Drug Use Research & Management Program
Oregon State University, 500 Summer Street NE, E35
Salem, Oregon 97301-1079
Phone 503-947-5220 | **Fax** 503-947-1119

Policy Evaluation: Safety Edit for Attention Deficit Hyperactivity Disorder (ADHD) Medications

Research Goals:

- What proportion of PA requests are for non-preferred drugs and is there opportunity to improve preferred options available on the Oregon Health Plan (OHP) Preferred Drug List (PDL)? Is there opportunity to reduce the number of PA requests?
- Has prescribing patterns improved according to the best practice standards improved since implementation of the safety edit, as measured by the proportion of claims within the age-specific dose and labeled indications, or prescribed by a psychiatric specialty?
- Has the safety edit interrupted therapy as measured by the proportion of patients who did not receive ADHD therapy within 14 days of index claim denial for PA?
- Is there a difference in harms since implementation of the safety edit, as measured by number of patients with emergency department (ED) visits for any cause within 90 days of the index event as well as differences in patients with ED visits specifically for substance abuse or cardiovascular events?

Conclusions:

- The majority of denied claims were for non-preferred agents, most commonly amphetamine ER, methylphenidate ER, and guanfacine ER.
- Since implementation of the safety edit, there has been an improvement in prescribing of ADHD medications according to the best practice standards. There were fewer children under the age of 6 years with paid claims, and little prescribing outside of the accepted dose range.
- There was an increase in use of ADHD medications in adults aged 18 years or older in the study group compared to the control (45% vs. 28%) with 33.4% (458/1373) having a history of substance or alcohol abuse/dependence.
- Similar to what was found in other policy evaluations, the majority of denied claims in both the control group (63.1%) and study group (72.8%) were not followed-up by a PA request within 14 days of denial. Of the PA requests that occurred within 14 days, nearly 100% were approved.
- No differences were observed between the treatment and study groups in terms of harm from the medications resulting in ED visits and/or hospitalizations within 90 days from the index event.

Recommendations:

- Approve lisdexamfetamine for binge eating disorder for adults with an absence of co-morbid mental health illness subject to clinical prior authorization (PA) criteria (**Appendix 2**).
- Continue to monitor use of ADHD medications in the adult population and evaluate trends in adults.
- Make Daytrana (methylphenidate transdermal patch) and generic equivalents non-preferred.
- Perform a RetroDUR with change order forms to promote preferred products.
- Streamline PA processing for stable ADHD regimens in children.

Authors: A. Jones, J. Cha and M. Herink

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Background:

Attention-Deficit/Hyperactivity Disorder (ADHD) is neurobehavioral disorder affecting over 11% of school-aged children in 2011.[1] Traditionally, ADHD has been thought of as a childhood disorder although symptoms may persist into adulthood for many individuals which may require some to be on life-long treatment.[2] It is estimated that ADHD affects approximately 3.4-4.4% of adults worldwide.[2,3] Untreated or sub-optimally treated adults may be subjected to executive functioning deficits, which may include inability to complete tasks, prioritize, and reduce overall quality of life.[2,3] Unfortunately, there are very little data on the effectiveness of treatment of ADHD with CNS stimulants in adults and more research is need to understand the potential benefits of the various treatments in adults with ADHD.[3] Comorbid mood, anxiety, substance use, and/or impulse disorders also commonly occur in combination with ADHD in adults.

In addition to the standard non-preferred PA policy, the OHP fee-for-service (FFS) program implemented a safety edit policy in October 2014 (see Appendix 1) for treatment regimens prescribed by a non-psychiatrist specialist. Specific criteria target prescribing outside of standard age and dose, and non-standard polypharmacy. A list of FDA-approved ADHD medications with minimum ages and maximum daily doses can be found in Table A1. Certain medications are carved-out from the traditional PDL. This safety edit was implemented to promote prescribing according to the best practice standards and evaluate use of ADHD medications by non-psychiatrists. The PA safety edit defined "best practices" as ADHD medications prescribed by non-psychiatrists to patients within standard age ranges, standard doses, and appropriate polypharmacy treatment.[4]

There are no published data evaluating the effects of ADHD specific policies in state Medicaid populations; however, many state Medicaid programs have similar policies in place.[4-8] These medications have a FDA black boxed warning regarding the high abuse potential,[9,10] which is likely the driving factor in states requiring the patient to have at least a 1-year history without substance abuse.[4,5] Other states, as well as some of the large private health insurance companies, only necessitate a PA for ADHD medications that are non-preferred or prescribed outside of standard age and dose ranges, or by a non-psychiatrist.[6-8,11,12]

The Centers for Disease Control and Prevention (CDC) estimates that only 6.1% of children between the ages 4-17 years are taking ADHD medications, while they estimated over 11% of children in the U.S. have an ADHD diagnosis.[1] The safety edits in place are a safeguard to ensure that patients are being prescribed medications appropriately, but it may also potentially serve as a barrier for patients in receiving treatment.[4] Recent data have shown an increased rate of ED visits due to dextroamphetamine-amphetamines and methylphenidate use in adults, many of which were due to nonmedical use of these prescription medications.[13] This study found that nonmedical use of these drugs contributed to 14.1% and 16.4% of adolescent ED visits involving dextroamphetamine-amphetamine or methylphenidate drugs, respectively, and 21.0% and 18.2% of adult ED visits involving dextroamphetamine-amphetamines or methylphenidates, respectively.[13] ADHD stimulants can have severe cardiovascular adverse effects if abused or misused, including myocardial infarction, heart arrhythmias, stroke, and sudden cardiac death.[3] A drug class review was completed in 2015 that compared stimulants (methylphenidates, amphetamine-derivatives) and non-stimulants and found no differences in treatment effects, with varying reports of adverse events and harms data between classes.[14]

The goal of this review it to evaluate if the current safety edit in place is meeting those goals specified in the PA document (**Appendix 2**), while also evaluating how the safety edit may be impacting access to ADHD medications and whether any changes should be implemented.

Methods:

Patients were included in this observational cohort study if they had a paid FFS drug claim for any drug in Table A1 or a denied FFS drug claim for any drug in TableA1 with Explanation of Benefit (EOB) code 1056 (i.e. "PA Required"), or 1059 or 3429 ("Non-Preferred Drug) or 0030 or 0148 ("Drug Quantity Per Day Exceeded) or 4268 ("Safety Edit) and simultaneously no EOB of 2017 (i.e. "Patient enrolled in MCO") from 10/8/2013 and through 12/31/2015. To evaluate for prescriptions based on best prescribing standards, a pre- and post- observational cohort was constructed to evaluate the policy. Patients with a paid or denied index claim from July 2013 to June 2014 were defined as the control group; patients with a paid or denied claim from October 2014 through September 2015 were defined as the study group.

