

Medically Accepted Indications for Pediatric Use of Psychotropic Medications

by

The Law Project for Psychiatric Rights (PsychRights®)

DRAFT

Drug	Indication (diagnosis)	FDA Approval	DRUGDEX Support for Off-Label Use	DRUGDEX Recommendation Level
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Key:

White Background: Medically Accepted Indication
Yellow Background: Medically Accepted Indication Status Not Ascertained
Orange Background: Pediatric Indication cited, but not supported by DRUGDEX
Red Background: No Pediatric FDA Approval or DRUGDEX citation

Abilify (Aripiprazole) - Antipsychotic				
	Bipolar I Disorder - Adjunctive therapy with lithium or valproate for Acute Manic or Mixed Episodes	Yes (for 10 yrs old and up)		
	Bipolar I Disorder, monotherapy, Manic or Mixed Episodes	Yes (for 10-17 years old re acute therapy)		
	Schizophrenia	Yes (for 13-17 years old)		
Adderall (amphetamine/dextroamphetamine) - Central Nervous System Agent; CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 3 years old and up re: [immediate-release] and 6 years old and up re: [extended-release] drug)		
	Narcolepsy	Yes (for 6 years old and up re: [immediate release] drug)		
Anafranil (clomipramine) - Antidepressant; Antidepressant, Tricyclic; Central Nervous System Agent				
	Depression	No		Class IIb
	Obsessive-Compulsive Disorder	Yes (for 10 years and up)		
Clorazil (clozapine) – Antipsychotic; Dibenzodiazepine				
	Bipolar I Disorder	No		Class IIb
	Schizophrenia, Treatment Resistant	No		cited, with no recommendation level
Concerta (methylphenidate) - Amphetamine Related; Central Nervous System Agent; CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old to 12 years old)		
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old and up) re ConcertaR		
	Autistic Disorder	No		Class IIb
	Impaired Cognition - in/ding related to coordination/ in coordination	No		Class IIb
	Schizophrenia	No		Class III
	Traumatic Brain Injury	No		Class IIb
Cymbalta (duloxetine) - Antidepressant; Central Nervous System Agent; Neuropathic Pain Agent; Serotonin/Norepinephrine Reuptake Inhibitor				
Depakote (valproic acid) – Anticonvulsant; Antimigraine; Valproic Acid (class)				
	Absence Seizure, Simple and Complex and/or Complex Partial Epileptic Seizure	Yes (10 years and older)		
	Mania	No		Class III
	Mental Disorder - Mood Disorder	No		Class IIb
	Chorea	No		Class IIb

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Dexedrine (dextroamphetamine) - Amphetamine (class); CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 3 years to 16 years old (immediate-release) and age 6 years to 16 years old (sustained-release))		
	Narcolepsy	Yes (for 6 years old and up)		
Desyrel (trazodone) - Antidepressant; Triazolopyridine				
Effexor (venlafaxine) – Antidepressant; Antidepressant, Bicyclic; Phenethylamine (class); Serotonin/ Norepinephrine Reuptake Inhibitor				
	Attention Deficit Hyperactivity Disorder (ADHD)	No		Class IIb
	Generalized Anxiety Disorder	No		Class IIb
	Major Depressive Disorder	No		Class IIb
	Severe Major Depression with Psychotic Features	"See Drug Consult Reference: PSYCHOTIC DEPRESSION - DRUG THERAPY"		
	Social Phobia	No		Class IIb
Focalin (dexamethylphenidate) - Amphetamine Related; CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years and older)		
Geodon (ziprasidone) - Antipsychotic; Benzisothiazoyl				
Haldol (haloperidol) - Antipsychotic; Butyrophenone; Dopamine Antagonis				
	Agitation	No		Class IIb
	Hyperactive Behavior, (Short-term treatment) after failure to respond to non-antipsychotic medication and psychotherapy	Yes (for 3 years old and up)	It does not appear the injectible form (decanoate) is FDA approved for any pediatric use. DRUGDEX says safety and efficacy not established.	
	Problematic Behavior in Children (Severe), With failure to respond non-antipsychotic medication or psychotherapy	Yes (for 3 years old and up)		
	Psychotic Disorder	Yes (for 3 years old and up but ORAL formulations only)		
	Schizophrenia	Yes (for 3 years old and up but ORAL formulations only)		
Invega (paliperidone) - Antipsychotic; Benzisoxazole				
Lamictal (lamotrigine) - Anticonvulsant; Phenyltriazine				
	Bipolar Disorder, Depressed Phase	No		Class IIb
	Epilepsy, Refractory	No	Class IIa	
Lexapro (escitalopram)- Antianxiety, Antidepressant, Serotonin Reuptake Inhibitor				
	Major Depressive Disorder	Yes (for 12 years old and up)		
Luvox (fluvoxamine) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor				
	Asperger's Disorder	No		Class IIb
	Obsessive-Compulsive Disorder	Yes (for 8 years old and up and immediate release formula only)		
	Severe Major Depression with Psychotic Features	"See Drug Consult Reference: PSYCHOTIC DEPRESSION - DRUG THERAPY"		

