

# MEDICATION COVERAGE POLICY

## PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

<b>POLICY:</b>	ADHD Medications	<b>P&amp;T DATE</b>	2/11/2020
<b>CLASS:</b>	Psychiatric Disorders	<b>REVIEW HISTORY</b>	2/19, 12/17, 12/16, 9/15,
<b>LOB:</b>	MCL	(MONTH/YEAR)	5/12, 5/10, 3/09

*This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.*

## OVERVIEW

Attention-Deficit/Hyperactivity Disorder (ADHD) is a chronic behavioral disorder which includes difficulties with attention, increased activity and difficulties with impulsivity. ADHD mostly manifests during childhood and can continue on to adulthood. According to American Academy of Child and Adolescent Psychiatry, about 11% of school aged-children and 4% of adults have ADHD. The CDC estimates up to 50% of adults who had ADHD in childhood.<sup>1</sup> If left untreated, ADHD can lead to cognitive, social, and emotional dysfunction. This review will examine the treatment guidelines of ADHD and the currently available drug products and their coverage criteria.

**Table 1: Formulary ADHD Agents: (Current as of 1/2020)**

Class	Drug	Available Strengths	Restrictions	Cost/RX	Notes
Stimulants	Amphetamine (Adzenys XR, Dyanavel XR)	ER ODT: 18.8mg	NF	\$326.16	
		ER Suspension: 2.5mg/mL	NF	\$133.37	
	Dexmethylphenidate (Focalin XR)	IR Tablets: 2.5mg, 5mg, 10mg	AL	\$17.73	Limited to persons ≥4 years of age.
		ER Capsules: 5mg, 10mg, 15mg, 20mg, 25mg, 30mg, 35mg, 40mg	ST, AL	\$129.72	Step therapy to at least one ER tier 1 formulary stimulant medication within the last 120 days. Limited to persons ≥4 years of age.
	Dextroamphetamine (Dexedrine XR, Procentra, Zenzedi)	IR Tablets: 5mg, 10mg	AL	\$23.20	Zenzedi is non-formulary
		ER Capsules: 5mg, 10mg, 15mg	AL	\$104.40	Limited to persons ≥4 years of age.
		IR Solution: 5mg/5mL	NF		ProCentra is non-formulary
	Dextroamphetamine/ Amphetamine (Adderall IR/XR)	IR Tablets: 5mg, 7.5mg, 10mg, 12.5mg, 15mg, 20mg, 30mg	AL	\$19.67	Limited to persons ≥4 years of age.
		ER Capsules: 5mg, 10mg, 15mg, 20mg, 25mg, 30mg	AL	\$90.76	Limited to persons ≥4 years of age.
	Lisdexamfetamine (Vyvanse)	IR Capsules: 10mg, 20mg, 30mg, 40mg, 50mg, 60mg, 70mg	PA, AL	\$305.55	Reserved for documentation of treatment failure or intolerance to one Methylphenidate ER-based and one Amphetamine ER-based stimulant medication. Limited to persons ≥ 4 years of age.
		IR Chewable: 10mg, 20mg, 30mg, 40mg, 50mg, 60mg	NF	--	
	Methylphenidate (Daytrana, Quillichew, Quillivant, Ritalin LA)	IR Tablet: 5mg, 10mg, 20mg	AL	\$10.81	Limited to persons ≥4 years of age.
IR Solution: 5mg/5mL, 10mg/5mL		AL	\$37.07	5mg/5mL solution is non-formulary	

		<i>IR Chewable: 2.5mg, 5mg, 10mg</i>	<b>PA, AL</b>	\$417.18	Reserved for documented inability to take methylphenidate IR solution by mouth. Limited to persons ≥ 4 years of age.
		<i>ER Chewable: 20mg, 30mg, 40mg</i>	<b>PA, AL</b>	\$384.25	Reserved for documented inability to take methylphenidate ER capsules by mouth with or without applesauce. Limited to persons ≥ 4 years of age.
		<i>ER Suspension: 25mg/5mL</i>	<b>PA, AL</b>	\$337.50	Reserved for documented inability to take methylphenidate ER capsules by mouth with or without applesauce. Limited to persons ≥4 years of age.
		<i>ER CD Capsules: 10mg, 20mg, 30mg, 40mg, 50mg, 60mg</i>	<b>AL</b>	\$96.39	Limited to persons ≥4 years of age.
		<i>ER Tablets: 10mg, 18mg, 20mg, 27mg, 36mg, 54mg</i>	<b>ST, AL</b>	\$165.91	Step therapy to at least one ER tier 1 formulary stimulant medication within the last 120 days. Limited to persons ≥4 years of age.
		<i>ER LA Capsules: 10mg, 20mg, 30mg, 40mg, 60mg</i>	<b>AL</b>	\$132.54	Limited to persons ≥4 years of age. 60mg LA capsules are non-formulary.
		<i>ER Patch: 10mg/9HR, 15mg/9HR, 20mg/9HR, 30mg/9HR</i>	<b>PA, AL</b>	\$351.06	Restricted to patients with documented inability to swallow tablets, capsules, chewables, solutions, or suspensions. Limited to persons ≥4 years of age.
<b>Non-stimulants</b>	<b>Atomoxetine HCL (Strattera)</b>	<i>IR Capsules: 10mg, 18mg, 25mg, 40mg, 60mg, 80mg, 100mg</i>	<b>ST, AL</b>	\$83.79	Step therapy to intolerance or treatment failure of stimulants. Limited to persons ≥4 years of age.
	<b>Clonidine HCL (Kapvay)</b>	<i>IR Tablets: 0.1mg, 0.2mg, 0.3mg</i>		\$2.40	
		<i>ER Tablets: 0.1mg</i>	<b>NF</b>	\$92.14	
	<b>Guanfacine HCL (Intuniv ER)</b>	<i>IR Tablets: 1mg, 2mg</i>			\$7.10
<i>ER tablets: 1mg, 2mg, 3mg, 4mg</i>		<b>ST, AL, QL</b>		\$11.46	Step therapy to treatment failure, intolerance or contraindication to stimulants. Limited to 1 tablet per day. Limited to persons ≥4 years of age.