Patients were excluded if they had Medicare Part D coverage as indicated by benefit packages of BMM, BMD, MND or MED. Using only FFS claims, the first ADHD medication paid or denied claim per patient during the study period was designated the index event (IE). Patients were excluded if they had a prior claim within 90 days (FFS or CCO) and if they had less than 75% days of combined FFS or coordinated care organization eligibility from 11 months prior to the index month to 3 months after the index month (for a total of 15 months) to ensure the most complete data possible. Modafinil and armodafinil were not included in this analysis and are managed through a separate PA policy.

Total PA requests based on brand name and form for denied index events restricted to the study group will be collected to determine how many PA requests are for non-preferred drugs at the time of the IE.

Baseline characteristics of age, gender, and ethnicity were assessed at the IE. Patients were categorized by whether the index event was a paid or denied claim. Patients were also categorized by the generic drug name, preferred status and dosage form (ER or IR) of index event. Patients with a paid FFS or encounter claim with an International Classification of Diseases (ICD-9) diagnosis code for each of the diagnostic groups from Table 1 were flagged in the year prior to the IE. Patients are categorized in the following mutually exclusive groups: 1) FDA labeled and funded, 2) Unfunded FDA labeled, 3) non-FDA labeled, and 4) None of the above.

Subsequently, contraindications or warnings (Table 1) for ADHD medications as well as patients with a history of substance abuse identified by the presence of any ICD9 code found in Table 2 will be identified.

Table 1: Indications and Contraindications/Precautions for ADHD Medications

ICD-9	**Diagnosis**
FDA Labeled Indications	
314.00-314.9	Attention-deficit hyperactivity disorder (ADHD)/ Attention deficit disorder (ADD)
347.10-347.11	Narcolepsy - symptomatic management
307.5	Binge Eating Disorder*
Unfunded FDA Labeled Indications	
278.01	Exogenous obesity
Unlabeled Indications	
296.3, 296.20-296.22, 296.25-296.26, 296.90-296.99, 298.0, 311, 625.4	Major depressive disorder (MDD) recurrent, unspecified
788.36	Nocturnal enuresis
Chronic Fatigue	
780.71-780.72,	Fatigue in adult cancer survivors

780.79, 140.xx, 209.xx	
340.xx	Multiple Sclerosis-related fatigue
780.71	Chronic Fatigue Syndrome
None of the Above	
Contraindications or precautions	
Cardiovascular Disease	
440.9	Advanced atherosclerosis
429.2	Symptomatic cardiovascular disease
429.XX	Severe cardiovascular disease unspecified
428.XX	Heart failure
427.9	Arrhythmia
410.XX	Recent MI
413.XX	Angina
402	Severe HTN
Substance or Alcohol Abuse/Dependence	
29181	Alcohol withdrawal
303.00-303.03	ALCOHOL DEPENDENCE SYNDROME
305.0x	Alcohol Abuse
305.2-305.23	Cannabis abuse
303.90-303.93	OTHER AND UNSPECIFIED ALCOHOL DEPENDENCE
304, 304.0 – 304.03, 304.2x 304.3x, 304.4x, 304.9x	Drug Dependence, opioid type dependence, cocaine dependence, cannabis dependence
305.5x, 305.6x, 305.7x	Other nondependent drug abuse
29181	Alcohol withdrawal
Other	
242	Hyperthyroidism
300.0X	Anxiety States, Marked anxiety, tension, agitation

*Approved for lisdexamfetamine only

To assess for appropriate age-specific dosing, the dose for a particular prescription was considered standard if the total daily dose was less than or equal to the

maximum daily dose listed in Table A1. IF the IE claim exceeded the maximum daily dose, the member was categorized as receiving non-standard dosing. The daily dose was calculated based on the strength x quantity dispensed/day supply. All claims that fall outside of the maximum dosing limit will be categorized by prescriber specialty (Table 2). All claims that fall outside of the recommended age range will also be categorized by prescriber specialty.

There was little (~5%) non-standard polypharmacy prescribing identified in a previous DUE and is not in the scope of this policy evaluation.

Patients whose index event was a denied pharmacy claim were categorized by final PA disposition: No PA Requested, PA requested – Approved and PA Requested – Denied. A further analysis by drug name will be included. Claims will be categorized by generic name, paid or denied, and final disposition of the PA.

The control and study group (both denied and paid index claims) will be categorized and compared as to whether they were hospitalized or had an emergency department encounter for any reason on the day of their index claim or in the 90 days after. All-cause hospitalizations will be captured first, followed by a search for a hospitalization due to any of the precautions or contraindications in Table 2.

