Stimulant and Related Medications: Use in Pediatric Patients

The Centers for Medicare & Medicaid Services (CMS), Medicaid Integrity Group (MIG) has identified issues with the utilization of stimulant and related medications. The U.S. Food and Drug Administration (FDA) approves product labeling for prescription drugs. The MIG has identified that some providers may have prescribed stimulant and related medications outside of FDA-approved product labeling for indication, age, dosage, or duration of therapy. Therefore, CMS's goal is to improve quality of care and enhance patient safety by educating providers on the proper use of stimulant and related medications in pediatric patients.

This fact sheet summarizes for providers the current FDA-approved product labeling for the use of stimulant and related medications in pediatric patients. After reading this fact sheet, providers should be able to accurately:

- Identify the FDA-approved indications for the use of stimulant and related medications in pediatric patients;
- Identify the available treatment guidelines for the management of attention-deficit/hyperactivity disorder (ADHD) in pediatric patients; and
- Summarize the adverse reactions and risks of using stimulant and related medications in pediatric patients.

Defining Pediatric Patients

For the purpose of this document, the term "pediatric patients" collectively includes infants, children, and adolescents younger than 18 years old. Infants are further defined to be any patient younger than one year old.

The literature on stimulant and related medications does not have well-defined age ranges for pediatric patients. Some studies define children as patients 1 to 12 years old and adolescents as patients 13 to 17 years old. Other studies define children as patients 1 to 17 years old. The ages of the patients were also inconsistent in the clinical trials conducted for medication approval. This inconsistency is reflected in the age ranges in Figure 1 and in the dosing table in the document "Stimulant and Related Medications: U.S. Food and Drug Administration-Approved Indications and Dosages for Use in Pediatric Patients."

FDA-Approved Pediatric Indications for Stimulant and Related Medications

Stimulant and related medications are FDA approved for the treatment of ADHD, narcolepsy, and exogenous obesity (a body mass index [BMI] at or above the 95th percentile for children of the same age and sex[1]) in pediatric patients. However, not all of the medications in this drug class are approved for each indication. Stimulant and related medications are most often used for the treatment of ADHD. The FDA-approved indications and age ranges for the use of stimulant and related medications in pediatric patients are provided in Figure 1 below.

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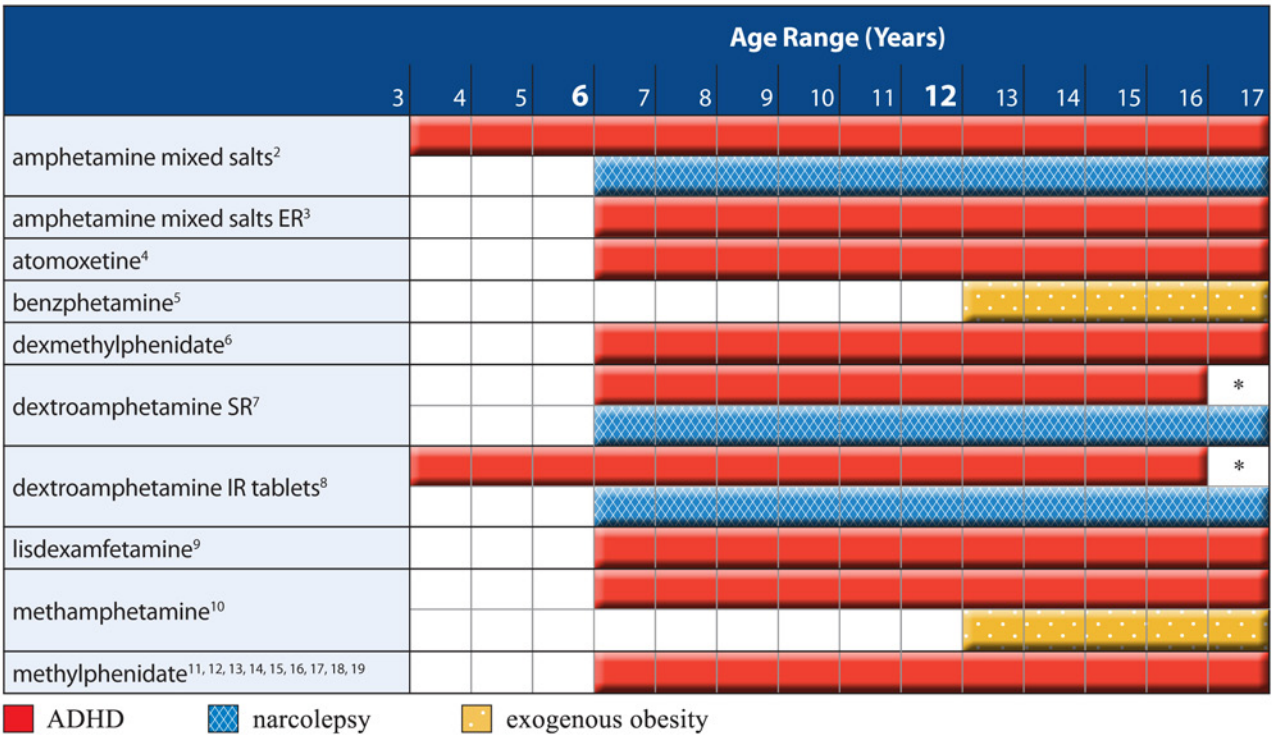
Figure 1. FDA-Approved Pediatric Age Ranges and Indications for Stimulant and Related Medications



