Clinical Policy: Psychotropic Medication Use Parameters for Children

Reference Number: NM.CP.PPA.18
Effective Date: 08/12/2019
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Revision Log

Description:
The purpose of this policy is to comply with State of New Mexico Human Services Department regarding psychotropic (behavioral health) medication use in children. The recommendation from New Mexico Children, Youth and Families Department is to use the Texas Health and Human Services Psychotropic Medication Utilization Parameters for Children and Youth in Texas Public Behavioral Health (6th Version). In addition, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act requires monitoring of antipsychotic prescribing for children.

Policy:
Western Sky Community Care will follow the Texas Health and Human Services Psychotropic Medication Utilization Parameters for Children and Youth in Texas Public Behavioral Health (6th Version) for review of psychotropic (behavioral health) medications for children (age <18 years old). **Please note: This criteria is only to be used for children and youth (age <18 years).**

I. Initial Approval Criteria

A. If a request meets the Texas Health and Human Services Psychotropic Medication Utilization Parameters for Children and Youth in Texas Public Behavioral Health (6th Version) available here; the medication will be approved. These parameters include, but are not limited to:

1. A DSM-5 diagnosis has been made for which the medication is indicated
2. Appropriate psychotropic medication and dose for age*
3. Dose of psychotropic medication **does not exceed literature based maximum dosage**.*

*Refer to appendix B

Approval duration: six months

B. Other Diagnoses/indications:

1. Refer to the off-label use policy: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Indication (must meet all)**:**

1. Documentation supports that member is currently receiving psychotropic medication or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Dose of psychotropic medication does not exceed max dose per Texas Health and Human Services Psychotropic Medication Utilization Parameters for Children and Youth in Texas Public Behavioral Health (6th Version) available here;
4. Appropriate medical/metabolic monitoring is occurring (refer to baseline/monitoring section of Appendix B), if applicable.

Approval duration: six months

B. Other Diagnoses/indications:

1. Refer to the off-label use policy: CP.PMN.53 for Medicaid.

Appendices

Appendix A: Definitions and abbreviations

DSM-5: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)

Appendix B: Drug Tables from Texas Health and Human Services Psychotropic Medication Utilization Parameters for Children and Youth in Texas Public Behavioral Health (6th Version)

Stimulants for Treatment of ADHD

Drug (generic)	Drug (brand)	Initial Dosage	Literature Based Maximum	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Patient Monitoring Parameters	Boxed Warning	Warnings & Precautions
Amphetamine mixed salts	Adderall®* (immediate-release tablet)	Age 3-5 years: 2.5 mg/day Age ≥ 6 years: 5mg once or twice daily	Age 3-5 years: 30 mg/day Age ≥ 6 years and ≤50 kg: 40 mg/day Age ≥ 6 years and >50 kg: 60 mg/day	Approved for age > 3 years: 40 mg/day	One to three times daily	Baseline and ongoing: height, weight, heart rate, and blood pressure Baseline: Assessment using a targeted cardiac history of the child and the family, and a physical examination of the child with an EKG and/ or a pediatric cardiology consult as indicated	Abuse potential Sudden death and serious cardiovascular events (boxed warning for amphetamine products and dextroamphetamine)	• Risk of sudden death in those with pre- existing structural cardiac abnormalities or other serious heart problems • Hypertension • Potential for psychiatric adverse events (hallucinations, delusional thinking, mania, aggression, etc.) • Current evidence is unclear regarding a definitive answer as to whether extended use of stimulants leads to a permanent reduction in ultimate adult height; however, a small statistically significant reduction is possible. If mild growth suppression occurs, it is likely reversible upon discontinuation of stimulant • Tics • Decreased appetite and weight • Sleep disturbance/ insomnia • Serotonin Syndrome: Increased risk when co-administered with serotonergic agents (e.g., SSRIs, SNRIs, triptans) • Peripheral vasculopathy, including Raynaud's phenomenon, and associated signs and symptoms: Instruct patients to report any numbness, pain, or color change in fingers or toes.
	Adderall®XR* (capsule with 50% IR: 50% ER beads)	Age 6-12 years: 5-10 mg/day Age ≥13 years: 10 mg/day	Age ≥ 6 years and ≤50 kg: 30 mg/day Age ≥ 6 years and >50 kg: 60 mg/day	Approved for age > 6 years: 30 g/day	Once daily			
	Mydayis® ER (capsule with triple-release beads; 16-hour duration)	Age 13-17 years: 12.5 mg/day	Age ≥ 13 years: 25 mg/day	Approved for age >13 years: 25 mg/day	Once daily			
Amphetamine sulfate	Evekeo® (immediate-release tablet)	Age 3-5 years: 2.5 mg once or twice daily Age ≥ 6 years: 5mg once or twice daily	Age ≥ 3 years: 40 mg/day	Approved for age > 3 years: 40 mg/day	1-3 times daily			
Amphetamine base	Adzenys®XR-ODT (oral disintegrating tablet; 50% IR: 50% ER; orange flavor) Must be fully dissolved on tongue before swallowing Adzenys®ER (extended release oral suspension; 50% IR: 50% ER; orange flavor)	Age ≥ 6 years: 6.3 mg/day (3.1 mg = 5 mg Adderall®XR)	Age 6-12 years: 18.8 mg/day Age 13-17 years: 12.5 mg/day	Approved for age > 6 years Ages 6-12 years: 18.8 mg/day (= to 30 mg Adderall®XR) Ages 13-17 years: 12.5 mg/day (= to 20 mg Adderall®XR); no evidence that higher doses conferred additional benefit in this age group	Once daily			
	Dyanavel® XR (extended-release oral suspension; bubblegum flavor)	Age ≥6 years: 2.5-5 mg/day (2.5 mg = 4 mg Adderall®XR)	Age ≥6 years: 20 mg/day	Approved for age > 6: 20 mg/day	Once daily			
Dextroamphetamine	Dextroamphetamine immediate-release tablet* (Dexedrine brand name not available) Zenzedi® (immediate-release tablet) Procentra® (immediate release oral suspension; bubblegum flavor)	Age 3-5 years: 2.5 mg/day Age ≥ 6 years: 5 mg once or twice daily	Age 3-5 years: 30 mg/day Age ≥ 6 years and ≤50 kg: 40 mg/day Age ≥ 6 years and >50 kg: 60 mg/day	Approved for age >3 years: 40 mg/day	Once or twice daily			
	Dexedrine* Spansule® (capsule with 50% IR: 50% ER beads)	Age 3-5 years: not recommended Age ≥ 6 years: 5 mg/day	Age ≥ 6 years and ≤50 kg: 40 mg/day Age ≥ 6 years and >50 kg: 60 mg/day	Age ≥ 6 years: 40 mg/day				

Drug (generic)	Drug (brand)	Initial Dosage	Literature Based Maximum	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Patient Monitoring Parameters	Boxed Warning	Warnings & Precautions
Lisdexamfetamine	Vyvanse® (long-lasting prodrug capsule) Vyvanse® (long-lasting chewable tablets; strawberry flavor) Chewable tabs must be chewed completely before swallowing	Age 3-5 years: No data Age ≥ 6 years: 30 mg/day	Age 3-5 years: No data Age ≥ 6 years: 70 mg/day	Approved for age ≥ 6 years: 70 mg/day	Once daily			

Symbols and abbreviations: IR, immediate-release; ER, extended-release, XR, extended-release; ODT, orally disintegrating tablet.
*Generic available.
Amphetamine Table Footnotes:
See FDA-approved product labeling for each individual medication for complete boxed warnings.
Many extended-release stimulants have been found to have higher plasma exposure for patients ≤ 12 years at the same dose as adolescents, and higher rates of adverse effects. Clinicians may choose whichever stimulant formulation (IR/SR/ER, etc.) they deem appropriate. Monitor more closely for dose titrations in younger patients and consider reducing dose of medications should adverse events arise.
It is generally recommended to adjust stimulant doses in weekly increments, until desired clinical effect is achieved
If switching between stimulant formulations/products, it is recommended to discontinue the previous treatment, and then initiate and titrate using recommended titration schedule for the new agent; increase stimulant dose in weekly increments.
Beaded formulations enclosed in capsules may be helpful for children with difficulty swallowing tablets or capsules, as the capsules may be opened and sprinkled on cold or room temperature applesauce or other soft foods. Contents of the entire capsule should be consumed immediately, not stored. Beads should be swallowed whole, and not chewed.
In rare instances, it may be necessary to exceed the FDA-based maximum dose of stimulant medication to achieve optimal clinical efficacy; however, this should be done on a case-by-case basis with careful monitoring for treatment-emergent adverse effects.

