

Medically Accepted Indications for Pediatric Use of Certain Psychotropic Medications by The Law Project for Psychiatric Rights (PsychRights®)

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

| | |
|-------------|--|
| Key: | White Background: Medically Accepted Indication |
| | Orange Background: Pediatric Indication cited, but not supported by DRUGDEX |
| | Red Background: No Pediatric FDA Approval or DRUGDEX citation |

| | | | | |
|--|---|---|-----------|-----------|
| Abilify (Aripiprazole) - Antipsychotic | | | | |
| | Autistic disorder-Psychomotor agitation | Yes (6-17) | | |
| | 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 3-16 years old and up re: [immediate-release] and 6-16 years old and up re: [extended-release] drug) | | |
| | Narcolepsy | Yes (for 6 years old and up (immediate release only)) | | |
| Ambien (zolpidem) - nonbarbiturate Hypnotic | | | | |
| | Insomnia, Short-term treatment | No | | Class III |
| Anafranil (clomipramine) - Antidepressant; Antidepressant, Tricyclic; Central Nervous System Agent | | | | |
| | Obsessive-Compulsive Disorder | Yes (for 10 years and up) | | |
| | Depression | No | | Class IIb |
| Ativan (lorazepam) - Antianxiety, Anticonvulsant, Benzodiazepine, Short or Intermediate Acting, Skeletal Muscle Relaxant. | | | | |
| | Anxiety | Yes, oral only, 12 years and older | | |
| | Chemotherapy-induced nausea and vomiting; Prophylaxis | No | Class IIa | |
| | Insomnia, due to anxiety or situational stress | Yes | | |
| | Seizure | No | Class IIa | |
| | Status epilepticus | No | Class IIa | |
| | Premedication for anesthetic procedure | No | | Class IIb |
| | Sedation | No | | Class IIb |
| | Seizure, drug-induced; Prophylaxis | No | | Class IIb |
| Buspar (buspirone) - Antianxiety, Azaspirodeconedione | | | | |
| | Anxiety | No | | Class III |
| | Autistic disorder | No | | Class IIb |
| | Behavioral syndrome | No | | Class IIb |
| | Pervasive developmental disorder | No | | Class IIb |
| Celexa (citalopram) - Antidepressant, Serotonin Reuptake Inhibitor | | | | |
| | Obsessive-compulsive disorder | No | | Class IIb |
| | Panic disorder | No | | Class IIb |

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| Clozaril (clozapine) – Antipsychotic; Dibenzodiazepine | | | | |
| Concerta (methylphenidate) - Amphetamine Related; Central Nervous System Agent; CNS Stimulant | | | | |
| | Attention Deficit Hyperactivity Disorder (ADHD) | Yes (for 6 years old and up) | | |
| | Narcolepsy | Yes (age 6 and older, immediate release formulations and Ritalin(r)-SR only) | | |
| | Autistic Disorder | No | | Class IIb |
| | Impaired Cognition - Finding related to coordination/ in coordination | No | | Class IIb |
| | Traumatic Brain Injury | No | | Class IIb |
| Cymbalta (duloxetine) - Antidepressant; Central Nervous System Agent; Neuropathic Pain Agent; Serotonin/Norepinephrine Reuptake Inhibitor | | | | |
| Dalmane (flurazepam) - Benzodiazepine, Long Acting, Hypnotic | | | | |
| | Insomnia | Yes, 15 years and older | | |
| Depakote/Depakene (valproate/valproic acid) – Anticonvulsant; Antimigraine; Valproic Acid (class) | | | | |
| | Absence Seizure, Simple and Complex | Yes (10 years and older) | | |
| | Chorea | Yes (10 years and older) | | |
| | Complex Partial Epileptic Seizure | Yes (10 years and older) | | |
| | Seizure, Multiple seizure types; Adjunct | Yes (10 years and older) | | |
| | Bipolar I disorder, Maintenance | No | | Class IIb |
| | Bipolar II disorder, Maintenance | No | | Class IIb |
| | Febrile Seizure | No | | Class IIb |
| | Mania | No | | Class III |
| | Manic bipolar I disorder | No | | Class IIb |
| | Mental Disorder - Mood Disorder | No | | Class IIb |
| | Migraine; Prophylaxis | No | | Class IIb |
| | Status epilepticus | No | | Class IIb |
| | West syndrome | No | | Class IIb |
| Desyrel (trazodone) - Antidepressant; Triazolopyridine | | | | |
| | Migraine, Pediatric; Prophylaxis | No | | Consult |
| 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) | | |
| 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 |
| | 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 | | | | |