ER = extended-release IR = immediate-release SR = sustained-release

* Dextroamphetamine and dextroamphetamine extended-release (Dexedrine® Spansules®) are not approved for the treatment of ADHD in patients older than 16 years old.

Diagnosing Attention-Deficit/Hyperactivity Disorder

It is important that a diagnosis for ADHD be established prior to starting medication therapy. The criteria for the diagnosis of ADHD are defined in the "Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR)." The American Academy of Pediatrics (AAP) states that information about the patient's behavior should be obtained from family members, teachers, coaches, and other caregivers.[20] The criteria for the diagnosis of ADHD can be found at http://www.cdc.gov/ncbddd/adhd/diagnosis.html on the Centers for Disease Control and Prevention (CDC) website.

Medications for the Treatment of Attention-Deficit/Hyperactivity Disorder in Pediatric Patients

Stimulant medications have been the mainstay of treatment for ADHD since the late 1930s.[21] Other nonstimulant medications, such as atomoxetine, extended-release clonidine, and extended-release guanfacine, are also FDA approved for the treatment of ADHD in pediatric patients. The FDA-approved indications and dosages for the stimulant and related medications are provided in the document "Stimulant and Related Medications: U.S. Food and Drug Administration-Approved Indications and Dosages for Use in Pediatric Patients."

ACRONYMS	
AACAP	American Academy of Child and Adolescent Psychiatry
AAP	American Academy of Pediatrics
ADHD	attention-deficit/ hyperactivity disorder
AHRQ	Agency for Healthcare Research and Quality
BMI	body mass index
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CMS	Centers for Medicare & Medicaid Services
DSM-IV-TR	Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision
FDA	U.S. Food and Drug Administration
MIG	Medicaid Integrity Group
OTC	over the counter

Stimulant Medications

The exact mechanism by which stimulant medications exert their effects in ADHD is unknown. They are thought to work by increasing the neurotransmission of dopamine and norepinephrine.[22, 23] Stimulant medications come in multiple dosage forms and strengths and are equally effective in the treatment of ADHD; however, individual response may vary.[24]

Treatment in older children and adolescents may be initiated with either a short-acting or long-acting stimulant medication. The short-acting stimulant medications may be easily titrated to dosages that produce symptom relief with manageable adverse reactions. They are often used as the initial treatment for children weighing less than 16 kg.

Atomoxetine

Atomoxetine was the first nonstimulant approved by the FDA for the treatment of ADHD[25] and is an option for patients who cannot take a stimulant medication. It inhibits presynaptic norepinephrine transport, which is thought to be the mechanism responsible for the therapeutic effects in ADHD, and studies have shown it is superior to placebo in the treatment of ADHD. Atomoxetine is not a controlled substance so it has a lower potential for substance abuse. It also has a long duration of action, which allows for once-a-day dosing.[26]

Treatment Guidelines for Attention-Deficit/Hyperactivity Disorder

The standard of care for the treatment of ADHD is determined by guidelines. Two of the treatment guidelines most often used in clinical practice were developed by the AAP and the American Academy of Child and Adolescent Psychiatry (AACAP). Other organizations and healthcare systems have also developed guidelines focused on the treatment of ADHD in children and adolescents. Please search "ADHD" in the National Guideline Clearinghouse database at http://www.guideline.gov for information on some of the ADHD guidelines. The database is hosted by the Agency for Healthcare Research and Quality (AHRQ), a branch of the U.S. Department of Health and Human Services. Some of the treatment guidelines for the use of stimulant and related medications in pediatric patients are provided in Table 1 below.

Table 1. Treatment Guidelines for the Use of Stimulant and Related Medications in Pediatric Patients

Sponsoring Organization	Title of Guideline	Link to Guideline
American Academy of Child and Adolescent Psychiatry	Practice parameter for the assessment and treatment of children and adolescents with attention-deficit/hyperactivity disorder.	http://www.guideline.gov/content.aspx?id=11375
American Academy of Pediatrics	ADHD: Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents.	http://www.cdc.gov/ncbddd/adhd/guidelines.html

Adverse Reactions and Risks of the Use of Stimulant and Related Medications in Pediatric Patients

Stimulant and related medications are generally well tolerated. The most common adverse reactions to stimulant and related medications are loss of appetite, upset stomach, insomnia, and headache. Other less common adverse effects include rebound irritability, dysphoria, agitation, tics, and growth impairment.[27, 28, 29] Because of the warnings associated with stimulant and related medications, the risks must be weighed against the potential benefits before they are prescribed to pediatric patients.

Patients may experience increases in heart rate and blood pressure as a result of the sympathomimetic properties of stimulant medications. Atomoxetine has been reported to cause a mild increase in blood pressure, which usually persists during treatment and resolves with discontinuation.

Cardiovascular Risks of Stimulant Medications and with Atomoxetine

Sudden death, stroke, and myocardial infarction have been reported with stimulant medications and with atomoxetine. Patients should have a medical history and physical exam conducted prior to the initiation of therapy to assess cardiac disease (including family history of sudden cardiac death), family history of ventricular arrhythmia, or structural cardiac abnormalities. Patients with preexisting cardiac conditions should avoid the use of stimulant medications and the use of atomoxetine. The manufacturers of stimulant and related medications recommend a cardiac evaluation for any patient who presents with cardiac symptoms.[30, 31]

The FDA and AHRQ sponsored a study on the cardiovascular risks associated with ADHD medications in children and young adults (2 to 24 years old). More than 1.2 million patient records were evaluated. Results showed no association between the use of stimulant medications and adverse cardiovascular events. However, the FDA recommends periodic monitoring of heart rate and blood pressure and recommends avoiding the use of stimulant medications in patients with serious heart problems.[32]

In 2007, the FDA instructed the manufacturers of medications approved for the treatment of ADHD to develop Medication Guides to be dispensed with every new or refilled prescription. The Medication Guides inform patients, families, and caregivers about the possible cardiovascular risks and the precautions that may be taken to minimize the cardiovascular risks.[33]

Risk of Psychiatric Adverse Events

An FDA review of stimulant medications showed an increase in the risk of medication-related psychiatric events, such as hearing voices or experiencing mania. The previously mentioned Medication Guides also inform patients, families, and caregivers about the risks of adverse psychiatric symptoms associated with stimulant and related medications.[34]

Growth Suppression

Growth suppression with long-term use of stimulant medications is an area of controversy. Studies have shown mixed results. A follow-up study on amphetamines suggests that children who are continuously treated with the medication experience a temporary decrease in growth rate.[35] In two studies referenced in a Surgeon General report, there were no long-term effects of stimulant medications on height or weight.[36]

Abuse of Stimulant Medications

Stimulant medications have significant abuse potential. Prescribing information warns of the high potential for abuse and also warns that extended use may lead to drug dependence. Stimulant medications with an FDA-approved indication should only be taken by patients for whom they have been prescribed.[37] A boxed warning has been added to stimulant medications due to their high potential for dependence and abuse.

The boxed warning for methylphenidate and methylphenidate derivatives is similar to the boxed warning for amphetamines. However, it informs providers to use caution when prescribing methylphenidate to patients with a history of drug dependence or alcoholism.