Stimulants for Treatment of ADHD Continued

Drug (generic)	Drug (brand)	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Baseline/ Monitoring	Boxed Warning	Warnings & Precautions
Methylphenidate	Ritalin®* (immediate-release tablet)	Age 3-5 years: 2.5 mg twice daily Age ≥ 6 years: 5mg twice daily	Age 3-5 years: 22.5 mg/day Age ≥ 6 years: ≤50 kg: 60 mg/day >50 kg: 100 mg/day Any dose of methylphenidate exceeding 60mg/day should be used with caution, and with attentive monitoring	Approved for children >6 years: 60 mg/day	One to three times daily	Baseline and ongoing: height, weight, heart rate, and blood pressure Baseline: Assessment using a targeted cardiac history of the child and the family, and a physical examination of the child with an EKG and/ or a pediatric cardiology consult as indicated	Abuse potential	• Risk of sudden death in those with pre-existing structural cardiac abnormalities or other serious heart problems • Hypertension • Potential for psychiatric adverse events (hallucinations, delusional thinking, mania, aggression, etc.) • Conflicting data exist regarding whether extended use of stimulants leads to a reduction in ultimate adult height. However, if stimulant treatment is persistent until growth is complete, a small statistically significant reduction is possible. • Tics • Decreased appetite and weight • Sleep disturbance • Serotonin Syndrome: Increased risk when co-administered with serotonergic agents (e.g., SSRIs, SNRIs, triptans) • Peripheral vasculopathy, including Raynaud's phenomenon, and associated signs and symptoms: Instruct patients to report any numbness, pain, or color change in fingers or toes • Daytrana®TD patch: Post marketing reports of acquired skin depigmentation or hypopigmentation of the skin
	Methylin®* (immediate-release chewable tab; grape flavor) Methylin®* (immediate-release oral solution; grape flavor)							
	Ritalin®SR* (intermediate-release tablet)	Age ≥ 3 years: 10 mg/day			Once daily			
	Methylin®ER* (intermediate-release tablet)							
	Metadate®ER* (intermediate-release tablet)							
	Ritalin®LA* (extended-release capsule; 50% IR: 50% ER)	Age ≥ 6years: 10 -20 mg/day			Once daily			
	Metadate®CD* (extended-release capsule; 30% IR: 70% ER)	Age ≥ 6years: 20 mg/day			Once daily			
	Quillivant®XR (extended-release oral suspension; 20% IR: 80% ER; banana flavor)				Once daily Shake vigorously for at least 10 seconds for accurate dosing			
	QuilliChew®ER (chewable extended-release tablet; 30% IR: 70% ER; cherry flavor)				Once daily			
	Aptensio®XR (extended-release capsule; 40% IR: 60% ER)	Age ≥ 6years: 10 mg/day			Once daily			
	Cotempla XR-ODT (oral disintegrating tablet; 25% IR: 75% ER; grape flavor)	Age ≥ 6 years: 17.3 mg/day	Age 6-17 years: 51.8 mg/day	Approved for 6 years and older: 51.8 mg/day	Once daily			

Drug (generic)	Drug (brand)	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children and Adolescents	Schedule	Baseline/ Monitoring	Boxed Warning	Warnings & Precautions
	Concerta®* (extended-release osmotic release oral tablet; 22% IR: 78% ER)	Age ≥ 6 years: 18 mg/day	Age 3-5 years: 36 mg Age ≥ 6 years: 72 mg/day	Approved for children ≥ 6 years Age 6-12 years: 54 mg/day Age 13-17 years: 72mg/day or 2 mg/kg/day, whichever is less	Once daily			
	Daytrana®TD patch (extended-release)	Age ≥ 6 years: 10 mg/day	Age 3-5 years: 20 mg/day Age ≥ 6 years: 30 mg/day	Approved for children ≥ 6 years	Once daily Note: Patch is designed to be worn for 9 hrs. Removing the patch early leads to a clinical effect, ending 2-3 hours after the patch is			
	Jornay PM (extended-release capsule containing beads with delayed-release coating and extended-release coating) Note: This is the ONLY stimulant formulation designed to be administered IN THE EVENING. Recommended time of administration is 8:00 pm (range: 6:30pm-9:30pm). Time of onset is approximately 10 hours following administration.	Age ≥ 6 years: 20 mg once a day given in the EVENING	Age ≥ 6 years: 100 once a day given in the EVENING	Approved for children ≥ 6 years: 100mg/day	Once daily in the EVENING			
	Focalin®* (immediate-release tablet)	Age ≥ 6 years: 2.5 mg twice daily	Age ≥ 6 years: 50 mg/day	Approved for children ≥ 6 years:	Twice daily			
	Focalin®XR* (extended-release capsule; 50% IR: 50% ER)	Age ≥ 6 years: 5-10 mg/day		Approved for children ≥ 6 years: 30 mg/day	Once daily			

Symbols and abbreviations: IR, immediate-release; ER, extended-release, XR, extended-release; SR, sustained-release; CD, controlled delivery; LA, long-acting; TD, transdermal; ODT, orally disintegrating tablet

* Generic available.

Methylphenidate Table Footnotes:

See FDA-approved product labeling for each individual medication for complete boxed warnings.

Many extended-release stimulants have been found to have higher plasma exposure for patients ≤ 12 years at the same dose as adolescents, and higher rates of adverse effects.

Clinicians may choose whichever stimulant formulation (IR/SR/ER, etc.) they deem appropriate. Monitor more closely for dose titrations in younger patients and consider reducing dose of medications should adverse events arise.

It is generally recommended to adjust stimulant doses in weekly increments, until desired clinical effect is achieved

If switching between stimulant formulations/products, it is recommended to discontinue the previous treatment, and then initiate and titrate using recommended titration schedule for the new agent.

Beaded formulations enclosed in capsules may be helpful for children with difficulty swallowing tablets or capsules, as the capsules may be opened and sprinkled on cold or room temperature applesauce or other soft foods. Contents of the entire capsule should be consumed immediately, not stored. Beads should be swallowed whole, and not chewed.

In rare instances, it may be necessary to exceed the FDA-based maximum dose of stimulant medication to achieve optimal clinical efficacy; however, this should be done on a case-by-case basis with careful monitoring for treatment-emergent adverse effects.

Other ADHD Treatments

Drug (generic)	Drug (brand)	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children & Adolescents	Schedule	Baseline/ Monitoring	Boxed Warning	Warnings & Precautions
Atomoxetine	Strattera®*	Age ≥ 6 years and weight ≤70 kg: 0.5 mg/kg/day	Age ≥ 6 years: 1.8 mg/kg/day or 100 mg/day, whichever is less	Approved for treatment of ADHD (age 6-17 years): 1.4 mg/kg/day or 100 mg/ day, whichever is less	Once or twice daily	Baseline and ongoing: height, weight, heart rate, and blood pressure	Suicidal ideation in children and adolescents being treated for ADHD	• Severe liver injury • Contraindicated to use within 14 days of an MAOI • Increased blood pressure and heart rate • Psychiatric adverse events