Table 2: Provider Specialists

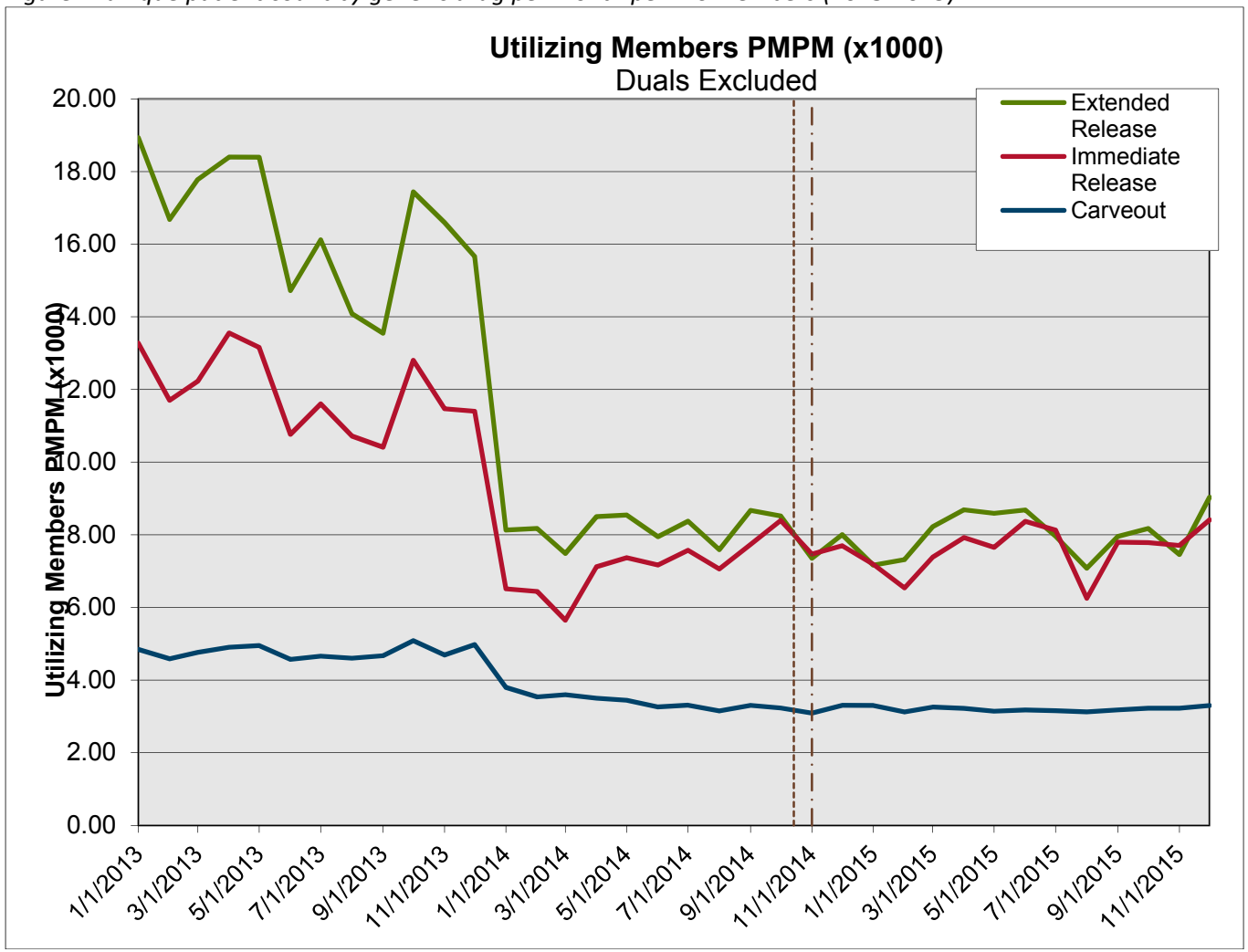
CodeSplProv	Specialty_Description
014	Addiction Medicine - Psychiatry
035	Behavioral Rehab Specialist
227	Psychiatrist
312	Psychiatrist
365	Psychiatric Mental Health Nurse Practitioner

Results:

Utilization

Figure 1 shows the utilization of ADHD medications by unique FFS members from January 2013 through November of 2015, categorized as extended release (ER), immediate release (IR) or carve out medications (guanfacine ER, clonidine ER, atomoxetine). The major decrease in January 2014 was due to the expansion population entering FFS. The safety edit was implemented in October of 2014, which did not appear to affect utilization. Extended release and immediate release medications appear to be utilized at similar frequency and are used more than the carveout medications.

Figure 1: unique patient count by generic drug per month per FFS members (2013-2015)



Demographics of Claims Data

Demographics of FFS members and respective claims in both the control and study group are listed in table 3. There were a total of 1,992 index events in the control group, and 3,065 index events in the study group. Mean age increased from 16.4 years in the control group to 21.0 years in the study group. The percentage of FFS members under the age of 6 years decreased from 6.4% to 2.9% from the control to the study group, respectively. The percentage of members above the age of 18 years increased from 27.5% to 44.8%. Index event paid claims for patients outside of normal age ranges decreased from 152 to 9 after implementation of the safety edit. Similarly, index event denied claims for patients outside of the normal age ranges increased from 12 to 197, as a result of the safety edit. There were 12 index event paid claims for patients receiving ADHD medications exceeding the maximum daily dose in the control group, and

only 1 in the study group. There were 42 index event paid claims for patients outside of the normal age ranges in the control group, and only 3 in the study group after the PA was implemented.

Table 3: Demographics

	Control Group						Study Group					
	All Index Events		Index Event Paid Claim		Index Event Denied Claim		All Index Events		Index Event Paid Claim		Index Event Denied Claim	
N=	**1,992**		1,596	80.1%	396	19.9%	**3,065**		2,074	67.7%	991	32.3%
Mean age (range)	16.4	(2-63)	16.8	(2-63)	14.5	(3-63)	21.0	(1-65)	22.6	(3-65)	17.7	(1-62)
< 6	127	6.4%	113	5.7%	14	0.7%	90	2.9%	19	0.6%	71	2.3%
6-17	1,317	66.1%	1,007	50.6%	310	15.6%	1,602	52.3%	1,017	33.2%	585	19.1%
>= 18	548	27.5%	476	23.9%	72	3.6%	1,373	44.8%	1,038	33.9%	335	10.9%
Female	835	41.9%	666	33.4%	168	8.4%	1,362	44.4%	953	31.1%	409	13.3%
White	1,453	72.9%	1,167	58.6%	286	14.4%	2,182	71.2%	1,471	48.0%	711	23.2%
Patients exceeding max dose per day	24	1.2%	12	0.6%	12	0.6%	46	1.5%	1	0.0%	45	1.5%
- Prescribed by mental health specialist	11	0.6%	4	0.2%	7	0.4%	13	0.4%	0	0.0%	13	0.4%
Patients out of age range	164	8.2%	152	7.6%	12	0.6%	206	6.7%	9	0.3%	197	6.4%
- Prescribed by mental health specialist	44	2.2%	42	2.1%	2	0.1%	61	2.0%	3	0.1%	58	1.9%

Note: Max dose and age range calculations taken on index claim only

Evaluation of PA Requests

To evaluate for opportunities to improve preferred options and decrease the quantity of PA requests, denied claims were broken down by generic drug name (Table 4). The majority of denied claims were for non-preferred agents, most commonly amphetamine ER, methylphenidate ER, and guanfacine ER. The disposition of the PA after a denied claim was also included in Table 3. Only 27.2% of denied claims had a PA requested within 14 days, and 27.1% of those PA requests were approved. Overall, 72.8% of denied claims did not have a PA request sent within 14 days. The number of claims with no PA follow up was particularly high for carve out medications including guanfacine ER (86.5%) and clonidine ER (97.9%). Patients who received a denied claim for carve out drugs and did not have a PA request sent within the 14 days were further evaluated for future pharmacy, including a carve out medication or IR formulation of guanfacine or clonidine in either FFS or CCO claims (Table 4a). The majority of patients (81.3%) with denied claims for carve out medications were switched to a different therapy, whether to the IR formulation or a completely different carve out medication.

