family-centric model. The Department hosted a series of webinars to educate stakeholders on the revisions. The ACD policy update will roll out over a 270-day phased implementation plan.

The Department is committed to ensuring all TRICARE-eligible beneficiaries diagnosed with ASD reach their maximum potential, and that all treatment and services provided support this goal. TRICARE continues to be the most robust ABA benefit nationwide, as some commercial plans still have age, dollar, and duration limits. TRICARE is leading the Nation in developing an effective ABA program model as one component of comprehensive treatment for ASD. The Department fully supports the continued research on the nature and effectiveness of ABA services, and the evolution of the field from an educational discipline toward a health care discipline.