Drug (generic)	Drug (brand)	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children & Adolescents	Schedule	Baseline/ Monitoring	Boxed Warning	Warnings & Precautions
		Age ≥ 6 years and weight >70 kg: 40 mg/day				Onset of therapeutic effect typically delayed 3 weeks		• Priapism (rare)
Clonidine	Catapres® (IR)*	Age ≥ 6 years and weight <45 kg: 0.05 mg/day Age ≥ 6 years and weight >45 kg: 0.1 mg/day	Age ≥ 6 years AND Weight 27-40.5 kg: 0.2 mg/day Weight 40.5-45 kg: 0.3 mg/day Weight >45 kg: 0.4 mg/day	Not approved for treatment of ADHD in children and adolescents	One to four times daily	Baseline and ongoing: heart rate and blood pressure Personal and family cardiovascular history	None	• Hypotension • Bradycardia • Syncope • Sedation/Somnolence • When tapering, total daily dose should be reduced in decrements of no more than 0.1mg for clonidine and 1mg for guanfacine every 3-7 days to avoid rebound hypertension • See product labeling for Kapvay® and Intuniv® for information about clinically significant drug interactions • Swallow ER tablets whole. Do not chew or break.
	Kapvay® (ER)*	Age ≥ 6 years: 0.1 mg/day	Age ≥ 6 years: 0.4 mg/day	Approved for monotherapy and adjunctive therapy to stimulants for treatment of ADHD (age 6-17 years): 0.4 mg/day	Once or twice daily			
Guanfacine	Tenex® (IR)*	Age ≥ 6 years and weight <45 kg: 0.5 mg/day Age ≥ 6 years and weight > 45 kg: 1 mg/day	Age ≥ 6 years AND Weight 27-40.5 kg: 2 mg/day Weight 40.5-45 kg: 3 mg/day Weight >45 kg: 4 mg/day	Not approved for children and adolescents	One to four times daily			CAUTION IF USED WITH ANTIPSYCHOTICS (↓ BP)
	Intuniv® (ER)*	Age ≥ 6 years: 1 mg/day	Age 6-12 years: 4 mg/day Age 13-17 years: 7 mg/day	Approved for monotherapy and adjunctive therapy to stimulants for treatment of ADHD Age 6-12 years: 4 mg/day Age 13-17 years: 7 mg/day **Doses > 4mg/day have not been studied in adjunctive trials.	Once daily Do not administer with high fat meals.			
Bupropion	Wellbutrin®*	Age ≥ 6 years: 3 mg/kg/day or 150 mg/day, whichever is less	Age ≥ 6 years: 6 mg/kg/day or 300 mg/day with no single dose >150 mg, whichever is less	Not approved for children and adolescents	One to three times daily	Blood pressure and Pulse Mental status exam and suicide assessment	Increased risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders	• Lowers seizure threshold (use caution with other agents that may lower seizure threshold-e.g. antipsychotics, TCA's, excessive alcohol) • Discontinuation syndrome • Activation of mania/ hypomania • Suicidal ideation potential • Contraindicated for use within 14 days of an MAOI
	Wellbutrin®SR*		400 mg/day		Once or twice daily			
	Wellbutrin®XL*		450 mg/day		Once daily			
Imipramine	Tofranil®*	Reviewed but not included/recommended						• Caution with cardiac disease • Cardiac conduction abnormalities • Orthostatic hypotension • Activation of mania/ hypomania • Anticholinergic and cognitive adverse effects • Lowers seizure threshold • Discontinuation syndrome • Suicidal ideation potential • Use caution in those with history of suicide attempts; may be cardiotoxic in overdose • Contraindicated for use within 14 days of an MAOI
Tricyclic Antidepressant	Multiple Individual medications	Reviewed but not included/recommended						

*Generic available.

Symbols and Abbreviations: IR, immediate release; SR, sustained-release formulation; ER, extended-release; XL, extended-length; BP, blood pressure; TCA, tricyclic antidepressant; MAOI, monoamine oxidase inhibitor.

Antidepressants - SSRIs

Drug (generic)	Drug (brand)	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children & Adolescents	Schedule	Patient Monitoring Parameters	Boxed Warning**	Warnings & Precautions
Citalopram	Celexa®*oral tablet Citalopram* oral solution (mint flavor)	Age 6-11 years: 10 mg/day Age ≥ 12 years: 20 mg/day	Age ≥ 6 years: 40 mg/day	Not approved for children and adolescents	Once daily	• Pregnancy test • as clinically indicated	Increased risk compared to placebo of suicidal thinking and behavior	• Suicidal ideation • Activation of mania/hypomania

Drug (generic)	Drug (brand)	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children & Adolescents	Schedule	Patient Monitoring Parameters	Boxed Warning**	Warnings & Precautions
Escitalopram	Lexapro®*oral tablet Escitalopram* oral solution (mint flavor)	Age 6-11 years: 5 mg/day Age ≥ 12 years (MDD): 10 mg/day	Age 6-11 years: 20mg/day Age ≥ 12 years: 30 mg/day	Not approved for children Approved for treatment of MDD in adolescents (age 12 17 years): 20 mg/day		• Monitor for emergence of suicidal ideation or behavior • Monitor weight and growth • Obtain serum sodium if symptoms of hyponatremia occur (e.g. headaches, confusion, etc.)	(suicidality) in children, adolescents, and young adults in short- term studies of major depressive disorder (MDD) and other psychiatric disorders	• QTc prolongation potential (citalopram, escitalopram, sertraline, fluoxetine) • Discontinuation syndrome • Abnormal bleeding • Contraindicated to use within 14 days of an MAOI; Do not start MAOI for 5 weeks after fluoxetine discontinuation • Serotonin Syndrome • Hyponatremia risk
Fluoxetine	Prozac®*oral capsule Fluoxetine* oral solution; (mint flavor)	Age 6-11 years: 5-10 mg/day Age ≥ 12 years: 10 mg/day	Age ≥ 6 years: 60/day	Approved for treatment of MDD (age 8-18 years): 20 mg/day Approved for treatment of OCD (age 7-17 years): 60 mg/day				
Paroxetine	Paxil®* oral tablet Paxil®* oral suspension (orange flavor) Paxil®CR*	Reviewed but not included/recommended – evidence of possible harm						
Fluvoxamine	Luvox®* *Brand name unavailable	Age ≥ 8 years: 25 mg/day	Age 8-11 years: 200 mg/day Age 12-17 years: 300 mg/day daily doses >50 mg(100mg)	Approved for treatment of OCD (age 8-17 years): Ages 8-11 years: 200 mg/day Ages 12-17 years: 300 mg/day	Immediate-release: should be divided -CR tablets: once daily			
	Luvox®CR*	Lowest available dose may not be an appropriate initial dose for pediatric patients						
Sertraline	Zoloft®*oral tablet Zoloft®*oral solution (menthol flavor) solution must be diluted before use	Age 6-12 years: 12.5-25 mg/day Age 13-17 years: 25-50 mg/day	Age ≥ 6 years: 200 mg/day	Approved for treatment of OCD (age 6-17 years): 200 mg/day	Once daily			
Vilazodone SSRI and 5 HT1A receptor partial agonist	Viibryd®	Age 12-17 years: 5mg/day on days 1-3, then 10mg/day on days 4-7	Age 12-17 years: 30mg/day	Not approved for children and adolescents	Once daily			

* Generic available.

Symbols and Abbreviations: CR, controlled-release; MDD, major depressive disorder; OCD, obsessive compulsive disorder, MAOI, monoamine oxidase inhibitor

** From Boxed Warning in FDA approved labeling for Antidepressants (SSRIs, SNRIs and Other Mechanisms): Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Both patients and families should be encouraged to contact the clinician if depression worsens, the patient demonstrates suicidal behavior or verbalizations, or if medication side effects occur. The appropriate utilization of non-physician clinical personnel who are knowledgeable of the patient population can aid in increasing the frequency of contact between the clinic and the patient/parent.

Footnote:

Unless there are concerns regarding specific issues, such as drug interactions, etc., fluoxetine has the most efficacy and safety data in the pediatric depression literature. Fluoxetine should be tried as the first-line option in children and adolescents aged 8 and older to treat moderate-to-severe major depressive disorder for which psychological therapy is insufficient to relieve symptoms after a reasonable trial (4-6 sessions).