Table 4: PA Requests within 14 days of a previously denied claims in the study group

PDL*	Brand	Form	All Patients with Denied Claim	Patients Requested PA within 14 Days						No PA Request	
				All PA Requests		Approved		Denied			
				#	%	#	%	#	%	#	%
			991	**270**	**27.2%**	**269**	**27.1%**	**1**	**0.1%**	**721**	**72.8%**
N	ADDERALL XR	CAP ER 24H	31	17	54.8%	17	54.8%			14	45.2%
N	CONCERTA	TAB ER 24	3	1	33.3%	1	33.3%			2	66.7%
N	DEXMETHYLPHENIDATE HCL	TABLET	16	6	37.5%	6	37.5%			10	62.5%
N	DEXTROAMPHETAMINE SULFATE	TABLET	11	8	72.7%	8	72.7%			3	27.3%
N	DEXTROAMPHETAMINE SULFATE ER	CAPSULE ER	11	4	36.4%	4	36.4%			7	63.6%
N	DEXTROAMPHETAMINE-AMPHET ER	CAP ER 24H	168	66	39.3%	66	39.3%			102	60.7%
N	METADATE ER	TABLET ER	3	1	33.3%	1	33.3%			2	66.7%
N	METHYLIN	TAB CHEW	1							1	100.0%
N	METHYLPHENIDATE ER	CPBP 50-50	1	1	100.0%	1	100.0%			0	0.0%
N	METHYLPHENIDATE ER	TAB ER 24	242	83	34.3%	83	34.3%			159	65.7%
N	METHYLPHENIDATE ER	TABLET ER	38	13	34.2%	13	34.2%			25	65.8%
N	METHYLPHENIDATE HCL	SOLUTION	3	1	33.3%	1	33.3%			2	66.7%
N	METHYLPHENIDATE HCL	TAB CHEW	4	2	50.0%	2	50.0%			2	50.0%
N	METHYLPHENIDATE HCL CD	CPBP 30-70	25	6	24.0%	6	24.0%			19	76.0%
N	METHYLPHENIDATE LA	CPBP 50-50	8	2	25.0%	2	25.0%			6	75.0%
N	METHYLPHENIDATE SR	TABLET ER	2	1	50.0%	1	50.0%			1	50.0%
N	QUILLIVANT XR	SU ER RC24	5	3	60.0%	3	60.0%			2	40.0%
N	RITALIN LA	CPBP 50-50	4	1	25.0%	1	25.0%			3	75.0%
V	CLONIDINE HCL ER	TAB ER 12H	48	1	2.1%	1	2.1%			47	97.9%
V	GUANFACINE HCL ER	TAB ER 24H	251	34	13.5%	33	13.1%	1	0.4%	217	86.5%
V	INTUNIV	TAB ER 24H	48	11	22.9%	11	22.9%			37	77.1%
V	KAPVAY	TAB ER 12H	1							1	100.0%
Y	DEXMETHYLPHENIDATE HCL ER	CPBP 50-50	2							2	100.0%
Y	DEXTROAMPHETAMINE-AMPHETAMINE	TABLET	15	3	20.0%	3	20.0%			12	80.0%
Y	METHYLPHENIDATE HCL	TABLET	9							9	100.0%
Y	STRATTERA	CAPSULE	39	4	10.3%	4	10.3%			35	89.7%
Y	VYVANSE	CAPSULE	2	1	50.0%	1	50.0%			1	50.0%

*PDL status at time of index event

Table 5a: Future Pharmacy for Patients with No PA Request in 14 Days of Denied Claim for Carve-out Drug
Future pharmacy includes only another carveout drug as shown below, or clonidine IR or guanfacine IR, from FFS or MCO sources.
Future pharmacy is checked in the 90 days following the date of the denied claim.

Denied Claim for:				Subsequent Pharmacy of type described		No Future Pharmacy of type described	
PDL	**Brand**	**Form**					
				#	%	**#**	%
V	CLONIDINE HCL ER	TAB ER 12H	47	33	70.2%	14	29.8%
V	GUANFACINE HCL ER	TAB ER 24H	217	186	85.7%	31	14.3%
V	INTUNIV	TAB ER 24H	37	24	64.9%	13	35.1%
V	KAPVAY	TAB ER 12H	1	1	100.0%	0	0.0%
Y	STRATTERA	CAPSULE	35	30	85.7%	5	14.3%

Associated Diagnoses and Contraindications

Sixty-two percent of patients in the control group and 60% in the study group had an FDA labeled and funded indication (ADD/ADHD, binge eating disorder, narcolepsy) for receiving ADHD medications (Table 5). These rates were lower for those 18 years of age and older (49% in the control group and 56% in the study group). There was low overall use for exogenous obesity, which is an unfunded condition. Off-label associated conditions were not significant, and the majority of claims were for major depressive disorder. Over half of patients (54%) over the age of 18 in the study group had a diagnosis that is considered a contraindication or precaution to using these medications. Most notable, 33% of patients 18 years of age or older in the study group had a diagnosis of alcohol or substance abuse or dependence (Table 6).

Table 5: Associated diagnoses in Year Prior to Index Event
Mutually-Exclusive categories

	Control Group				Study Group			
	< 18 Years Old		>= 18 Years Old		< 18 Years Old		>= 18 Years Old	
N=	1,444	72.5%	548	27.5%	1,692	55.2%	1,373	44.8%
FDA Labeled and Funded	963	48.3%	270	13.6%	1,080	63.8%	765	55.7%
ADD/ADHD	963	48.3%	270	13.6%	1,080	63.8%	763	55.6%
Binge Eating Disorder		0.0%		0.0%		0.0%		0.0%
Narcolepsy - symptomatic management		0.0%		0.0%		0.0%	2	0.1%
Unfunded, FDA Labeled	2	0.1%	12	0.6%	2	0.1%	26	1.9%
Exogenous obesity	2	0.1%	12	0.6%	2	0.1%	26	1.9%
Off-Label Indications	91	4.6%	100	5.0%	126	7.4%	218	15.9%
Major Depressive Disorder	77	3.9%	85	4.3%	106	6.3%	182	13.3%
Chronic Fatigue	19	1.0%	36	1.8%	14	0.8%	73	5.3%
Nocturnal enuresis	4	0.2%		0.0%	11	0.7%	2	0.1%
None of the Above	388	19.5%	166	8.3%	484	28.6%	364	26.5%

Table 6: Contraindications in Year Prior to Index Event

	Control Group				Study Group			
	< 18 Years Old		>= 18 Years Old		< 18 Years Old		>= 18 Years Old	
N=	1,444	72.5%	548	27.5%	1,692	55.2%	1,373	44.8%
Contraindications/Precautions	323	16.2%	318	16.0%	372	22.0%	748	54.5%
Cardiovascular Disease	7	0.4%	9	0.5%	11	0.7%	29	2.1%
Hyperthyroidism		0.0%		0.0%		0.0%		0.0%
Anxiety States	252	12.7%	225	11.3%	316	18.7%	534	38.9%
Substance or Alcohol Abuse/Dependence	91	4.6%	187	9.4%	74	4.4%	458	33.4%

PA Requests – Control and Study Group

As seen in table 7, the majority of denied claims in both the control group (63.1%) and study group (72.8%) were not followed by a PA request within 14 days of denial. Of the PA requests within 14 days, almost 100% of them were approved.