PA = Prior Authorization; ST = Step Therapy; QL = Quantity Limit; NF = Non-Formulary

## **EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION**

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

## Stimulants

**IMMEDIATE RELEASE: *Dexmethylphenidate IR (Focalin), Dextroamphetamine Sulfate IR (Dexedrine), Dextroamphetamine/Amphetamine IR (Adderall), Methylphenidate IR (Ritalin, Methylin)***

- Coverage Criteria:** None
- Limits:**
  - Age Limit: Greater than or equal to 4 years of age
- Required Information for Approval:** None
- Non-Formulary:** Methylphenidate 5 mg/5 ml solution, Zenzedi, Procentra

**EXTENDED RELEASE: *Dexmethylphenidate XR (Focalin), Dextroamphetamine Sulfate ER (Dexedrine), Dextroamphetamine/Amphetamine ER (Adderall), Methylphenidate ER/SR (Ritalin, Methylin)***

- Coverage Criteria:**
  - Methylphenidate ER capsules, Dextroamphetamine/Amphetamine ER capsules, Dextroamphetamine ER capsules: None
  - Methylphenidate ER tablets, Dexmethylphenidate ER capsules: Step therapy to at least one ER tier 1 formulary stimulant medication within the last 120 days.
- Limits:**
  - Age Limit: Greater than or equal to 4 years of age
- Required Information for Approval:**
  - Methylphenidate ER tablets, Dexmethylphenidate ER capsules: Fill history of a tier 1 formulary stimulant medication in the prior 120 days.

***Lisdexamfetamine (Vyvanse)***

- Coverage Criteria:** PA required. Reserved for documentation of treatment failure or intolerance to one Methylphenidate ER-based and one Amphetamine ER-based stimulant medication.
- Limits:**
  - Age Limit: Greater than or equal to 4 years of age
- Required Information for Approval:** Clinic notes documenting patient has tried and failed or is intolerant to at least one Methylphenidate ER-based and one Amphetamine ER-based stimulant medication.
- Non-Formulary:** Vyvanse chewables

***Methylphenidate IR chewable tablets, ER chewable tablets (Quillichew), ER suspension (Quillivant XR), Patch (Daytrana)***

- Coverage Criteria:** PA required.
  - IR chewable tablet: Reserved for documented inability to take methylphenidate IR solution by mouth.
  - ER chewable tablet (Quillichew): Reserved for documented inability to take methylphenidate ER capsules by mouth with or without applesauce.
  - ER suspension (Quillivant XR): Reserved for documented inability to take methylphenidate ER capsules by mouth with or without applesauce.
  - Patch (Daytrana): Reserved for patients with documented inability to swallow tablets, capsules, chewables, solutions, or suspensions.
- Limits:**
  - Age Limit: Greater than or equal to 4 years of age
- Required Information for Approval:** Clinic notes documenting patient is unable to swallow oral formulations or alternatives as listed within each specific criteria (e.g. methylphenidate IR solution, methylphenidate ER capsules with applesauce).
- Other Notes:** Methylphenidate ER (LA) 60mg capsules are non-formulary.

## Non-Stimulants

***Guanfacine IR, Clonidine IR***

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** None
- Other Notes:** None

### ***Atomoxetine (Strattera), Guanfacine ER (Intuniv)\****

- Coverage Criteria:** Step therapy to intolerance or treatment failure of stimulants.
- Limits:**
  - Age Limit: Greater than or equal to 4 years of age
  - Guanfacine ER (Intuniv) limited to 1 tablet per day.
- Required Information for Approval:** Prescription history or clinic notes documenting previous stimulant(s) used.
- Other Notes: None**
- Non-Formulary:** Clonidine ER (Kapvay)