Antidepressants - SNRIs

Drug (generic)	Drug (brand)	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children & Adolescents	Schedule	Patient Monitoring Parameters	Boxed Warning	Warnings & Precautions
Venlafaxine*	Effexor®* Effexor®XR*	Reviewed but not included/recommended – evidence of possible harm				• Pregnancy test as clinically indicated Monitor for emergence of suicidal ideation or behavior • Blood pressure during dosage titration and as clinically indicated • Monitor weight and growth Hepatic function testing baseline and as clinically indicated • CBC and EKG at baseline and as clinically indicated for Clomipramine	Increased risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders	• Suicidal ideation • Abnormal bleeding • Activation of mania/ hypomania • Hepatotoxicity • Elevated blood pressure and pulse • Serotonin Syndrome • Seizures • Hyponatremia • Contraindicated for use within 14 days of an MAOI • Rare cases of drug rash with eosinophilia and systemic symptoms (DRESS)
Duloxetine	Cymbalta®*	Age 7-17 years: 30 mg/day	Age 7-17 years: mg/day	Approved for treatment of Generalized Anxiety Disorder Age 7-17 years: 120 mg/day Target dose 30-60mg/day	Once or twice daily			
Desvenlafaxine	Pristiq®*	Age 7-17 years 20 - <35 kg: 25mg 35 - <70 kg: 35mg ≥70 kg: 50mg	Age 7-17 years: 50mg/day	Not approved for children and adolescents	Once daily			
Levomilnacipran	Fetzima®	Reviewed but not included/recommended - insufficient evidence						
Clomipramine	Anafranil®*	Age 10-17 years: 25 mg/day	Age 10-17 years: 3 mg/kg/day or 200 mg/ day, whichever is less	Approved for treatment of OCD Age 10-17 years: 3 mg/kg/day or 200 mg/ day, whichever is less	Once daily			

Antidepressants – Other Mechanisms

Drug (generic)	Drug (brand)	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children & Adolescents	Schedule	Patient Monitoring Parameters	Boxed Warning	Warnings & Precautions
Mirtazapine	Remeron®* Remeron® Soltab ODT (orange flavor)	Age 7-17 years: 7.5 mg/day See comments – age of 3 based on one open label study, n=26	Age ≥ 3 years: 45 mg/day	Not approved for children & adolescents	Once daily	• Pregnancy test – as clinically indicated • Monitor for emergence of suicidal ideation or behavior • Blood pressure during dosage titration and as clinically indicated • Monitor weight and height • Serum cholesterol levels • CBC baseline and • periodically • Activation of Mania/Hypomania • Selegiline: Monitor for tyramine induced hypertensive crisis	Increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short term studies of major depressive disorder (MDD) and other psychiatric disorders In addition: EMSAM is contraindicated in patients less than 12 years of age (due to potential for hypertensive crisis)	• Suicidal ideation • Abnormal bleeding • Weight gain • Discontinuation syndrome • Activation of mania/ hypomania • Orthostatic hypotension and syncope • Serotonin Syndrome • Hyponatremia • Contraindicated for use within 14 days of an MAOI • Mirtazapine: Rare cases of hepatotoxicity, seizures, and neutropenia • Selegiline TD: tyramine rich foods and beverages should be avoided with doses of selegiline patch ≥ 9 mg per 24 hours or greater
Vortioxetine	Trintellix®	Reviewed but not included/recommended - insufficient evidence						
Selegiline	Emsam® (transdermal system)	Age ≥ 12 years: 6 mg per 24 hours	Age ≥ 12 years: 12 mg per 24 hours	Approved for treatment of Major Depressive Disorder: Age ≥ 12 maximum dose of 12 mg per 24 hours	One patch daily			
Monoamine oxidase inhibitors (MAOIs) oral formulations	Reviewed but not included/recommended – increased risk of adverse events possible; risk of safety issues in youth given drug-food interactions, drug-drug interactions, etc.							
St. John's Wort	Reviewed but not included/recommended - insufficient evidence							

* Generic available.

Symbols and Abbreviations: CR, controlled-release; MDD, major depressive disorder; OCD, obsessive compulsive disorder, MAOI, monoamine oxidase inhibitor; ODT = orally disintegrating tablet; TD = transdermal

** From Boxed Warning in FDA approved labeling for Antidepressants (SSRIs, SNRIs and Other Mechanisms): Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Both patients and families should be encouraged to contact the clinician if depression worsens, the patient demonstrates suicidal behavior or verbalizations, or if medication side effects occur. The appropriate utilization of non-physician clinical personnel who are knowledgeable of the patient population can aid in increasing the frequency of contact between the clinic and the patient/parent.

Footnote:

Unless there are concerns regarding specific issues, such as drug interactions, etc., fluoxetine has the most efficacy and safety data in the pediatric depression literature. Fluoxetine should be tried as the first-line option in children and adolescents aged 8 and older to treat moderate-to-severe major depressive disorder for which psychological therapy is insufficient to relieve symptoms after a reasonable trial (4-6 sessions).

Antipsychotics: Second Generation (Atypical)

Drug (generic)	Drug (brand)	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children &	Schedule Parameters Adolescents	Patient Monitoring	Boxed Warning	Warnings & Precautions
Aripiprazole	Abilify® oral tablet* Abilify Discmelt®* (oral disintegrating tablet; vanilla flavor) Abilify® oral solution* (orange flavor)	Age ≥ 4 years: 2 mg/day	Age 4-11 years: 15 mg/day Age ≥12 years: 30 mg/day	Approved for treatment of Bipolar Mania or Mixed Episodes (age 10-17 years) and Schizophrenia(13-17 years): 30 mg/day Approved for treatment of irritability associated with Autistic Disorder (age 6-17 years): 15 mg/day Approved for Tourette's Disorder (6-18 years): weight < 50 kg 10mg/day; weight ≥ 50 kg 20mg/day	Once daily	• Fasting plasma glucose level or HbA1c – at baseline, at 12 weeks, then annually. • Lipid screening - at baseline, at 12 weeks, and as clinically indicated • Blood pressure, pulse – at baseline, 12 weeks, and annually • Weight (BMI) – at baseline, at 4 weeks, at 8 weeks, 12 weeks, and annually. BMI should be compared against growth charts www.cdc.gov/growthcharts Weight gain exceeding 90th percentile for age or a change of 5 BMI units for youths obese at treatment initiation should have weight management intervention and increased frequency of glucose and lipid monitoring	Increased the risk of suicidal thoughts and behavior in short-term studies in children, adolescents, and young adults with major depressive disorder and other psychiatric disorders	• Extrapyramidal side effects • Neuroleptic Malignant • Syndrome • Tardive Dyskinesia • Hyperglycemia and Diabetes Mellitus • Prolactinemia and gynecomastia (most common with risperidone andpaliperidone) • Weight gain • Dyslipidemia • Orthostatic Hypotension • Leukopenia, neutropenia, and agranulocytosis • Lowers seizure threshold • Cognitive and motor impairment potential • Hyperthermia • Dysphagia
Quetiapine	Seroquel® * Seroquel®XR*	Age 5- 9 years: 12.5 25 mg/day Age 10-17 years: 25 mg twice day	Age 5- 9 years: 400mg/day Age 10-17 years: 800 mg/day	Approved for treatment of Bipolar Mania (age 10-17 years): 600 mg/day Approved for treatment of Schizophrenia (13-17 years): 800 mg/day	IR: One to three times daily XR: Once daily			

