### Attention Deficit Hyperactivity Disorder (ADHD) in Children under Age 6

#### Level 0

Conduct comprehensive assessment and provide psychoeducation about ADHD, including clearly defined treatment expectations. Consider co-morbid developmental language disorder, Specific Learning Disorder or Autism Spectrum Disorder (ASD).

Facilitate family engagement, psychoeducation about ADHD (evidence-based behavioral interventions, educational interventions and medication treatments), and treatment preference assessment. Treatment response should be monitored using rating scales and appropriate health (vital signs, height, weight) and safety assessments. Refer to *General Principles of Practice Regarding the Use of Psychotropic Medications in Children under Age 6* on pg. 6.



#### Level 1

Provide parent management/skills training or other behavioral intervention at home and/or school for a minimum of 12 weeks.



#### Level 2

Initiate monotherapy with methylphenidate formulation.



#### Level 3

If methylphenidate is unsuccessful, could consider monotherapy with atomoxetine (caution: child must be able to swallow medication whole).



#### Level 4

Consider amphetamine formulations which have FDA indication for ages 3 to 5 years old, but limited clinical trial evidence base. May also consider alpha-2 agonists, but no published data are available.

◆ After 6 months of any sustained improvement on any effective medication treatment, taper in order to determine the lowest effective dose and possibility of discontinuation.

#### **Not Recommended:**

- Antipsychotic medication to treat core symptoms of ADHD.
- Concurrent use of two or more alpha-2 agonists.

### Attention Deficit Hyperactivity Disorder (ADHD) in Children under Age 6 (continued)

#### Table 4.

ADHD Medication Treatm	ent for Children under Age 6
Drug Name	Starting Dose Recommendation
Methylphenidate and Amphetamine preparation	ns
Shor	t-acting
Methylphenidate¹:	1.25 mg tid – titrate as needed to doses not exceeding 1 mg/kg/day.
Short Acting: Ritalin®, Methylin®, Methylin® Chewable Tablets, Methylin® Oral Solution	Recommendations extrapolated from the Preschool ADHD Treatment Study (PATS).
Amphetamine <sup>3</sup> :	2.5 mg/day – titrate as needed to doses not exceeding 0.5 mg/kg/day.
Short Acting: Mixed amphetamine salts (Adderall®), D-amphetamine (Zenzedl®, ProCentra® Oral Solution). D- & L-amphetamine (Evekeo®)	Amphetamine target dose is generally one-half to two-thirds of methylphenidate dose.
Selective norepinephrine inhibitor	
Atomoxetine (Strattera®)²	10mg/day – titrate as needed to doses not to exceed 1.4 mg/kg/day.
	Recommendations extrapolated from the Kratochvil et al. 2011 study.
Alpha-2 Agonists4	
Alpha-2 Agonists <sup>4</sup> :	Starting dose not to exceed:
Clonidine (Catapres®, KAPVAY®) Guanfacine (Tenex®, Intuniv®)	0.05 mg/day (clonidine) 0.5 mg/day (guanfacine)
	Monitor carefully for excessive sedation, increased irritability.
	Recommendations based on expert opinion.

#### Notes:

There is no new data on extended release stimulants in preschoolers, but the 2007 American Academy of Child and Adolescent Psychiatry guideline algorithm included extended-release formulations to address compliance concerns (Pliszka et al., 2007).

No FDA indication for children younger than 6 years old; based on Preschool ADHD Treatment Study results (Greenhill et al., 2006).

<sup>&</sup>lt;sup>2</sup>No FDA indication for children younger than 6 years old; based on Kratochvil, C.J., B.S. Vaughan, et al. (2011). A double-blind, placebo controlled study of atomoxetine in young children with ADHD. Pediatrics 127(4):e862-868.

<sup>&</sup>lt;sup>3</sup>FDA indication for ADHD treatment of children 3-5 years old, but no clinical trial study results available.

<sup>&</sup>lt;sup>4</sup>No FDA indication for ADHD except guanfacine extended-release (Intuniv®) and clonidine extended-release (KAPAVY®) in children 6 years and older; no clinical trial study results available for alpha-2 agonist use for ADHD in children below age 6 years old.

#### Level 0

Comprehensive assessment including a detailed developmental and symptom history.

- ◆ ADHD Rating Scale-IV.
- ◆ Vanderbilt ADHD Diagnostic Parent and Teacher Rating Scales

Links to rating scales available at http://medicaidmentalhealth.org/.

Facilitate family engagement, psychoeducation about ADHD (evidence-based behavior and medication treatments, and educational interventions), and treatment preference assessment.

Ensure that treatment response is monitored using rating scales and appropriate health (vital signs, height and weight) and safety assessments.



#### Level 1

Psychostimulant monotherapy (methylphenidate class or amphetamine class, either short or long-acting). If first choice is ineffective, try monotherapy with another stimulant (Refer to Tables 5 and 6 of ADHD medications on pgs. 17–20. If supplementation of long-acting with short-acting psychostimulant required for sufficient coverage, stay within same drug class.

OR

Extended-release alpha-2 agonist monotherapy.



#### Level 2

◆ Combination of extended-release alpha-2 agonist with psychostimulant.
OR

Atomoxetine.



#### Level 3

Immediate-release alpha-2 agonist (as monotherapy or combination with other ADHD medication classes).



#### I evel 4

Diagnostic reconsideration if none of the above agents result in satisfactory treatment. Consider bupropion or tricyclic antidepressant. Despite limited evidence, these medications may be considered. Desipramine is not recommended due to safety concerns.

#### **Not Recommended:**

- ♠ Antipsychotic medication to treat core symptoms of ADHD.
- Concurrent use of two or more alpha-2 agonists.
- Concurrent use of two different stimulant classes.
- ♦ Desipramine due to safety concerns.

Table 5.

FDA Approved ADHD Medications in Children and Adolescents Ages 6 to 17 Years Old				
Generic Class/ Brand Name	Typical Starting Dose	FDA Max Dose/Day	Off-Label Max Dose/Day	Comments
Methylphenidate pre	parations			
	Short-actin	g		
Focalin® (dexmethylphenidate hcl tablet)	2.5 mg bid	20 mg	50 mg	
Methylin® (methylphenidate hcl tablet)	5 mg bid	60 mg	>50 kg: 100 mg	Short-acting stimulants often used as initial treatment
Methylin® Solution (methylphenidate hcl oral solution)	5 mg bid	60 mg	>50 kg: 100 mg	in children (<16 kg), have disadvantage of bid – tid dosing to control symptoms
Methylin® Chewable (methylphenidate hcl chewable tablet)	5 mg bid	60 mg	>50 kg: 100 mg	throughout the day.
Ritalin® (methylphenidate hcl tablet)	5 mg bid	60 mg	>50 kg: 100 mg	
	Intermediate-a	cting		
Metadate ER® (methylphenidate hcl extended-release tablets)	10 mg qam	60 mg	>50 kg: 100 mg	
Metadate CD® (methlypheidate hcl extended-release capsule)	20 mg qam	60 mg	>50 kg: 100 mg	Longer acting stimulants offer greater convenience,
Methylin ER® (methylphenidate hcl extended-release tablet)	10 mg qam	60 mg	>50 kg: 100 mg	confidentiality, and compliance with single daily dosing but may have greater problematic effects on evening appetite and sleep.
Ritalin LA® (methylphenidate hcl extended-release tablet)	20 mg qam	60 mg	>50 kg: 100 mg	
Ritalin SR® (methylphenidate hcl sustained-release tablet)	10 mg qam	60 mg	>50 kg: 100 mg	

### Table 5 (continued).

FDA Approved ADHD Medications in Children and Adolescents Ages 6 to 17 Years Old				
Generic Class/ Brand Name	Typical Starting Dose	FDA Max Dose/Day	Off-Label Max Dose/Day	Comments
	Long-acting	g		
Aptensio XR® (methylphenidate hcl extended-release capsule)	Begin with 10 mg qam then titrate by 10 mg at weekly intervals	60 mg	>50 kg: 100 mg	Aptensio XR®,Metadate CD®,
Concerta® (methylphenidate extended-release tablet)	18 mg qam	72 mg	>50 kg: 108 mg	Ritalin LA® and Focalin XR® capsules may be opened and sprinkled on soft food for immediate consumption.
Daytrana® patch (methylphenidate transdermal system)	Begin with 10 mg patch qd, then titrate up by patch strength 5 mg qam	30 mg	Not yet known	Beads should not be crushed or chewed.  Concerta® should not be crushed, chewed, or broken.  Swallow whole with liquids.  Non-absorbable tablet shell does not dissolve and may be seen in stool. This is normal.
Focalin XR® (dexmethylphenidate hcl extended-release capsule)	5 mg qam	30 mg	50 mg	
Quillivant XR® (methylphenidate hcl extended-release oral suspension)	Begin with 20 mg qam, then titrate up by 10-20 mg at weekly intervals	60 mg	>50 kg: 100 mg	Qillivant XR® is an extended release once-daily suspension.  QuilliChew ER® can be broken
QuilliChew ER® (methylphenidate hcl extended-release chewable tablet)	Begin with 20 mg qam then titrate in incre- ments of 10mg, 15mg or 20mg at weekly intervals	60 mg	>50 kg: 100 mg	in half.

### Table 6.

FDA Approved ADHD Medications in Children and Adolescents Ages 6 to 17 Years Old				
Generic Class/ Brand Name	Typical Starting Dose	FDA Max Dose/Day	Off-Label Max Dose/Day	Comments
Amphetamine prepar	ations			
Short-acting				Short-acting stimulants often
Adderall® (amphetamine mixed salts tablet)	5 mg qd – bid	40 mg	>50 kg: 60 mg	used as initial treatment in children (<16 kg), but have disadvantage of bid – tid
Procentra Oral Solution® (d-amphetamine oral solution)	5 mg qd – bid	40 mg	>50 kg: 60 mg	dosing to control symptoms throughout the day. Note that Adderall®, Procentra Oral Solution®, Eveko® and Zenzedi® have the same dosing recommendations
Evekeo® (d & l amphetamine tablet)	5 mg qd – bid	40 mg	>50 kg: 60 mg	
Zenzedi® (d-amphetamine tablet)	5 mg qd – bid	40 mg	>50 kg: 60 mg	

### Table 6 (continued).

FDA Approved ADHD Medications in Children and Adolescents Ages 6 to 17 Years Old					
Generic Class/ Brand Name	Typical Starting Dose	FDA Max Dose/Day	Off-Label Max Dose/Day	Comments	
Dexedrine Spansule® (dextroamphetamine sulfate extended-re- lease capsule)	<b>Long-actin</b> 5–10 mg qd – bid	<b>g</b> 40 mg	Not yet known	Longer acting stimulants offer greater convenience, confidentiality, and compliance with single daily dosing but may have greater problematic effects on	
Adderall XR® (amphetamine extended-release mixed salts capsule)	10 mg qd	6–12 years: 30 mg 13–17 years: 20 mg	>50 kg: 60 mg	evening appetite and sleep.  Adderall XR® capsule may be opened and sprinkled on soft foods.	
Vyvanse® (lisdexamfetamine capsule)	20-30 mg qd	70 mg	Not yet known	Vyvanse® capsule can be opened and mixed with yogurt, water or orange juice.	
Dyanavel XR® 2.5mg/ mL (amphetamine extended-release oral suspension)	2.5 to 5 mg qd	20 mg	Not yet known	For Dyanavel XR® do not substitute for other amphetamine products on mg-per-mg basis.	
Adzenys XR-ODT® (amphetamine ex- tended-release orally disintegrating tablet)	6.3 mg qam unless switched from Adderall XR (Refer to conver- sion schedule)	6–12 years: 18.8 mg 13–17 years: 12.5 mg	Not yet known	For Adzenys®, do not substitute for other amphetamine products on mg-per-mg basis. For children and adolescents on Adderall XR®, specific starting doses corresponding to Adderall XR® doses are recommended, ranging from 3.1 mg (for those on 30mg Adderall XR®).	

Table 7.

FDA Approved ADHD Medications in Children and Adolescents Ages 6 to 17 Years Old				
Typical Starting Dose	FDA Max Dose/Day	Off-Label Max Dose/Day	Comments	
rine reuptake inhib	oitor			
< 70 kg: 0.5 mg/ kg/day for 4 days; then 1 mg/kg/ day for 4 days; then 1.2 mg/kg/ day	Lesser of 1.4 mg/kg or 100 mg	Lesser of 1.8 mg/kg or 100 mg	Not a Schedule II medication. Consider if active substance abuse or severe side effects of stimulants (mood lability, tics). Give qam or divided doses bid (for effects on late evening behavior). Do not open capsule; must be swallowed whole. Monitor closely for suicidal thinking and behavior, clinical worsening, or unusual changes in behavior.	
onists	•			
1 mg qd then titrate up by 1 mg increments once per week	Lesser of 0.12 mg/kg or 4 mg qd (6-12 years) 7 mg q.d. (13-17 years)	Lesser of 0.17 mg/kg or 4 mg qd (6-12 years) 7 mg q.d. (13-17 years)	Not a Schedule II medication. Sedation, somnolence and fatigue are common and tend to decline over time. Consider baseline electrocardiogram (EKG) before starting.  Tablets should not be crushed, chewed or broken before swallowing because this will increase the rate of	
0.1 mg/day at bed time	0.4 mg/day in divided dose of 0.2 mg bid	0.4 mg/day	release.  Do not administer with high fat meals due to increased exposure.  May not see effects for 4-6 weeks. Review personal and family cardiovascular history.  Do not abruptly discontinue.  Taper the daily dose of Intuniv by no more than 1 mg, and that of Kapvay® by no more than 0.1 mg every 3 to 7 days to avoid rebound hypertension.	
	rine reuptake inhiber of the property of the p	Typical Starting Dose Tine reuptake inhibitor  < 70 kg: 0.5 mg/kg/day for 4 days; then 1 mg/kg/day day for 4 days; then 1.2 mg/kg/day day   Donists  1 mg qd then titrate up by 1 mg increments once per week  1 mg qd. (6-12 years)  7 mg q.d. (13-17 years)  0.1 mg/day at bed time  0.4 mg/day in divided dose of	Typical Starting Dose  Typical Starting Dose  FDA Max Dose/Day  FDA Max Dose/Day  FDA Max Dose/Day  FOR Max Dose/Bay  FO	