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Mellaril (thioridazine) - Antipsychotic; Phenothiazine; Piperidine	Behavioral Syndrome	No		Class III
	Schizophrenia, Refractory	Yes		
Orap (pimozide) - Antipsychotic; Diphenylbutylpiperidine; Dopamine Antagonist				
Paxil (paroxetine) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor				
Prozac (fluoxetine) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor	Anxiety Disorder of Childhood	No		Class IIb
	Major Depressive Disorder	Yes (for 8 years old and up)		
	Obsessive-Compulsive Disorder	Yes (for 7 years old and up)		
	Severe Major Depression with Psychotic Features	"See Drug Consult Reference: PSYCHOTIC DEPRESSION - DRUG THERAPY"		
Ritalin (methylphenidate) - Amphetamine Related; Central Nervous System Agent; CNS Stimulant	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years to 12 years old)(extended release)		
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old and up)(immediate release)		
	Narcolepsy	Yes (for 6 years and up, and Ritalin(R) -SR only)		
	Schizophrenia	No		Class III
	Traumatic Brain Injury	No		Class IIb
Risperdal (risperidone) - Antipsychotic; Benzisoxazole	Autistic Disorder – Irritability	Yes (for 5 years old and up)		
	Bipolar I Disorder	Yes (for 10 years old and up)		
	Schizophrenia	Yes (for 13 years old and up, ORALLY)		
Seroquel (QUETIAPINE) - Antipsychotic; Dibenzothiazepine	Schizophrenia	No		Class IIb
Sinequan (doxepin) - Antianxiety Antidepressant; Antidepressant, Tricyclic; Antiulcer Dermatological Agent	Alcoholism - Anxiety – Depression	Yes (for 12 years old and up)		
	Anxiety – Depression	Yes (for 12 years old and up)		
	Anxiety - Depression - Psychoneurotic personality disorder	Yes (for 12 years old and up)		

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Strattera (atomoxetine) - Central Nervous System Agent; Norepinephrine Reuptake Inhibitor				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old and up)		
	Attention Deficit Hyperactivity Disorder (ADHD) - Social phobia	No		Class IIb
Symbyax (fluoxetine hydrochloride/olanzapine) - Antidepressant; Antipsychotic				
Tegretol (carbamazepine) - Anticonvulsant; Antimanic; Dibenzazepine Carboxamide; Neuropathic Pain Agent				
	Epilepsy, Partial, Generalized, and Mixed types	Yes		
	Migraine; Prophylaxis			Class IIb
	Neuropathy, General			Class IIb
Tofranil (imipramine) - Antidepressant; Antidepressant, Tricyclic; Urinary Enuresis Agent				
	Attention Deficit Hyperactivity Disorder (ADHD), Predominantly Inattentive Type	No		Class IIb
	Depression	No		Class IIb
	Nocturnal enuresis	Yes (for 6 years old and up)		
	Separation Anxiety Disorder of Childhood	No		Class III
	Schizophrenia, Adjunct	No		Class III
Trileptal (oxcarbazepine) - Anticonvulsant; Dibenzazepine Carboxamide				
	Partial Seizure, monotherapy	Yes (for 4 years old and up)		
	Partial seizure; Adjunct	Yes (for 2 years old and up)		
Vyvanse (lisdexamfetamine) - Amphetamine (class); CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old to 12 years)		
Zoloft (sertraline) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor				
	Obsessive-Compulsive Disorder	Yes (6 years old and up)		
	Anorexia nervosa	No		Class III
	Generalized Anxiety Disorder	No		Class IIb
	Major Depressive Disorder	No		Class IIb
	Severe Major Depression with Psychotic Features	"See Drug Consult Reference: PSYCHOTIC DEPRESSION - DRUG THERAPY"		
Zyprexa (olanzapine) - Antipsychotic; Thienobenzodiazepine				
	Bipolar I Disorder, Acute Mixed or Manic Episodes	No	Class IIa	
	Pervasive Developmental Disorder	No		Class IIb
	Schizophrenia	No		Class IIb
	Schizophrenia, Refractory	No		Class IIb
	Severe Major Depression with Psychotic Features	"See Drug Consult Reference: PSYCHOTIC DEPRESSION - DRUG THERAPY"		

RECOMMENDATION, EVIDENCE AND EFFICACY RATINGS

RESPONSE

The Thomson Efficacy, Strength of Evidence and Strength of Recommendation definitions are outlined below:

Table 1. Strength Of Recommendation		
Class I	Recommended	The given test or treatment has been proven to be useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test, or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended, In Some Cases	The given test, or treatment may be useful, and is indicated in some, but not most, cases.
Class III	Not Recommended	The given test, or treatment is not useful, and should be avoided.
Class Indeterminant	Evidence Inconclusive	

Table 2. Strength Of Evidence	
Category A	Category A evidence is based on data derived from: Meta-analyses of randomized controlled trials with homogeneity with regard to the directions and degrees of results between individual studies. Multiple, well-done randomized clinical trials involving large numbers of patients.
Category B	Category B evidence is based on data derived from: Meta-analyses of randomized controlled trials with conflicting conclusions with regard to the directions and degrees of results between individual studies. Randomized controlled trials that involved small numbers of patients or had significant methodological flaws (e.g., bias, drop-out rate, flawed analysis, etc.). Nonrandomized studies (e.g., cohort studies, case-control studies, observational studies).
Category C	Category C evidence is based on data derived from: Expert opinion or consensus, case reports or case series.
No Evidence	

Table 3. Efficacy		
Class I	Effective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is effective
Class IIa	Evidence Favors Efficacy	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion favors efficacy.
Class IIb	Evidence is Inconclusive	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion argues against efficacy.
Class III	Ineffective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is ineffective.