Drug (generic)	Drug (brand)	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children & Adolescents	Schedule	Patient Monitoring Parameters	Boxed Warning	Warnings & Precautions
Olanzapine *Not recommended to try as a first-line treatment option due to risk of significant weight gain*	Zyprexa®* Zyprexa Zydis®* (oral disintegrating tablet; unflavored, sweetened)	Age 4-5 years: 1.25 mg/day Age 6-12years: 2.5 mg/day Age ≥ 13years: 2.5-5 mg/day	Age 4-5 years: 12.5 mg/day Age 6-17 years: 20 mg/ day	Approved for treatment of Bipolar Mania or Mixed Episodes Schizophrenia (age 13-17 years): 20 mg/day Approved for treatment of depressive episodes associated with Bipolar I Disorders (age 10-17 years): 12 mg/day in combination with 50mg/day fluoxetine	Once daily	• CBC as clinically indicated. • Pregnancy test – as clinically indicated • EPS evaluation (examination for rigidity, tremor, akathisia) – before initiation of any antipsychotic medication, then weekly for the first 2 weeks after initiating treatment with a new antipsychotic or until the dose has been stabilized and weekly for 2 weeks after a dose increase • Tardive Dyskinesia evaluation (AIMS or NRS) at regular intervals throughout treatment (at least every 3 months) • Sexual function– inquire for evidence of galactorrhea/gynecomastia, menstrual disturbance, libido disturbance or erectile/ ejaculatory disturbances in males (priapism has been reported with SGAs); This inquiry should be done at each visit for the first 12 months and every 6 months thereafter. • Vision questionnaire – ask whether the patient has experienced a change in vision and should specifically ask about distance vision and blurry vision-yearly • Cardiovascular – obtain family history at baseline. In patients with family history of cardiac abnormalities or sudden death, personal history of syncope, palpitations, or cardiovascular abnormalities, baseline EKG and subsequent monitoring is recommended • For patients with resting HR > 130 bpm, PR interval > 200 msec, QRS > 120 msec, or QTc > 460 msec, consider alternate therapy (AACAP Practice Parameter for the use of atypical antipsychotic medications in children and adolescents 2011) • **Clozapine** Monitoring Parameters: Clozapine is associated with severe neutropenia(absolute neutrophil count (ANC) less than 500/µL). The requirements toprescribe, dispense, and receive clozapine are incorporated into a single, shared program called the Clozapine Risk Evaluation and Mitigation Strategy (REMS). Must follow specific requirements for CBC monitoring as per product labeling and clozapine REMS website. • Prescribers and pharmacies must certify the	Increased the risk of suicidal thoughts and behavior in short-term studies in children, adolescents, and young adults with major depressive disorder and other psychiatric disorders	• Rare cases of DRESS (DrugReaction with Eosinophilia andSystemic Symptoms) Presence of a fever with a rash and swollen lymphglands, or swellingto the face. Requires immediate medicalattention. • Possible increase in the risk of unexplained sudden death. However, this is still rare, and causality has not been established.
Risperidone	Risperdal®* Risperdal M Tab®*(oral disintegrating tablet; peppermint flavor) Risperdal® (oral solution; unflavored)	Age 4-5 years: <20 kg: 0.25 mg/day >20 kg: 0.5 mg/day Age ≥6 years: 0.5 mg/day	Age 4-11 years: 3 mg/day Age ≥12 years: 6 mg/day	Approved for treatment of Schizophrenia (age 13-17 years) and Bipolar Mania or Mixed Episodes (age 10-17 years): 6mg/day Approved for treatment of irritability associated with autistic disorder (age 5-16 years): 3 mg/day	Once or twice daily		None related to youth	
Clozapine *Reserved for treatment-resistant psychosis, folowing 2 failed trials of antipsychotic medications with adequate dose/duration*	Clozaril®* FazaClo®* (oral disintegrating tablet; mint flavor) Versacloz® oral suspension (unflavored, sweetened)	Age 8-11 years: 6.25-12.5 mg/day Age ≥ 12 years: 6.25-25 mg/day	Age 8-11 years: 150-300 mg/day Age ≥ 12 years: 600 mg/day Target serum clozapine level of 350 ng/mL for optimal efficacy	Not approved for children and adolescents	Once or twice daily		• Severe neutropenia • Seizures • Orthostasis, bradycardia, syncope • Myocarditis, cardiomyopathy, mitral valve incompetence	
Asenapine	Saphris® (sublingual tablet; black cherry flavor)	Age ≥ 10 years: 2.5 mg twice daily	Age ≥ 10 years: 10 mg twice daily	Approved for acute treatment of Bipolar Mania and Mixed Episodes (age 10-17 years): 10 mg twice daily	Twice daily. Avoid eating or drinking for 10 minutes after sublingual administration		None related to youth	

Drug (generic)	Drug (brand)	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children & Adolescents	Schedule	Patient Monitoring Parameters	Boxed Warning	Warnings & Precautions
						use of Clozapine at www.clozapinerems.com		
Iloperidone	Fanapt®	Reviewed but not included/recommended - insufficient evidence					None related to youth	
Paliperidone	Invega®*	Children:Insufficient Evidence Adolescent: (Age ≥ 12years): 3 mg/day	Children: Insufficient Evidence Adolescents (Age ≥ 12 years), Schizophrenia: Weight < 51 kg: 6 mg/day Weight ≥ 51 kg: 12 mg/day	Approved for treatment of Schizophrenia (age 12-17 years): Weight < 51 kg: 6 mg/day Weight ≥ 51 kg: 12 mg/day	Once daily		None related to youth	
Ziprasidone	Geodon®*	Bipolar Disorder(age 10-17years): 20 mg/day	Bipolar Disorder (age 10-17 years) Weight ≤ 45 kg: 80 mg/day Weight > 45 kg: 160 mg/day	Not approved for children and adolescents	Twice daily; take with ≥500 calorie meal		None related to youth	
Lurasidone	Latuda®	Schizophrenia (age 13-17 years): 40 mg/day Bipolar I Depression monotherapy (age 10-17 years): 20 mg/day	Schizophrenia (age 13-17 years) 80 mg/day Bipolar I Depression (age 10-17 years) 80 mg/day	Approved for treatment of Schizophrenia (age 13-17 years) and Bipolar I Disorder, depressed phase, as monotherapy: 80 mg/day	Insufficient Evidence Once daily taken with >350 calorie meal		Increased the risk of suicidal thoughts and behavior in short-term studies in children, adolescents, and young adults with major depressive disorder and other psychiatric disorders	
Brexpiprazole	Rexulti®	Reviewed but not included/recommended - insufficient evidence Not approved for children and adolescents					None related to youth	
Cariprazine	Vraylar®	Reviewed but not included/recommended - insufficient evidence Not approved for children and adolescents					None related to youth	
Combination Antipsychotic-Antidepressant Formulation(s)								
Olanzapine/ Fluoxetine	Symbyax®*	Age 10-17 years: 3 mg olanzapine/25 mg fluoxetine once daily	Age 10-17 years: 12 mg olanzapine/50 mg fluoxetine once daily	Acute Depressive Episodes Associated with Bipolar I Disorder for age 10-17 years: 12 mg olanzapine/50 mg fluoxetine	Once Daily		Increased the risk of suicidal thoughts and behavior in short-term studies in children, adolescents, and young adults with major depressive disorder and other psychiatric disorders	

Symbols and Abbreviations: XR, extended-release; HbA1c, hemoglobin A1c; BMI, body mass index; kg, kilograms; HR, heart rate; msec, milliseconds; AACAP, American Academy of Child and Adolescent Psychiatry; AIMS, Abnormal Involuntary Movement Scale; NRS, Neurological Rating Scale.

*Generic available.

+ XR, extended-release

** While iloperidone alone can cause QTc prolongation, concomitant administration with a CYP2D6 inhibitor (e.g., paroxetine) or a CYP3A4 inhibitor (e.g., ketoconazole) can double QTc prolongation compared with administering iloperidone alone. No long-acting injectable antipsychotic formulations are FDA-approved for use in children and adolescents.

Note: A cohort study found an increase of an additional 5.9 deaths/10,000-person years (7.7 – 1.8 deaths/10,000 person years) in children and youth receiving antipsychotics as compared with the control group. Their sample size was not adequate to compare potential risk of different antipsychotics (Ray 2019).