## **NEWLY APPROVED MEDICATIONS NOT ON FORMULARY**

- None

## **‡ GUIDELINE & LITERATURE REVIEW**

- 2019 American Academy of Pediatric Clinical Practice Guidelines for the Diagnosis, Evaluation, and Treatment of ADHD in Children and Adolescents<sup>2</sup>
  - Guidance is for persons aged 4 through 18 years of age
  - Diagnosis is based on the Diagnostic and Statistical Manual of Mental Disorders – Fifth edition:
    - Documentation that the child has difficulties in more than 1 major setting (e.g. in school and at home)
    - Exclude any other possible causes for the symptoms (e.g. emotional or behavioral disorders, developmental disorders, physical conditions)
  - Elaborates that ADHD should be recognized as a chronic (long-standing) condition
  - Treatment varies per age groups
    - Preschool (4-5 years of age)
      - First line is behavioral therapy
      - May prescribe methylphenidate if behavioral therapy does not provide significant improvement
      - If behavioral therapy cannot be provided, physicians need to decide pros and cons of starting medication versus delaying treatment
    - Elementary (6-11 years of age)
      - Prescribe FDA approved ADHD medications and/or behavioral therapy (preference is concurrent use)
      - Evidence weighted more towards stimulant medications
      - Followed by atomoxetine, guanfacine ER, then clonidine ER
    - Adolescents (12-18 years of age)
      - Prescribe FDA approved ADHD medications and may prescribe behavioral therapy concurrently
  - In summary, treatment options for ADHD available within the USA are all tiered on the same level without a specific preference per the AAP. The only preferences are for behavioral therapy as monotherapy or concurrently with prescription medication and that methylphenidate be the agent of choice when prescribing ADHD treatment for preschoolers. For most adolescents, stimulant medications are more effective in reducing symptoms compared to atomoxetine, extended-release guanfacine, and extended-release clonidine.

## **‡ CRITERIA REVIEW FOR UNNECESSARY BARRIERS**

Current requirements are appropriate

## # CLINICAL JUSTIFICATION

The 2019 American Academy of Pediatrics (AAP) recommends behavioral modification therapy as first line treatment for children ages 4-5.<sup>2</sup> For ages 6 and up, the AAP recommends using a combination of behavioral modification therapy and stimulants.<sup>2</sup> Stimulants have shown better efficacy than non-stimulants (e.g. Atomoxetine, Guanfacine, and Clonidine).<sup>3,4</sup> In general, stimulants exhibit comparable efficacy. Between 70-80% of patients with ADHD respond to stimulants.<sup>5</sup> The choice of stimulant is dependent on mode and frequency of administration. Non-stimulants may be preferred in patients with a past history or family history of substance abuse. Dosing of ADHD medications also tends to not be weight dependent nor have standard dosages based on a child's weight. The typical process is to gradually increase to the child's best tolerated dose.<sup>2</sup>

## # REFERENCES

1. Searight HR, Burke HM, Rottnek F. Adult ADHD: evaluation and treatment in family medicine. *Am Fam Physician*. 2000; 62(9): 2077-2086.
2. Wolraich ML, Hagan JF, Allan C, et al. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. *Pediatrics*. 2019;144(4)
3. Faraone SV, Glatt SJ. A comparison of the efficacy of medications for adult attention-deficit/hyperactivity disorder using meta-analysis of effect sizes. *J Clin Psychiatry*. 2010; 71(6): 754-763.
4. Bitter I, Angyalosi A, Czobor P. Pharmacological treatment of adult ADHD. *Curr Opin Psychiatry*. 2010; 25(6): 529-534.
5. Bararesi WJ, Katusic SK, Colligan RC, Weaver AL, Leibson CL, Jacobsen SJ. Long-term stimulant medication treatment of attention-deficit/hyperactivity disorder: results from a population-based study. *J Dev Behav Pediatr*. 2006; 27(1): 1.
6. Ritalin LA ®. [prescribing information]. East Hanover, NJ. Novartis Pharmaceuticals Corporation; 2019.

## # REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	ADHD Stimulant - Class Review (3-09)	3/2009	Allen Shek, PharmD
Updated Policy	Intuniv Monograph 5-18-2010.docx	5/2010	Allen Shek, PharmD
Updated Policy	ADHD review 20120515.docx	5/2012	Allen Shek, PharmD
Updated Policy	HPSJ Coverage Policy – Psychiatric – ADHD 2015-05.doc	5/2015	Jonathan Szkotak, PharmD, BCACP
Updated Policy	HPSJ Coverage Policy – Psychiatric – ADHD 2015-09.docx	9/2015	Johnathan Yeh, PharmD
Updated Policy	HPSJ Coverage Policy – Psychiatric – ADHD 2016-12.docx	12/2016	Johnathan Yeh, PharmD
Updated Policy	HPSJ Coverage Policy – Psychiatric – ADHD 2017-12.docx	12/2017	Johnathan Yeh, PharmD
Updated Policy	HPSJ Coverage Policy – Psychiatric – ADHD 2019-02.docx	2/2019	Matthew Garrett, PharmD
Updated Policy	ADHD.docx	2/2020	Matthew Garrett, PharmD

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy