Pharmacy Policy Bulletin

Title: Attention Deficit Hyperactivity Disorder Agents
Policy #: Rx.01.12

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:
The intent of this policy is to communicate the medical necessity criteria for clonidine (Kapvay), guanfacine extended release (Intuniv™), methylphenidate transdermal (Daytrana®), Concerta, Dexedrine, Desoxyn, Metadate CD, Ritalin LA, Focalin XR, and Adderall as provided under the member's pharmacy benefit.

Description:
Attention deficit hyperactivity disorder (ADHD) is a neurobehavioral disorder characterized by ongoing patterns of hyperactivity, inattention, and impulsivity. People with ADHD might experience only one symptom or a combination of symptoms throughout their lives. A combined-type ADHD is seen mostly in children that can affect their performance and interfere with daily activities. Many risk factors are associated with this disorder such as genetics, smoking, brain injuries, and exposure to toxic environments. Currently, there are medications that help patients in reducing symptoms and improve their daily functions.

Clonidine (Kapvay®), Guanfacine Extended Release (Intuniv™) and methylphenidate transdermal (Daytrana®), methylphenidate extended-release (Concerta®, Metadate CD®, Ritalin LA®), Dextroamphetamine (Dexedrine®), Methamphetamine (Desoxyn®), Dexamphetamine (Focalin XR®), Dextroamphetamine/Amphetamine (Adderall®) are indicated for the treatment of attention deficit hyperactivity disorder (ADHD).

Clonidine (Kapvay) stimulates alpha adrenergic receptors in the brain. Clonidine is not a central nervous system stimulant and the mechanism of action of clonidine in ADHD is not known.

Guanfacine Extended Release (Intuniv™) is a selective alpha 2A adrenergic receptor agonist.
Guanfacine Extended Release (Intuniv™) is not a central nervous system stimulant and the mechanism of action in ADHD is not known.

Methylphenidate transdermal patch (Daytrana®) is a central nervous system (CNS) stimulant. Its mode of therapeutic action in attention deficit hyperactivity disorder (ADHD) is unknown, but methylphenidate is thought to block the reuptake of norepinephrine and dopamine into the presynaptic neurons and to increase the release of these monoamines into the extraneuronal space. At this time there are no clinical trials showing methylphenidate transdermal patch (Daytrana) to have superior efficacy to other agents used to treat ADHD.

Methylphenidate extended-release (Concerta®, Metadate CD®, Ritalin LA®) is a mild central nervous system (CNS) stimulant. Concerta®, Metadate CD®, Ritalin LA® are indicated for ADHD treatment in patients from 6 years old up to the age of 65. Concerta® uses osmotic pressure to deliver methylphenidate at a controlled rate. Metadate CD® includes immediate-release (IR) and extended-release (ER) beads in 30%/70% ratio. Ritalin LA® contains 50% IR and 50% delayed-release methylphenidate in each capsule. They can be opened and sprinkled on to applesauce for immediate use.

Dextroamphetamine (Dexedrine®) is a sympathomimetic amine of the amphetamine group that has CNS stimulant activity. Dexedrine is not recommended for patients under age of 3. Dose may be adjusted for the pediatric populations.

Methamphetamine (Desoxyn®) is a sympathomimetic amine of the amphetamine group that has CNS stimulant activity. Desoxyn is part of total treatment program for a stabilizing effect in children over 6 years of age who get diagnosed with ADHD.

Dexmethylphenidate extended-release (Focalin XR®), the d-enantiomer of methylphenidate, is a CNS stimulant agent. It can be opened and sprinkled on to applesauce for immediate use. It is indicated for ADHD patients 6 years old and older.

Dextroamphetamine/Amphetamine (Adderall®) is a mixed salt of amphetamine product. It works as a CNS stimulant agent. Pediatric patients less than 3 years old are not recommended to take Adderall. Dose may be adjusted in children from 3 to 5 years of age.

**Policy:**
Clonidine hydrochloride (Kapvay®) or guanfacine hydrochloride (Intuniv®) is approved when there is documentation of a diagnosis of ADHD and BOTH of the following:

1. Inadequate response or inability to tolerate generic clonidine ER or guanfacine ER, respectively; and
2. One of the following
   a. Inadequate response or inability to tolerate any TWO of the following medications:
      
      i. Methylphenidate
      ii. Mixed amphetamine salts (e.g. amphetamine-dextroamphetamine [Adderall or Adderall XR])
      iii. Atomoxetine hydrochloride (Strattera)
      iv. Lisdexamfetamine (Vyvanse®)
      v. Dextroamphetamine
      vi. Methamphetamine hydrochloride (Desoxyn)
      vii. Dexmethylphenidate
   
   b. History of or a potential for drug abuse among the individual or a member of the
Methylphenidate transdermal patch (Daytrana®) is approved when there is documentation of ALL of the following:

1. Diagnosis of attention deficit hyperactivity disorder (ADHD); and
2. Inadequate response or inability to tolerate any TWO of the following agents:
   a. Methylphenidate
   b. Mixed amphetamine salts (e.g. amphetamine-dextroamphetamine [Adderall or Adderall XR])
   c. Atomoxetine hydrochloride (Strattera)
   d. Lisdexamfetamine (Vyvanse®)
   e. Dextroamphetamine
   f. Methamphetamine hydrochloride (Desoxyn)
   g. Dexamphetamine

Concerta, Dexedrine spansule, Desoxyn, Metadate CD, Ritalin LA (20mg, 30mg, 40mg), Focalin XR (5mg, 10mg, 15mg, 20mg, 30mg, 40mg), or Adderall is approved when there is inadequate response or inability to tolerate the generic equivalent of the requested medication.

**Black Box Warning:**

None

**Guidelines:**

Refer to the specific manufacturer’s prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company’s products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**


Desoxyn ®[package insert] Lebanon, NJ: Recordati Rare Disease Inc. 2015. Available at
Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td>Kapvay</td>
<td>Clonidine</td>
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<tr>
<td>Intuniv</td>
<td>Guanfacine</td>
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<tr>
<td>Daytrana</td>
<td>Methylphenidate transdermal patch</td>
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<tr>
<td>Concerta</td>
<td>Methylphenidate tab ER</td>
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<tr>
<td>Dexedrine spansule</td>
<td>Dextroamphetamine sulfate</td>
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<tr>
<td>Desoxyn</td>
<td>Methamphetamine</td>
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<tr>
<td>Metadate CD</td>
<td>Methylphenidate</td>
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<tr>
<td>Ritalin LA 20mg, 30mg, 40mg</td>
<td>Methylphenidate</td>
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<tr>
<td>Focalin XR 5mg, 10mg, 15mg, 20mg, 30mg, 40mg</td>
<td>Dextroamphetamine</td>
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<tr>
<td>Adderall</td>
<td>Dextroamphetamine/amphetamine</td>
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