Antipsychotics: First Generation (Typical)

Drug (generic)	Drug (brand)	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children & Adolescents	Schedule	Patient Monitoring Parameters	Boxed Warning	Warnings & Precautions
Chlorpromazine*	Thorazine® (Brand name discontinued)	Age > 6 months: 0.25 mg/lb. every 4-6 hours, as needed Adolescents: 10-25 mg/dose every 4-6 hours	Age < 5 years: 40 mg/day Age 5-12 years: 75 mg/day Age > 12 years: 800 mg/day	Approved for treatment of severe behavioral problems (age 6 months-12 years) Outpatient Children: 0.55 mg/kg every 4-6 hours, as needed Approved for the management of manifestations of Psychotic Disorders (age> 12 years): 1000 mg/day	1-6 times daily	• Fasting plasma glucose level or HbA1c – at baseline, at 12 weeks, then annually. • Lipid screening - at baseline, at 12 weeks, and as clinically indicated • Blood pressure, pulse – at baseline, 12 weeks, and annually • Weight (BMI) – at baseline, at 4 weeks, at 8 weeks, 12 weeks, and annually. BMI should be compared against growth charts www.cdc.gov/growthcharts Weight gain exceeding 90th percentile for age or a change of 5 BMI units for youths obese at treatment initiation should have weight management intervention and increased	None related to youth	• Tardive Dyskinesia • Neuroleptic Malignant Syndrome • Leukopenia, neutropenia, and agranulocytosis • Drowsiness • Orthostatic hypotension • EKG changes • EEG changes and seizures possible • Extrapyramidal symptoms • Ocular changes • Hyperprolactinemia • Anticholinergic effects (constipation, dry mouth, blurred vision, urinary retention) • Risk of prolonged QTc interval and torsades de pointes (particularly with pimozide)
Haloperidol*	Haldol® (Brand name discontinued)	Age 3-12 years: Weight 15-40 kg: 0.025-0.05 mg/kg/day Weight ≥ 40 kg: 1 mg/day	Age 3-12 years: 0.15 mg/kg/day or 6 mg/day, whichever is less	Approved for treatment of Psychotic Disorders, Tourette's Disorder, and severe behavioral problems (age ≥3 years).	One to three times daily		None related to youth	

Drug (generic)	Drug (brand)	Initial Dosage	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children & Adolescents	Schedule	Patient Monitoring Parameters	Boxed Warning	Warnings & Precautions
		Age > 12 years: 1 mg/day	Age >12 years: Acute agitation: 10 mg/dose Psychosis: 15 mg/day bourette's Disorder: 15 mg/ day	Psychosis: 0.15 mg/kg/day bourette's Disorder and severe behavioral problems: 0.075 mg/kg/day Severely disturbed children: 6 mg/day		frequency of glucose and lipid monitoring • CBC as clinically indicated. • Pregnancy test – as clinically indicated • EPS evaluation (examination for rigidity, tremor, akathisia) – before initiation of any antipsychotic medication, then weekly for the first 2 weeks after initiating treatment with a new antipsychotic or until the dose has been stabilized and weekly for 2 weeks after a dose increase • Tardive Dyskinesia evaluation (AIMS or NRS) at regular intervals throughout treatment (at least every 3 months) • Sexual function– inquire for evidence of galactorrhea/ gynecomastia, menstrual disturbance, libido disturbance or erectile/ ejaculatory disturbances in males (priapism has been reported with SGAs); This inquiry should be done at each visit for the first 12 months and every 6 months thereafter. • Vision questionnaire – ask whether the patient has experienced a change in vision and should specifically ask about distance vision and blurry vision-yearly • Cardiovascular – obtain family history at baseline. In patients with family history of cardiac abnormalities or sudden death, personal history of syncope, palpitations, or cardiovascular abnormalities, baseline EKG and subsequent monitoring is recommended for patients with resting HR > 130 bpm, PR interval > 200 msec, QRS > 120 msec, or QTc > 460 msec, consider alternate therapy (AACAP Practice Parameter for the use of atypical antipsychotic medications in children and adolescents 2011) EKG required at baseline and as clinically indicated for pimozide (use with other medications with QTc prolongation potential is contraindicated e.g., escitalopram, citalopram, macrolides, etc.)		
Perphenazine*	Trilafon®* (Brand name discontinued)	Age 6-12 years: Insufficient Evidence Age > 12 years: 4-16 mg two to four times daily	Age 6-12 years: Insufficient Evidence Age > 12 years: 64 mg/day	Approved for treatment of psychotic disorders (age≥12 years). Outpatient: 24 mg/day Inpatient: 64 mg/day	Two to four times daily		None related to youth	
Pimozide	Orap®*	Age ≥7 years: 0.05 mg/kg once a day At doses > 0.05mg/kg/day CYP2D6 genotyping should be performed. In poor 2D6 metabolizers, dose should not exceed 0.5mg/kg/day	Age 7-12 years: 6 mg/day or 0.2 mg/kg/day, whichever is less Age ≥ 12 years: 10 mg/day or 0.2 mg/kg/day, whichever is less	Approved for treatment of bourette's Disorder (age ≥12 years): 10 mg/day or 0.2 mg/kg/ day, whichever is less	Once or twice daily		None	

*Generic available.

Symbols and Abbreviations: HbA1c, hemoglobin A1c; BMI, body mass index; kg, kilograms; HR, heart rate; msec, milliseconds; AACAP, American Academy of Child and Adolescent Psychiatry.

Mood Stabilizers

Drug (generic)	Drug (brand)	Initial Dosage	Target Dosage Range	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children& Adolescents	Schedule	Patient Monitoring Parameters	Boxed Warning	Warnings & Precautions
Carbamazepine	Epitol®* tablet Tegretol®* tablet Tegretol®* (oral suspension; citrus vanilla flavor) Tegretol®* (chewable tab, cherry flavor some generic formulations) Tegretol®XR* tablet	Age 4-5 years: 10-20 mg/ kg/day in 2-3 divided doses Age 6-12 years: 100mg twice daily Age ≥ 13 years: 200mg twice daily	Age 4-5 years: 35 mg/kg/day Ages 6-12 years: 400-800 mg/day Age ≥ 13 years: 800- 1200 mg/day	Age 4-5 years: 35 mg/ kg/day Ages 6-12 years: 800 mg/day Age 13-15 years: 1000 mg/day Age >15	Approved for treatment of Seizure Disorders in all ages Age < 6 years: 35 mg/kg/day Age 6-12 years: 1000 mg/day Age >15 years: 1200 mg/day	Two to four times daily Twice daily	• CBC with differential - baseline and 1 to 2 weeks after each dose increase, annually, and as clinically indicated • Electrolytes - baseline and 1 to 2 weeks after each dose increase, annually, and as clinically indicated	Serious dermatological reactions and HLA-B*1502 allele Aplastic anemia and agranulocytosis	• Stevens-Johnson Syndrome • Aplastic anemia • Suicidality • Teratogenicity • Neutropenia and • agranulocytosis • Hyponatremia • Induces metabolism of itself and many other drugs (strong CYP 3A4 inducer)

Drug (generic)	Drug (brand)	Initial Dosage	Target Dosage Range	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children& Adolescents	Schedule	Patient Monitoring Parameters	Boxed Warning	Warnings & Precautions
	Carbatrol®* (extended release capsule) Equetro® (extended release capsule)			years: 1200 mg/day	The safety and effectiveness of EQUETRO in pediatric and adolescent patients have not been established.		• Hepatic function - baseline, monthly for first three months, annually and as clinically indicated. • Pregnancy Test -- baseline as appropriate, and as clinically indicated • Carbamazepine levels ---obtain 1 week after initiation and 3-4 weeks after dose adjustment, then as clinically indicated • For patients with Asian descent, genetic test for HLA-B*1502 at baseline (prior to the initiation of carbamazepine). May use results of previously completed testing. Patients testing positive for the allele should not use carbamazepine unless benefit outweighs the risk • Consider HLA-A*3101 genetic testing at baseline for those to be considered at high risk (most common in Asian, Native American, European, American descents) • Monitor for the emergence of suicidal ideation or behavior • Usual therapeutic trough level is between 4-12 mcg/ml		• Decreased efficacy of oral contraceptives • Withdrawal seizures • Contraindicated to use within 14 days of an MAOI
Divalproex Sod	Depakote®* delayed-release tablets Depakote® ER* extended- release tablets Depakote® sprinkle capsules*	Age ≥6 years: 10-15 mg/kg/d	Age ≥6 years: 30 60mg/kg/day	Age ≥6 years: Serum level: 125 µg/mL, or 60 mg/kg/day	Approved for treatment of Seizure Disorders (age ≥ 10 years) Maximum dose based upon serum level: 50-100 µg/mL, or 60 mg/kg/day	One to three times daily	• CBC - with differential and platelet count - baseline then 1 to 2 weeks after each dosage increase, every 3 months for the first year of treatment, then annually and as clinically indicated • Comprehensive Metabolic Panel (hepatic function, serum creatinine, BUN and electrolytes) – patients baseline, every 3 months for the first year of treatment, then annually and as clinically indicated. • Pregnancy Test – baseline as appropriate, and as clinically indicated • Trough Valproic acid level – 1-2 weeks after initiation and dosage change, then as clinically indicated. • Weight – baseline, quarterly for the first year of treatment, then annually and as clinically indicated • Monitor for the emergence of suicidal ideation or behavior	• Hepatotoxicity (increased risk with young children) (i.e., between 3 months and 10 years) have 50% higher clearances (i.e., mL/min/kg) than do adults. Over the age of 10 years, children have pharmacokinetic parameters that approximate those of adults. • Teratogenicity • Pancreatitis	• Hepatotoxicity • Pancreatitis • Urea cycle disorders • Teratogenicity • Suicidal ideation • Neutropenia and leukopenia (significant increased risk with quetiapine co-administration) • Thrombocytopenia • Hyperammonemia • Multi-organ hypersensitivity reaction • Withdrawal seizures • Polycystic ovarian syndrome • Weight gain potential • Aecia