Table 8.

ADHD Medications NOT FDA APPROVED in Children and Adolescents Ages 6 to 17 Years Old					
Generic Class/ Brand Name	Typical Starting Dose	Max Dose/Day	Comments		
Alpha- adrenergic a	gonists				
Catapres® (clonidine)	<45 kg: 0.05 mg nightly, titrate in 0.05 mg	27–40.5 kg: 0.2 mg;	The following applies to both alpha-2 adrenergic agonists:		
	increments two times per day, three times per day, or four times per day.	lay, or four times per lay.  40.5–45 kg: 0.3 mg;  40.5–45 kg: 0.4 mg  45 kg: 0.1 mg nightly;	May be used alone or as adjuvant to another medication class for ADHD.		
	>45 kg: 0.1 mg nightly; titrate in 1mg increments		Do not combine different alpha-2-adrenergic agents with each other		
two times per day, three times per day, or four times per day.		Effective for inattention, impulsivity and hyperactivity; modulating mood level; tics worsening from stimulants; sleep disturbances.			
		Taper the daily dose of Clonidine by no more than 0.1 mg every 3 to 7 days to avoid rebound hypertension.			
(guanfacine) titrate in 0.5 mg	increments two times	27–40.5 kg: 2 mg;	May not see effects for 4-6 weeks. Review personal and family cardiovascular history.		
	per day, three times per day, or four times per	40.5.–45 kg: 3 mg;	Consider pre-treatment EKG.		
day.  >45 kg: 1 mg night titrate in 1 mg increments. May do increments two tin per day, three time	day.  >45 kg: 1 mg nightly, titrate in 1 mg increments. May dose increments two times per day, three times per day, or four times per	>45 kg: 4 mg	Taper the daily dose of guanfacine by no more than 1 mg every 3 to 7 days to avoid rebound hypertension.		

#### Table 8 (continued).

ADHD Medications NOT FDA APPROVED in Children and Adolescents Ages 6 to 17 Years Old					
Generic Class/ Brand Name	Typical Starting Dose Max Dose/Day		Comments		
Antidepressants					
Wellbutrin®† (bupropion)	Lesser of 3 mg/kg/day or 150 mg/day as 75 mg bid	Lesser of 6 mg/kg or 300 mg/day. Dose should not exceed 150 mg per dose.	Lowers seizure threshold; contraindicated if current seizure disorder, anorexia nervosa or bulimia nervosa. Usually given in divided doses, bid or tid for children and adolescents, for both safety and efficacy.		
Wellbutrin SR®† (bupropion SR)	Same as above	150 mg per dose or 400 mg/day	Same as above		
Wellbutrin XL®† (bupropion XL)	Not recommended	Not recommended	Not recommended		
Tofranil® (imipramine)	1 mg/kg/day	Lesser of 4 mg/kg or 200 mg	Obtain baseline EKG before starting imipramine.		
Pamelor® Aventil® (nortriptyline)	0.5 mg/kg/day	Lesser of 2 mg/kg or 100 mg	Obtain baseline EKG before starting nortriptyline.		

<sup>\*&</sup>lt;u>Note:</u> Long-acting formulations of clonidine (Kapvay) and guanfacine (Intuniv) are FDA-approved ADHD medications in children and adolescents 6-17 years old, but short-acting formulations of clonidine (Catapres) and guanfacine (Tenex) are not FDA-approved for ADHD.

†Bupropion and bupropion SR have more data on off-label use than bupropion XL. Bupropion XL is not recommended in children and adolescents as the safety and efficacy have not been well established in this population.

For a full list of references, visit http://medicaidmentalhealth.org/.