Table 7: PA Status within 14 days for Patients with Denied Pharmacy Claim as Index Event
PA Requested within 14 days of Denied Claim

	Control Group		Study Group	
Patients with Denied Claim =	396		991	
PA Requested	146	36.9%	270	27.2%
Approved	146	36.9%	269	27.1%
Denied	0	0.0%	1	0.1%
No PA Request	250	63.1%	721	72.8%

Emergency Department Visits/Hospitalizations

No differences in all-cause ED visits or hospitalizations were found between the control and study groups (15.1% and 16.9%, respectively [Table 8]). No differences in ED visits or hospitalizations due to contraindications were found between the control and study groups (1.3% and 1.5%, respectively).

Table 8: ED/Hospitalizations within 90 Days of Index Event

	Control Group		Study Group	
N=	1,992		3,065	
All Cause ED/Hospitalizations	301	15.1%	517	16.9%
ED/Hospitalizations due to contraindications	25	1.3%	47	1.5%

Discussion:

Implementation of the PA safety edit for dose restrictions in October 2014 and age restrictions in November 2014 did not appear to affect utilization of ADHD medications in FFS members. The decline observed in January 2014 was due to the ACA expansion population. However, the policy appears to have improved prescribing according to best practice. There was a decrease in paid claims for patients outside of the standard age range and standard dose range after the PA policy was implemented. Additionally, fewer patients under the age of 6 years in the study group received paid claims compared to the control group (0.3% vs. 7.6%, respectively) demonstrating an increase in the mean age of patients who received ADHD medication after policy implementation. A further look into these paid claims in the study group revealed that these claims were paid prior to implementation of the new PA policy and no claims outside of best practices were paid after implementation. Therefore, the actual difference in comparing paid claims between groups for prescriptions outside of best practices was actually larger.

Due to the high number of PA requests in this class, drug utilization for denied index events were evaluated and found that the top 5 prescribed medications were all non-preferred and 3 are carved-out medications. Other than continuing to evaluate cost opportunities, there is no way at this time to reduce the volume of PA requests. Presumably, the reason for the denial is their non-preferred status and not due to clinical inappropriateness. Consistent with previous PA policy evaluations, there is an overall high rate of no PA requests following denied claims. The highest rate comes from the carve-out medications (clonidine ER, Strattera, and guanfacine ER). However, the majority of these patients eventually received some type of subsequent pharmacy claim.

An interesting trend is the increased number of claims for patients over the age of 18 years after the PA safety edit was implemented. This increased utilization by adults is something that should be explored in greater depth, as the evidence is limited for the treatment of ADHD in adults.[14,15,16] Four small short-term trials provide low-strength evidence of similar effects on ADHD symptoms after 2 to 6 weeks, as well as low-strength evidence of no difference in harms in adults.[14] Currently, the policy does not address the treatment in adults. The exact reason for the increase in utilization in adults is unknown; however, this finding is consistent with recent literature showing an increase of ADHD being diagnosed in adults. There is controversy over the validity of the diagnosis in adults, as the diagnostic criteria are fairly non-specific.[17]

It is also interesting to note 54.5% of patients over the age of 18 years were prescribed an ADHD medication with a contraindication or precaution, primarily comorbid anxiety and substance abuse. Roughly one-third of all combined patients included in the data have a documented history of substance or alcohol abuse or dependence. This number parallels the data found from the previous DUE,[4] in which 34% of those patients also had a history of substance abuse. ADHD medications have a high abuse potential, and therefore use of these agents should be cautioned in patients with known substance abuse and a higher baseline chance of abuse. The literature consistently demonstrates that adults with ADHD are more likely to have comorbidities than adults without ADHD, including anxiety, bipolar disorder, depression, and drug or alcohol abuse.[4,13,16] Other states (Delaware, Idaho, Texas, Utah, and Missouri) have incorporated extensive screening for substance abuse into their PA policies,[4] with Idaho and Texas[4,5] automatically excluding patients with a history of substance abuse within the previous 12 months. This criterion should be considered because of the increasing abuse of these medications.[13,14] This illustrates the importance of patients having appropriate diagnoses for these medications, especially adults. Otherwise, patients may be receiving medications that are potentially harmful and the risks may outweigh the benefits.

Current NICE guidance for the treatment and diagnosis of adult ADHD recommend that adult patients presenting with ADHD symptoms, with or without a childhood diagnosis, be referred for assessment by a mental health specialist for proper diagnosis of ADHD.[15] First-line therapy recommendations for adult ADHD is methylphenidate. Alternatively, atomoxetine may be considered for patients who do not respond to methylphenidate or have potential of misuse/abuse for stimulants. After atomoxetine, controlled-release formulations should be used in patients with a history of drug abuse/misuse due to less likelihood of abuse.[15] Survey data suggests that lifetime nonmedical use is more frequent with immediate-release methylphenidate or dextroamphetamine compared with mixed amphetamine salts and that amphetamine/dextroamphetamine had the highest rate of diversion.[14] The Center for Disease Control (CDC) also recommends the following criteria are met in adults: 1) several symptoms were present before age 12 years; 2) several symptoms are present in 2 or more settings; 3) clear evidence that the symptoms interfere with, or reduce the quality of work functioning; and 4) the symptoms are not better explained by another mental health disorder and do not happen only during the course of another psychotic disorder. [1]

Emergency department visits and hospitalization rates seemed to match what is expected, and did not vary between the control and study groups. While it is important to evaluate for major harms such as hospitalizations, these data do not show that the PA safety edit had any impact on harms within 90 days of an index event.

Limitations:
All of the data collected and analyzed were claims data, which limits the ability to directly associate a patient's diagnosis with the medications being prescribed. Claims data only allow us to make associations and assumptions about why patients are taking certain medications of interest, especially if patients do not have a diagnosis code on file. Data regarding provider types were collected using specialty provider codes in attempt to compare and contrast prescriptions coming from recognized mental health providers as opposed to non-mental health specialists. However, these codes are also not great at identifying all recognized mental health specialties, and therefore it was difficult to infer how many prescriptions were from mental health specialists. We also only looked at claims data for index events. The data could be analyzed more in depth if recurrent patients and utilization was included. Including recurrent claims data would help to support the decision for implementation of an automatic PA approval for a subset of patients meeting pre-defined criteria.

Recommendations for the PA Policy
Overall, the data show that the goals of the PA safety edit were met. Decreased utilization in inappropriate populations was observed, the majority of claims were for FDA-approved indications and OHP-funded conditions, and the PA denied claims for prescriptions were outside of best practices. A potentially beneficial amendment to make to the PA would be to tighten control in adults because the data show that nearly one-third of patients taking these ADHD medications have a prior history of substance abuse. Currently, there is no mechanism to ensure patients with treatment-resistant ADHD symptoms are receiving specialty care nor is there a process to support increased monitoring for members receiving CNS Stimulants with an increased risk of substance misuse. DSM-IV criteria defines substance abuse as a maladaptive pattern of substance use leading to clinically significant impairment or distress, manifested by at least one major criterion in the past 12 months, listed in DSM-IV.[18]This amendment would ideally increase safety and decrease abuse of ADHD medications.

Other considerations are to require non-stimulants as first line treatment for adults with a history of substance abuse or misuse or to include appropriate diagnostic criteria in the policy according to DSM-IV for adults.

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Appendix 1:

Table A1: Codes identifying ADHD drugs in fee-for-service or managed care pharmacy or professional claims

GSN	Generic	Strength	mg per Unit	FormDesc	ER	PDL	Min Age (Yrs)	Max Age (Yrs)	Max Daily Units
004999	DEXTROAMPHETAMINE/AMPHETAMINE	5 mg	5	TABLET	0	1	3		12
005000	DEXTROAMPHETAMINE/AMPHETAMINE	10 mg	10	TABLET	0	1	3		6
005001	DEXTROAMPHETAMINE/AMPHETAMINE	20 mg	20	TABLET	0	1	3		3
034359	DEXTROAMPHETAMINE/AMPHETAMINE	30 mg	30	TABLET	0	1	3		2
047131	DEXTROAMPHETAMINE/AMPHETAMINE	7.5 mg	7.5	TABLET	0	1	3		8
047132	DEXTROAMPHETAMINE/AMPHETAMINE	12.5 mg	12.5	TABLET	0	1	3		4.8
047133	DEXTROAMPHETAMINE/AMPHETAMINE	15 mg	15	TABLET	0	1	3		4
048701	DEXTROAMPHETAMINE/AMPHETAMINE	10 mg	10	CAP ER 24H	1	0	6		3
048702	DEXTROAMPHETAMINE/AMPHETAMINE	20 mg	20	CAP ER 24H	1	0	6		1.5
048703	DEXTROAMPHETAMINE/AMPHETAMINE	30 mg	30	CAP ER 24H	1	0	6		1
050428	DEXTROAMPHETAMINE/AMPHETAMINE	5 mg	5	CAP ER 24H	1	0	6		6
050429	DEXTROAMPHETAMINE/AMPHETAMINE	15 mg	15	CAP ER 24H	1	0	6		2
050430	DEXTROAMPHETAMINE/AMPHETAMINE	25 mg	25	CAP ER 24H	1	0	6		1.2
061443	METHYLPHENIDATE HCL	10 mg	10	CSBP 40-60	1	0	6		7.2
061444	METHYLPHENIDATE HCL	15 mg	15	CSBP 40-60	1	0	6		4.8
061445	METHYLPHENIDATE HCL	20 mg	20	CSBP 40-60	1	0	6		3.6
061446	METHYLPHENIDATE HCL	30 mg	30	CSBP 40-60	1	0	6		2.4
061447	METHYLPHENIDATE HCL	40 mg	40	CSBP 40-60	1	0	6		1.8
061448	METHYLPHENIDATE HCL	50 mg	50	CSBP 40-60	1	0	6		1.4
061449	METHYLPHENIDATE HCL	60 mg	60	CSBP 40-60	1	0	6		1.2
060615	METHYLPHENIDATE	10 mg /9 hr	10	PATCH TD24	1	1	6		3
060616	METHYLPHENIDATE	15 mg/ 9 hr	15	PATCH TD24	1	1	6		2
060617	METHYLPHENIDATE	20 mg/ 9 hr	20	PATCH TD24	1	1	6		1.5
060618	METHYLPHENIDATE	30 mg/ 9 hr	30	PATCH TD24	1	1	6		1
005009	DEXTROAMPHETAMINE SULFATE	10 mg	10	TABLET	0	0	6		4
005011	DEXTROAMPHETAMINE SULFATE	5 mg	5	TABLET	0	0	6		8
048982	DEXMETHYLPHENIDATE HCL	2.5 mg	2.5	TABLET	0	0	6		8
048983	DEXMETHYLPHENIDATE HCL	5 mg	5	TABLET	0	0	6		4
048984	DEXMETHYLPHENIDATE HCL	10 mg	10	TABLET	0	0	6		2

064090	DEXTROAMPHETAMINE SULFATE	5 mg/5 mL	1	SOLUTION	0	0	6		40
005005	DEXTROAMPHETAMINE SULFATE	10 mg	10	CAPSULE ER	1	0	6		6
005006	DEXTROAMPHETAMINE SULFATE	15 mg	15	CAPSULE ER	1	0	6		4
005007	DEXTROAMPHETAMINE SULFATE	5 mg	5	CAPSULE ER	1	0	6		12
075025	DEXTROAMPHETAMINE/AMPHETAMINE	2.5 mg/mL	2.5	SUS BP 24H	1	0	6		24
005002	AMPHETAMINE SULFATE	10 mg	10	TABLET	0	0	3		6
005003	AMPHETAMINE SULFATE	5 mg	5	TABLET	0	0	3		12
059190	DEXMETHYLPHENIDATE HCL	5 mg	5	CPBP 50-50	1	1	6		6 if <18 yo 8 if ≥18 yo
059191	DEXMETHYLPHENIDATE HCL	10 mg	10	CPBP 50-50	1	1	6		3 if <18 yo 4 if ≥18 yo
059192	DEXMETHYLPHENIDATE HCL	20 mg	20	CPBP 50-50	1	1	6		1.5 if <18 yo 2 if ≥18 yo
061317	DEXMETHYLPHENIDATE HCL	15 mg	15	CPBP 50-50	1	1	6		2 if <18 yo 2.7 if ≥18 yo
065909	DEXMETHYLPHENIDATE HCL	30 mg	30	CPBP 50-50	1	1	6		1 if <18 yo 1.3 if ≥18 yo
066611	DEXMETHYLPHENIDATE HCL	40 mg	40	CPBP 50-50	1	1	6		0.75 if <18 yo 1 if ≥18 yo
067692	DEXMETHYLPHENIDATE HCL	25 mg	25	CPBP 50-50	1	1	6		1.2 if <18 yo 1.6 if ≥18 yo
067693	DEXMETHYLPHENIDATE HCL	35 mg	35	CPBP 50-50	1	1	6		0.86 if <18 yo 1.1 if ≥18 yo
065570	GUANFACINE HCL	1 mg	1	TAB ER 24H	1	0	6	17	4
065572	GUANFACINE HCL	2 mg	2	TAB ER 24H	1	0	6	17	2
065573	GUANFACINE HCL	3 mg	3	TAB ER 24H	1	0	6	17	1.3
065574	GUANFACINE HCL	4 mg	4	TAB ER 24H	1	0	6	17	1
066895	CLONIDINE HCL	0.1 mg	0.1	TAB ER 12H	1	0	6	17	4
005014	METHAMPHETAMINE HCL	5 mg	5	TABLET	0	0	6		Not established
054676	METHYLPHENIDATE HCL	2.5 mg	2.5	TAB CHEW	0	0	4		24
054677	METHYLPHENIDATE HCL	5 mg	5	TAB CHEW	0	0	4		12
054678	METHYLPHENIDATE HCL	10 mg	10	TAB CHEW	0	0	4		6
054679	METHYLPHENIDATE HCL	5 mg/5 mL	1	SOLUTION	0	0	4		60
054680	METHYLPHENIDATE HCL	10 mg/5 mL	2	SOLUTION	0	0	4		30

004029	METHYLPHENIDATE HCL	20 mg	20	TABLET ER	1	0	6		3.6
044072	METHYLPHENIDATE HCL	10 mg	10	TABLET ER	1	0	6		7.2
045981	METHYLPHENIDATE HCL	18 mg	18	TAB ER 24	1	0	6		4
045982	METHYLPHENIDATE HCL	36 mg	36	TAB ER 24	1	0	6		2
047318	METHYLPHENIDATE HCL	54 mg	54	TAB ER 24	1	0	6		1.3
050172	METHYLPHENIDATE HCL	27 mg	27	TAB ER 24	1	0	6		2.7
004026	METHYLPHENIDATE HCL	10 mg	10	TABLET	0	1	4		10
004027	METHYLPHENIDATE HCL	20 mg	20	TABLET	0	1	4		3
004028	METHYLPHENIDATE HCL	5 mg	5	TABLET	0	1	4		12
053056	METHYLPHENIDATE HCL	10 mg	10	CPBP 30-70	1	0	6		7.2
053057	METHYLPHENIDATE HCL	20 mg	20	CPBP 30-70	1	0	6		3.6
053058	METHYLPHENIDATE HCL	30 mg	30	CPBP 30-70	1	0	6		2.4
060545	METHYLPHENIDATE HCL	40 mg	40	CPBP 30-70	1	0	6		1.8
060546	METHYLPHENIDATE HCL	50 mg	50	CPBP 30-70	1	0	6		1.4
060547	METHYLPHENIDATE HCL	60 mg	60	CPBP 30-70	1	0	6		1.2
075263	METHYLPHENIDATE HCL	20 mg	20	TAB CBP24H	1	0	6		3.6
075264	METHYLPHENIDATE HCL	30 mg	30	TAB CBP24H	1	0	6		2.4
075265	METHYLPHENIDATE HCL	40 mg	40	TAB CBP24H	1	0	6		1.8
070374	METHYLPHENIDATE HCL	5 mg/mL (25 mg/5 mL)	5	SU ER RC24	1	0	6		14.4
053059	METHYLPHENIDATE HCL	20 mg	20	CPBP 50-50	1	0	6		3.6
053060	METHYLPHENIDATE HCL	30 mg	30	CPBP 50-50	1	0	6		2.4
053061	METHYLPHENIDATE HCL	40 mg	40	CPBP 50-50	1	0	6		1.8
053974	METHYLPHENIDATE HCL	10 mg	10	CPBP 50-50	1	0	6		7.2
072092	METHYLPHENIDATE HCL	60 mg	60	CPBP 50-50	1	0	6		1.2
051489	ATOMOXETINE HCL	10 mg	10	CAPSULE	0	1	6		10
051490	ATOMOXETINE HCL	18 mg	18	CAPSULE	0	1	6		5.6
051491	ATOMOXETINE HCL	25 mg	25	CAPSULE	0	1	6		4
051492	ATOMOXETINE HCL	40 mg	40	CAPSULE	0	1	6		2.5
051493	ATOMOXETINE HCL	60 mg	60	CAPSULE	0	1	6		1.7
060390	ATOMOXETINE HCL	80 mg	80	CAPSULE	0	1	6		1.25
060391	ATOMOXETINE HCL	100 mg	100	CAPSULE	0	1	6		1
062283	LISDEXAMFETAMINE DIMESYLATE	30 mg	30	CAPSULE	0	1	6		2.3

062284	LISDEXAMFETAMINE DIMESYLATE	50 mg	50	CAPSULE	0	1	6		1.4
062285	LISDEXAMFETAMINE DIMESYLATE	70 mg	70	CAPSULE	0	1	6		1
063645	LISDEXAMFETAMINE DIMESYLATE	20 mg	20	CAPSULE	0	1	6		3.5
063646	LISDEXAMFETAMINE DIMESYLATE	40 mg	40	CAPSULE	0	1	6		1.75
063647	LISDEXAMFETAMINE DIMESYLATE	60 mg	60	CAPSULE	0	1	6		1.2
073292	LISDEXAMFETAMINE DIMESYLATE	10 mg	10	CAPSULE	0	1	6		7
005009	DEXTROAMPHETAMINE SULFATE	10 mg	10	TABLET	0	0	6		4
005010	DEXTROAMPHETAMINE SULFATE	15 mg	15	TABLET	0	0	6		2.7
005011	DEXTROAMPHETAMINE SULFATE	5 mg	5	TABLET	0	0	6		8
071048	DEXTROAMPHETAMINE SULFATE	2.5 mg	2.5	TABLET	0	0	6		16
071049	DEXTROAMPHETAMINE SULFATE	7.5 mg	7.5	TABLET	0	0	6		5.3
072313	DEXTROAMPHETAMINE SULFATE	20 mg	20	TABLET	0	0	6		2
072314	DEXTROAMPHETAMINE SULFATE	30 mg	30	TABLET	0	0	6		1.3

HSN = hierarchical ingredient code list (HICL) sequence number as reported by First DataBank™

PDL = preferred drug list

0= no; 1=yes

Table A2: Codes Identifying IR clonidine and guanfacine

GSN	Generic	Strength	FormDesc	ER
000364	Guanfacine	1 mg	TABLET	0
011984	Guanfacine	2 mg	TABLET	0
000346	Clonidine	0.1 mg	TABLET	0
000347	Clonidine	0.2 mg	TABLET	0
000348	Clonidine	0.3 mg	TABLET	0

Appendix 2: Proposed PA Criteria

Attention Deficit Hyperactivity Disorder (ADHD) Safety Edit

Goals:

- Cover ADHD medications only for diagnoses funded by the OHP and medications consistent with current best practices.
- Promote care by a psychiatrist for patients requiring therapy outside of best-practice guidelines.
- Promote preferred drugs in class.

Length of Authorization:

- Up to 12 months

Requires PA:

- Non-preferred drugs on the enforceable preferred drug list.
- Regimens prescribed outside of standard doses and age range (Tables 2)
- Non-standard polypharmacy (Table 3)

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Table 1. FDA-approved and OHP-funded Indications.

	STIMULANTS		NON-STIMULANTS		
Indication	**Methylphenidate and derivatives**	**Amphetamine and derivatives**	**Atomoxetine**	**Clonidine ER**	**Guanfacine ER**
ADHD	**Age ≥6 years**	**Age ≥3 years**	**Age ≥6 years**	**Children age 6-17 years only**	**Children age 6-17 years only**
Narcolepsy	**Age ≥6 years**	**Age ≥6 years**	**Not approved**	**Not approved**	**Not approved**
Binge-eating Disorder	**Not approved**	**Age ≥18 years lisdexamfetamine only**	**Not approved**	**Not Approved**	**Not approved**

Table 2. Standard Age and Maximum Daily Doses.

Drug Type	Generic Name	Minimum Age	Maximum Age	Maximum Daily Dose (adults or children <18 years of age unless otherwise noted)
CNS Stimulant	amphetamine/dextroamphetamine salts IR	3		40 mg
CNS Stimulant	amphetamine/dextroamphetamine salts ER	6		60 mg
CNS Stimulant	dexmethylphenidate IR	6		20 mg
CNS Stimulant	dexmethylphenidate LA	6		40 mg for adults or

				30 mg if age <18 years
CNS Stimulant	dextroamphetamine IR	6		40 mg
CNS Stimulant	dextroamphetamine LA	6		60 mg
CNS Stimulant	lisdexamfetamine	6		70 mg
CNS Stimulant	methamphetamine	6	17	not established
CNS Stimulant	methylphenidate IR	4		60 mg
CNS Stimulant	methylphenidate LA	6		72 mg
CNS Stimulant	methylphenidate transdermal	6	17	30 mg
Non-Stimulant	atomoxetine	6		100 mg
Non-Stimulant	clonidine LA	6	17	0.4 mg
Non-Stimulant	guanfacine LA	6	17	4 mg

Abbreviations: IR = immediate-release formulation; LA = long-acting formulation (extended-release, sustained-release, etc.)

Table 3. Standard Combination Therapy for ADHD

Age Group	Standard Combination Therapy
Age <6 years*	**Combination therapy not recommended**
Age 6-17 years*	**1 CNS Stimulant Formulation (LA or IR) + Guanfacine LA** **1 CNS Stimulant Formulation (LA or IR) + Clonidine LA**
Age ≥18 years**	**Combination therapy not recommended**

Abbreviations: IR = immediate-release formulation; LA = long-acting formulation (extended-release, sustained-release, etc.)

* As recommended by the American Academy of Pediatrics 2011 Guidelines www.pediatrics.org/cgi/doi/10.1542/peds.2011-2654

**As identified by Drug Class Review: Pharmacologic Treatments for Attention Deficit Hyperactivity Disorder: Drug Effectiveness Review Project, 2011.

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the treated diagnosis an OHP-funded condition?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; not funded by OHP.
3. Is the requested drug on the PDL?	**Yes:** Go to #5	**No:** Go to #4

Approval Criteria		
4. Will the prescriber consider a change to a preferred agent? Message: • Preferred drugs do not require co-pay and are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics (P&T) Committee.	**Yes:** Inform prescriber of preferred alternatives	**No:** Go to #5
5. Is the prescription for lisdexamfetamine for management of binge eating disorder?	**Yes:** Go to #6	**No:** Go to #8
6. Does the patient have significant mental health diagnosis (e.g., major depressive disorder, PTSD, social phobia, etc.)?	**Yes:** Pass to RPh: Deny for medical appropriateness	**No:** Go to #7
7. Has the patient tried and failed a trial of cognitive-behavior therapy (CBT)?	**Yes:** Go to #8	**No:** Pass to RPh; Deny for medical appropriateness
8. Is the request for an approved FDA indication defined in Table 1?	**Yes:** Go to #9	**No:** Go to #12
9. Are the patient's age and the prescribed dose within the limits defined in Table 2?	**Yes:** Go to #10	**No:** Go to #12
10. Is the prescribed drug the only stimulant or non-stimulant filled in the last 30 days?	**Yes:** Approve for up to 12 months	**No:** Go to #11
11. Is the multi-drug regimen considered a standard combination as defined in Table 3?	**Yes:** Approve for up to 12 months	**No:** Go to #12

Approval Criteria		
12. Was the drug regimen developed by, or in consultation with, a psychiatrist, developmental pediatrician, psychiatric nurse practitioner, sleep specialist or neurologist?	**Yes:** Document name and contact information of consulting provider and approve for up to 12 months	**No:** Pass to RPh. Deny; medical appropriateness. Doses exceeding defined limits or non-recommended multi-drug regimens of stimulants and/or non-stimulants are only approved when prescribed by a psychiatrist or in consultation with a mental health specialist. May approve continuation of existing therapy once up to 90 days to allow time to consult with a mental health specialist.

P&T Review: *7/16 (MH); 5/16 (KK); 3/16 (AG); 5/14; 9/09; 12/08; 2/06; 11/05; 9/05; 5/05; 2/01; 9/00; 5/00*
Implementation: *TBD; 10/9/14; 1/1/15; 9/27/14; 1/1/10; 7/1/06; 2/23/06; 11/15/05*