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| Haldol (haloperidol) - Antipsychotic; Butyrophenone; Dopamine Antagonis | | | | |
| | Gilles de la Tourette's syndrome | Yes (for 3 years old and up) | It does not appear the injectible form (decanoate) is FDA approved for any pediatric use, nor is it | |
| | Hyperactive Behavior, (Short-term treatment) after failure to respond to non-antipsychotic medication and psychotherapy | Yes (for 3 years old and up) | | |
| | 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, ORAL formulations only) | | |
| | Schizophrenia | Yes (for 3 years old and up, ORAL formulations only) | | |
| Invega (paliperidone) - Antipsychotic; Benzisoxazole | | | | |
| | Schizophrenia | Yes (12-17 years) | | |
| Klonopin (clonazepam) -antianxiety, Anticonvulsant, Bensodiazepine, Short or Intermediate Acting | | | | |
| | Seizure | Yes, upt to 10 years or up to 30 kg | | |
| | Gilles de la Tourette's syndrome | No | | Class IIb |
| | Hyperreflexia | No | | Class IIb |
| | Nocturnal epilepsy | No | | Class IIb |
| | Panic disorder | No | | Class IIb |
| | Status epilepticus | No | | Class IIb |
| Lamictal (lamotrigine) - Anticonvulsant; Phenyltriazine | | | | |
| | Convulsions in the newborn, Intractable | No | | Class IIa |
| | Epilepsy, Refractory | No | | Class IIa |
| | Lennox-Gastaut syndrome; Adjunct | yes (2 years and older) | | |
| | Partial seizure, Adjunct or monotherapy | yes (13 years and older, extended-release only; 2 years and older, chewable dispersible | | |
| | Tonic-clonic seizure, Primary generalized; Adjunct | yes (2 years and older) | | |
| | Absence seizure; Adjunct | No | | Class IIb |
| | Bipolar Disorder, Depressed Phase | No | | Class IIb |
| | Infantile neuronal ceroid lipofuscinosis | No | | Class IIb |
| | Juvenile myoclonic epilepsy | No | | Class III |
| | Paroxysmal choreoathetosis, Paroxysmal | No | | Class IIb |
| | Rett's disorder | No | | Class IIb |
| | Status epilepticus | No | | Class IIb |
| | West syndrome | No | | Class IIb |
| Lexapro (escitalopram)- Antianxiety, Antidepressant, Serotonin Reuptake Inhibitor | | | | |
| | Major Depressive Disorder | Yes (for 12 years old and up) | | |
| Librium-Limbitrol (chlordiazepoxide/amitriptyline) - Tricyclic Antidepressant/Benzodiazepine Combination | | | | |
| Lunesta (eszopiclone) - Nonbarbiturate Hypnotic | | | | |
| Luvox (fluvoxamine) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor | | | | |
| | Obsessive-Compulsive Disorder | Yes (for 8 years old and up and immediate release formula only) | | |

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| Mellaril (thioridazine) - Antipsychotic; Phenothiazine; Piperidine | | | | |
| | Schizophrenia, Refractory | Yes | | |
| | Behavioral Syndrome | No | | Class III |
| Moban (molindone) - antipsychotic, Dihydroindolone | | | | |
| | Schizophrenia | Yes, 12 years and older | | |
| | Aggressive behavior, In children | No | | Class IIb |
| Neurontin (gabapentin) anticonvulsant | | | | |
| | Partial seizure; Adjunct | Yes (3- 12 years old, Neurontin only) | | |
| Orap (pimozide) - Antipsychotic; Diphenylbutylpiperidine; Dopamine Antagonist | | | | |
| | Gilles de la Tourette's syndrome | Yes (12 years and older) | | |
| | Anorexia Nervosa | No | | Class III |
| Paxil (paroxetine) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor | | | | |
| | Social Phobia | No | Class IIa | |
| | Obsessive-compulsive disorder | No | | Class IIb |
| | Panic disorder | No | | Class IIb |
| Pristiq (desvenlafaxine) Antidepressant, Serotonin/Norepinephrine Reuptake Inhibitor | | | | |
| Prozac (fluoxetine) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor | | | | |
| | Major Depressive Disorder | Yes (for 8 years old and up) | | |
| | Obsessive-Compulsive Disorder | Yes (for 7 years old and up) | | |
| | Anxiety Disorder of Childhood | No | | Class IIb |
| | Bulimia nervosa | No | | Class IIb |
| | Vasovagal syncope; Prophylaxis | No | | Class III |
| Restoril (temazepam) - Antianxiety, Benzodiazepine, Short or Intermediate Acting, Hypnotic | | | | |
| 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) | | |
| | Behavioral syndrome - Mental retardation | No | | Class IIb |
| | Pervasive developmental disorder | No | | Class IIb |
| Ritalin (methylphenidate) - Amphetamine Related; Central Nervous System Agent; CNS Stimulant | | | | |
| | Attention Deficit Hyperactivity Disorder (ADHD) | Yes (6 to 17 years (immediate release) | | |
| | Attention Deficit Hyperactivity Disorder (ADHD) | Yes (for 6 years & up) (extended release) | | |
| | Narcolepsy | Yes (for 6 and up, and Ritalin(R) -SR only) | | |
| | Autistic disorder | No | | Class III |
| | Finding related to coordination / incoordination - Impaired cognition | No | | Class IIb |
| | Traumatic Brain Injury | No | | Class IIb |
| Rozerem (ramelteon) - Melatonin Receptor Agonist, Nonbarbiturate Hypnotic | | | | |
| Saphris (asenapine) - neuroleptic | | | | |
| Seroquel (QUETIAPINE) - Antipsychotic; Dibenzothiazepine | | | | |
| | Manic bipolar I disorder Monotherapy in acute management | Yes, 10-17 regular release only (12/4/09) | | |
| | Schizophrenia | Yes 13-17, regular release only (12/4/09) | | |