The boxed warning for amphetamine and amphetamine derivatives states:[38]

AMPHETAMINES HAVE A HIGH POTENTIAL FOR ABUSE. ADMINISTRATION OF AMPHETAMINES FOR PROLONGED PERIODS OF TIME MAY LEAD TO DRUG DEPENDENCE AND MUST BE AVOIDED. PARTICULAR ATTENTION SHOULD BE PAID TO THE POSSIBILITY OF SUBJECTS OBTAINING AMPHETAMINES FOR NONTHERAPEUTIC USE OR DISTRIBUTION TO OTHERS, AND THE DRUGS SHOULD BE PRESCRIBED OR DISPENSED SPARINGLY.

MISUSE OF AMPHETAMINE MAY CAUSE SUDDEN DEATH AND SERIOUS CARDIOVASCULAR ADVERSE EVENTS.

The boxed warning for one of the methylphenidate medications, which is very similar to the warnings for other methylphenidate medications, states:[39]

DRUG DEPENDENCE

CONCERTA® should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during withdrawal from abusive use since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up.

Hepatotoxicity with Atomoxetine

Atomoxetine has been shown to cause severe liver injury manifested by significantly elevated bilirubin concentrations and hepatic enzymes. Prescribing information states: **"STRATTERA should be discontinued in patients with jaundice or laboratory evidence of liver injury, and should not be restarted."**[40] This bolded warning was added after two patients were reported to have developed severe liver injuries which resolved after the medication was discontinued.[41]

Suicidality with Atomoxetine

An increased risk of suicidality (suicidal thinking and behavior) in children and adolescents has been identified through an analysis of placebo-controlled trials that included more than 2,200 patients. There was an increased risk of suicidal thinking in patients treated with atomoxetine. As a result of this analysis, a boxed warning was added to the product information for atomoxetine.[42]

The FDA also requires that a Medication Guide be dispensed with every new or refilled prescription for atomoxetine. The Medication Guide informs patients, families, and caregivers about the increased risk of suicidal thinking and behavior with atomoxetine.[43]

The boxed warning for atomoxetine states:[44]

WARNING: SUICIDAL IDEATION IN CHILDREN AND ADOLESCENTS

STRATTERA (atomoxetine) increased the risk of suicidal ideation in short-term studies in children or adolescents with Attention-Deficit/Hyperactivity Disorder (ADHD). Anyone considering the use of STRATTERA in a child or adolescent must balance this risk with the clinical need. Co-morbidities occurring with ADHD may be associated with an increase in the risk of suicidal ideation and/or behavior. Patients who are started on therapy should be monitored closely for suicidality (suicidal thinking and behavior), clinical worsening, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. STRATTERA is approved for ADHD in pediatric and adult patients. STRATTERA is not approved for major depressive disorder.

Pooled analyses of short-term (6 to 18 weeks) placebo-controlled trials of STRATTERA in children and adolescents (a total of 12 trials involving over 2200 patients, including 11 trials in ADHD and 1 trial in enuresis) have revealed a greater risk of suicidal ideation early during treatment in those receiving STRATTERA compared to placebo. The average risk of suicidal ideation in patients receiving STRATTERA was 0.4% (5/1357 patients), compared to none in placebo treated patients (851 patients). No suicides occurred in these trials *[see Warnings and Precautions (5.1)]*.

Resources

Please visit http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-State/By-State.html for links to State Medicaid program websites.

The FDA requires that a Medication Guide be issued with some medications to provide patients with information on serious adverse effects and recommendations on how to avoid them. Links to the required Medication Guides can be found at http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm on the FDA website.

A BMI calculator for use with children and teens (from 2 to 19 years old) can be found at http://apps.nccd.cdc.gov/dnpabmi on the CDC website.

The Center for Drug Evaluation and Research (CDER) hosts a website providing health professionals with current information on over-the-counter (OTC) and prescription drugs. Visit http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals to access drug-related databases, information on drug recalls and alerts, current information on new and generic drug approvals, and information on drug safety and availability.

Section 1927(g)(1)(B) of the Social Security Act identifies the predetermined standards that the State's drug use review program must use to assess data on drug use. Visit http://www.ssa.gov/OP_Home/ssact/title19/1927.htm for information on the compendia.

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