Drug (generic)	Drug (brand)	Initial Dosage	Target Dosage Range	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children& Adolescents	Schedule	Patient Monitoring Parameters	Boxed Warning	Warnings & Precautions
							Usual therapeutic trough levels: Bipolar disorder: 50-125 mcg/ml for valproic acid and Divalproex delayed release (Depakote®). Acute mania: 85-125 mcg/ml for divalproex extended release (Depakote ER®). A lower therapeutic trough level may be needed with divalproex extended release for maintenance treatment. For extended release products, a trough level is considered to be 18 to 24 hours after		
Lithium	Lithium carbonate capsules Eskalith® CR (450 mg) extended-release tablet) Lithobid® ER (300 mg extended-release tablet) Lithium citrate* (oral solution, 300mg/5mL, raspberry flavor)	Age 6-11 years: 150mg twice per day Age ≥12 years: 300 mg twice per day	Dose adjustment based upon serum level; increase in weekly increments 12-hour post dose serum level: 0.6-1.2 mEq/L	Age ≥12 years: Serum level: 1.2 mEq/L, or 1800 mg	Approved for treatment of manic episodes and maintenance of Bipolar Disorder (age ≥ 7 years) Maximum dose: 20-30 kg: acute: 1500 mg maintenance: 1200 mg >30 kg: 1800 mg 12-hour post dose serum level: acute: 0.8-1.2 mEq/L maintenance: 0.8-1 mEq/L	One to four times daily	• EKG – baseline, yearly • CBC – baseline, yearly • Thyroid studies – baseline; then TSH every 6 months • Comprehensive Metabolic Panel, baseline, 3 months, annually. Caution: BUN: serum creatinine ratio >20 may be an indication of dehydration. • UA - baseline • Pregnancy Test • Trough Lithium Levels – one week (i.e., 5-7 days) after initiation or dosage change, 3 months after initiation; for maintenance treatment every 6 months • Weight – baseline, every 6 months • Usual trough therapeutic level: 0.61.2 meq/L (12 hrs. post dose)	Toxicity above therapeutic serum levels	• Toxicity above therapeutic serum levels; narrow therapeutic index • Chronic renal function impairment • Increased risk of toxicity possible for patients with significant renal disease, dehydration, sodium depletion, concomitant drug interactions (ACEI, ARBS, NSAIDs, COXII inhibitors, diuretics, etc.) • Polyuria • Tremor • Diarrhea • Nausea • Hypothyroidism • Teratogenicity

*Generic Available.

Symbols and Abbreviations: CR, controlled-release; ER and XR, extended-release; CYP, cytochrome P450; MAOI, monoamine oxidase inhibitor; ODT = orally disintegrating tablet; ACEI, Ace Inhibitor antihypertensive medication; ARP, Angiotensin Receptor Blocker antihypertensive medication, NSAIDs, non-steroidal anti-inflammatory drug; COX II inhibitors, cyclooxygenase II inhibitor pain medication; EKG, electrocardiogram; CBC, complete blood count; BUN, blood urea nitrogen; UA, urinalysis.

Drug (generic)	Drug (brand)+	Initial Dosage	Target Dosage Range	Literature Based Maximum Dosage	FDA Approved Maximum Dosage for Children & Adolescents	Schedule	Patient Monitoring Parameters	Boxed Warning	Warnings & Precautions
Lamotrigine	Lamictal® * Lamictal® CD* (chewable dispersible tablets) Lamictal® ODT* (oral disintegrating tablet; blackcurrant flavor)	Age 6-11 years: 2-5 mg/ day Age ≥12 years: 25 mg/day (increase by 25 mg every 2 weeks)	Epilepsy dosing Age 6-11 years Monotherapy: 4.5-7.5 mg/kg/day With Valproate: 1-3 mg/kg/day With Valproate and EIAEDs : 1-5 mg/kg/day With EIAED's: 5-15 mg/kg/day Age ≥12 years Monotherapy: 225-375 mg/day With Valproate: 100-200 mg/day With Valproate and EIAEDs : 100-400 mg/day With EIAEDs : 300-500 mg/day See product labeling for detailed charts for alternate dosing in the presence of drug interactions i.e., divalproex/valproic acid OR EIAEDs (carbamazepine, phenytoin, phenobarbital, primidone)	See dosing tables below main table for recommended lamotrigine titration for 10-12-year-old and 13 17 year olds for pediatric bipolar disorder. Dosing is from a t randomized, placebo-controlled study conducted by Findling and colleagues for youth with bipolar disorder	Approved for adjunctive therapy for Seizure Disorders: Age 2-12: 400 mg/ day Age >12: 500 mg/day Use of doses > 200mg/day in adults with bipolar depression has not conferred additional efficacy) Not FDA-approved for treatment of Bipolar Disorder in patients younger than 18 years	Once or twice daily	• Renal Function - baseline and as clinically indicated • Hepatic Function - baseline and as clinically indicated • Pregnancy Test - baseline and as clinically indicated • CBC – baseline and as clinically indicated • Monitor for the emergence of suicidal ideation or behavior • Monitor for rash, especially during the first two months of therapy	Serious rashes including Stevens-Johnson syndrom e	• Dermatological reactions • Potential Stevens-Johnson Syndrome; risk increased with too-rapid titration • Drug reaction with eosinophilia and systemic symptoms (DRESS) reactions have occurred • Suicidal ideation • Aseptic meningitis • Concomitant use with divalproex increases serum lamotrigine levels significantly (increased risk of rash/SJS without lamotrigine dose adjustment) • Concomitant use with enzyme inducing AEDs (carbamazepine, phenytoin, phenobarbital, primidone) reduces serum lamotrigine levels significantly (reduced lamotrigine efficacy possible without lamotrigine dose adjustment) • Concomitant use with oral contraceptives increases lamotrigine clearance • Withdrawal seizure potential
	Lamictal XR® * (extended release tablet)	Age ≥ 13 years: 25 mg/day	Age ≥13 years (without concomitant drug interactions): 25mg once daily for 2 weeks, then 50mg once daily for 2 weeks, then 100mg once daily for 1 week, then 150mg once daily for 1 week, then 200mg once daily for 1 week, then increase to maintenance dose of 300 400mg/day thereafter. (Use of doses > 200mg/day in adults with bipolar depression has not conferred additional efficacy) See product labeling for detailed charts for alternate dosing in the presence of drug interactions i.e., divalproex/valproic acid OR EIAEDs (carbamazepine, phenytoin, phenobarbital, primidone)	Lamictal XR® has no published data for mood stabilization in pediatrics	Approved for adjunctive therapy for Seizure Disorder 13 years or older Maximum dose depends on presence of concomitant drug interactions, see product labeling Not FDA-approved for treatment of Bipolar Disorder in patients younger than 18 years	Once daily			
Oxcarbazepine	Trileptal® (film coated tablet) Trileptal® oral suspension* (plum-lemon flavor) Oxtellar XR® extended-release tablet	Reviewed but not included/recommended - insufficient evidence						None related to youth	

*Generic Available.

Symbols and Abbreviations: CD, chewable dispersible; ER and XR, extended-release; ODT, oral disintegrating tablet; kg, kilograms; XR, extended-release; EIAED's - Enzyme Inducing Anti-Epileptic Drugs (e.g. Carbamazepine, Phenobarbital, Phenytoin, Primidone

Lamotrigine Dosing

Lamotrigine Dose Titration for Adolescents 10-12 years of age.