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| 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) | | |
| | Pruritus (Moderate), Due to atopic dermatitis or lichen simplex chronicus | No | | Class IIb |
| Sonata (zaleplon) - Nonbarbiturate Hypnotic | | | | |
| 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 | | | | |
| | Bipolar disorder, depressed state | Yes (10 to 17 years of age) | | |
| Tegretol (carbamazepine) - Anticonvulsant; Antimanic; Dibenzazepine Carboxamide; Neuropathic Pain Agent | | | | |
| | Epilepsy, Partial, Generalized, and Mixed types | Yes | | |
| | Chorea | | | Class IIb |
| | Migraine; Prophylaxis | | | Class IIb |
| | Myokymia | | | Class IIb |
| | Neuropathy, General | | | Class IIb |
| | Schwartz-Jampel syndrome | | | Class IIb |
| Tofranil (imipramine) - Antidepressant; Antidepressant, Tricyclic; Urinary Enuresis Agent | | | | |
| | Nocturnal enuresis | Yes (for 6 years old and up) | | |
| | Attention Deficit Hyperactivity Disorder (ADHD), Predominantly Inattentive Type | No | | Class III |
| | Depression | No | | Class IIb |
| | Schizophrenia, Adjunct | No | | Class III |
| | Separation Anxiety Disorder of Childhood | No | | Class III |
| | Trichotillomania | No | | Class IIb |
| | Urinary incontinence | No | | Class IIb |
| Topamax (topiramate) - anticonvulsant, Fructopyranose Sulfamate | | | | |
| | Lennox-Gastaut syndrome; Adjunct | Yes, 2 years and older Topomax; Trokendi XR 6 years or older | | |
| | Partial seizure, Initial monotherapy | Yes, 10 years and older | | |
| | Partial seizure; Adjunct | Yes, 2 years and older Topomax; Trokendi XR 6 years or older | | |
| | Tonic-clonic seizure, Primary generalized; Adjunct | Yes, 2 years and older Topomax; Trokendi XR 6 years or older | | |
| | Tonic-clonic seizure, Primary generalized (initial monotherapy) | Yes, 2 years and older Topomax; Trokendi XR 6 years or older | | |
| | Migraine; Prophylaxis | No | | Class IIb |
| Tranxene (clorazepate) - Antianxiety, Anticonvulsant, Benzodiazepine, Long Acting | | | | |
| | Partial seizure; Adjunct | Yes, 9 years and older | | |
| | Epilepsy | No | | Class IIb |
| 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) | | |

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| Valium (diazepam) - antianxiety, anticonvulsant, skeletal muscle relaxant | | | | |
| | Anxiety | Yes, 6 months & older- oral | | |
| | Seizure, Refractory, increased frequency | Yes, 2 years & older (rectal gel) | | |
| | Seizure, Adjunct. | Yes (6 months and older (oral); greater than 30 days (injectable); 2 years and older (rectal)) | | |
| | Skeletal muscle spasm; Adjunct | Yes, (6 months & older (oral)) | | |
| | Skeletal muscle spasm - Tetanus | Yes, (greater than 30 days (injectable)) | | |
| | Status epilepticus | Yes, (greater than 30 days (injectable only)) | | |
| | Febrile Seizure | No | | Class IIb |
| | Sedation, Premedication before surgery, endoscopic procedure and cardioversion | No | | Class IIb |
| Vyvanse (lisdexamfetamine) - Amphetamine (class); CNS Stimulant | | | | |
| | Attention Deficit Hyperactivity Disorder (ADHD) | Yes (for 6 years old to 17 years) | | |
| Wellbutrin (bupropion) - Aminoketone, Antidepressant, Smoking Cessation Agent | | | | |
| Xanax (alprazolam) - Antianxiety, Benzodiazepine, Short or Intermediate Acting | | | | |
| 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 |
| Zyprexa (olanzapine) - Antipsychotic; Thienobenzodiazepine | | | | |
| | Bipolar 1, Disorder, Acute Mixed or Manic Episodes | Yes (ages 13-17), oral formulations only | | |
| | Schizophrenia | Yes (ages 13-17), oral formulations only | | |

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. |