	For Patients Taking Valproate[a] (mg/kg/day)	For Patients not Taking Carbamazepine (or Other Enzyme-Inducing Drugs) and not Taking Valproate[b] (mg/kg/day)	For Patients Taking Carbamazepine (or Other Enzyme-Inducing Drugs) and not Taking Valproate[b] (mg/kg/day)
Study Week			
Weeks 1 and 2	0.15	0.3[a]	0.6
Weeks 3 and 4	0.3	0.6	1.2
Week 5	0.6	1.2	2.4
Week 6	0.9	1.8	3.6
Week 7	1.2	2.4	4.8
Week 8	1.5	3.0	6.0
Week 9	1.8	3.6	7.2
Week 10	2.1	4.2	8.4
Week 11	2.4	4.8	9.6
Week 12	2.7	5.4	10.8
Weeks 13–18	3.0	6.0	12.0
Maximum Dose	3 mg/kg/day or 100 mg/day[a] whichever occurred first	6 mg/kg/day or 200 mg/day[b] whichever occurred first	12 mg/kg/day or 300 mg/day[b] whichever occurred first

Note: [a]In 1 or 2 divided doses.
[b]In 2 divided doses (unless noted otherwise).

Lamotrigine Dose Titration for Adolescents 13-17 years of age.

Study Week	For Patients Taking Valproate	For Patients not Taking Carbamazepine (or Other Enzyme-Inducing Drugs) and not Taking Valproate	For Patients Taking Carbamazepine (or Other Enzyme-Inducing Drugs) and not Taking Valproate
Weeks 1 and 2	25 mg every other day	25 mg/day	50 mg/day
Weeks 3 and 4	25 mg/day	50 mg/day	100 mg/day[a]
Week 5	50 mg/day (minimum dose)	100 mg/day (minimum dose)	150 mg/day[a]
Week 6	75 mg/day	150 mg/day	200 mg/day[a] (minimum dose)
Week 7	100 mg/day (target dose)	200 mg/day (target dose)	250 mg/day[a]
Week 8	125 mg/day	250 mg/day[a]	300 mg/day[a] (target dose)
Week 9	150 mg/day (maximum dose)	300 mg/day[a] (maximum dose)	350 mg/day[a]
Weeks 10–18	150 mg/day	300 mg/day[a]	400 mg/day[a] (maximum dose)

Note: [a]In two divided doses.

Sedatives/Hypnotics

Drug (generic)	Drug (brand)	Initial Dosage	Literature Based Maximum Dosage**	FDA Approved Maximum Dosage for Children & Adolescents	Schedule	Black Box Warning**	Warnings & Precautions
Diphenhydramine	Benadryl®*	Age 3-5 years: 6.25-12.5 mg (1mg/kg max) Age 5-11 years: 12.5-25 mg Age ≥12 years: 25-50 mg	25-37 lbs: 12.5 mg 38-49 lbs: 19 mg 50-99 lbs: 25 mg ≥100 lbs: 50 mg Evidence suggests that tolerance develops to the hypnotic effects of diphenhydramine within 5-7 of continuous use.	Approved for treatment of insomnia (age ≥12 years): 50 mg at bedtime	Once at bedtime	None	• Drowsiness • Dizziness • Dry mouth • Nausea • Nervousness • Blurred vision • Diminished mental • alertness • Paradoxical excitation • Hypersensitivity reactions • May lower seizure threshold (avoid in epilepsy)
Trazodone*	Desyrel®*	Children: Insufficient Evidence Adolescents: 25 mg	Children: Insufficient Evidence Adolescents: 100 mg/day	Not approved for use as a hypnotic.	Once at bedtime	Increased the risk compared to placebo of suicidal thinking and behavior (Suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders	• Serotonin Syndrome • Use Contraindicated within 14 days of an MAOI • Suicidal ideation • Activation of mania/hypomania • Discontinuation syndrome • Abnormal bleeding • QT prolongation and risk of sudden cardia death • Orthostatic hypotension and syncope • Abnormal bleeding • Priapism • Hyponatremia • Cognitive and motor impairment
Eszopiclone	Lunesta®*	Reviewed but not included/recommended - insufficient evidence/increased rate of adverse events in pediatric patients				None	• Complex sleep behaviors possible • Abnormal thinking and behavior changes • Withdrawal effects • Drug abuse and dependence • Tolerance
Melatonin	No brand name	Age 3-5 years: 0.5mg Age ≥6 years: 1mg	Age 3-5 years: 0.15 mg/kg or 3 mg, whichever is less Age ≥6 years: 0.15mg/kg or 6mg, whichever is less	Regulated by FDA as a dietary supplement and not as a medication (no FDA approved indications)	Once at bedtime or alternatively, give 5-6 hrs before Dim Light Melatonin Onset (DLMO)	None	• Sedation • Should be given directly before onset of sleep is desired due to short half-life
Ramelteon	Rozerem®	Reviewed but not included/recommended - insufficient evidence				None	• Hypersensitivity reactions • Need to evaluate for comorbid diagnoses • Abnormal thinking and behavioral changes • CNS depression • Decreased testosterone possible • Hyperprolactinemia possible
Hydroxyzine*	Vistaril®*	Age 3-5 years: 25 mg Age ≥6 years: 50mg	Age 3-5 years: 25 mg Age 6-11 years: 50mg Age 12 years and older: 100 mg	Approved for treatment of anxiety and tension: Age <6 years: 50 mg/day in divided doses Age = 6 years: 50-100 mg/day in divided doses Approved as a sedative when used as a premedication and following general anesthesia: 0.6 mg/kg	Once at bedtime	None	• Drowsiness • Involuntary motor activity • Blurred vision, dizziness, diminished mental alertness • Paradoxical excitation associated with a small but definite risk of QT interval prolongation and torsades de pointes
Suvorexant	Belsomra®	Reviewed but not included/recommended - insufficient evidence				None related to youth	• Sleep paralysis • Somnolence
Zolpidem	Ambien®*	Reviewed but not included/recommended – evidence of possible harm				None related to youth	• Hallucinations in children 6-17 have been reported • Complex sleep behaviors possible • Abnormal thinking and behavior changes • Withdrawal effects • Drug abuse and dependence • Tolerance
Benzodiazepines	Alprazolam/ Xanax®* Clonazepam/ Klonopin®* Diazepam/ Valium®* Lorazepam/ Ativan®* Oxazepam/ Serax®* (brand name unavailable) Temazepam/ Restoril®*	Reviewed but not included/recommended – evidence of possible harm/increased incidence of effects and potential for abuse and/or addiction concomitant use with adverse				Risks from opioids	• Withdrawal effects • Drug abuse and dependence • Tolerance • Sedation potential

*Generic Available

References

1. https://hhs.texas.gov/sites/default/files/documents/doing-business-with-hhs/provider-portal/facilities-regulation/psychiatric/psychotropic-medication-utilization-parameters.pdf

2. Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018, H. R. 6, 115th Cong. (2018)3.

Revision Log

Reviews, Revisions, and Approvals	Date	Approval Date
New clinical policy created for WSCC based on directive from State of New Mexico	7/2019	
Approved by WSCC P&T Committee		7/31/2019
Edited hyperlink to 6th version; Edited "Texas DFPS Psychotropic Medication Utilization Parameters for Children and Youth in Foster Care" to "Texas DFPS Psychotropic Medication Utilization Parameters for Children and Youth in Texas Public Behavioral Health". Added other diagnoses/indications section to refer to CP.PMN.53. Edited References to updated 6th version. Added Appendix B that lists the drug tables as provided by Texas DFPS Psychotropic Medication Utilization Parameters for Children and Youth in Texas Public Behavioral Health (6th Version)	9/24/2019	
Approved by NM WSCC P&T Committee		10/9/2019
Annual review completed and approved by WSCC P&T Committee.		7/8/2020
No clinically significant updates. Annual review completed and approved by WSCC P&T Committee.		7/14/2021
No clinically significant updates. References reviewed. Annual review completed and approved by WSCC P&T Committee.		7/13/2022