Central Nervous System Stimulants
Drug Class Prior Authorization Protocol

Line of Business: Medi-Cal
Effective Date: August 16, 2017
Revision Date: August 16, 2017

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutics Subcommittee.

Drugs: Adderall (amphetamine, dextroamphetamine), Adderall XR (amphetamine, dextroamphetamine ER), Adzenys XR-ODT (amphetamine ER-ODT), Aptsensio XR, Concerta, Metadate CD, Metadate ER, Ritalin LA (methylphenidate ER), Cotempla XR-ODT (methylphenidate ER-ODT), Daytrana (methylphenidate transdermal patch), Desoxyn (methylamphetamine), Dexamphetamine, Zenergi (dextroamphetamine), Dexedrine Spansule SR (dextroamphetamine ER), Dyanavel XR (amphetamine ER suspension), Evekeo (amphetamine), Focalin (dexamphetamine), Focalin XR (dexamphetamine ER), Methylin (methylphenidate chewable, oral solution), Procentra (dextroamphetamine oral solution), QuillChew ER (methylphenidate ER chewable), Quillivant XR (methylphenidate ER oral suspension), Ritalin (methylphenidate), Vyvanse (lisdexamfetamine)

FDA Approved Indications:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Adults</th>
<th>Pediatrics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ADHD</td>
<td>Narcolepsy</td>
</tr>
<tr>
<td>Adderall, Adderall XR</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Evekeo</td>
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<tr>
<td>Adzenys XR-ODT, Aptsensio XR, Concerta, Dyanavel XR, Metadate CD, Ritalin LA, Cotempla XR-ODT, Daytrana, QuillChew ER, Quillivant XR</td>
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<td></td>
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<tr>
<td>Methylin, Ritalin, Metadate ER</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Daytrana</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Desoxyn</td>
<td>✓</td>
<td>Obesity</td>
</tr>
<tr>
<td>Dexedrine, Zenergi, Procentra</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Dexedrine Spansule SR</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Focalin, Focalin XR</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>
**Vyvanse**

**Policy/Criteria:**

* Generic-mandatory protocol applies. Please refer to the Brand Name Drug Request Policy.

**A. Drugs:** Adderall (amphetamine, dextroamphetamine)*, Adderall XR (amphetamine, dextroamphetamine ER)*, Concerta, Metadate CD, Metadate ER (methylphenidate ER), Dexedrine, Zenzedi (dextroamphetamine)*, Dexedrine Spansule SR (dextroamphetamine ER)*, Focalin (dexamphetamine)*, Focalin XR (dexamphetamine ER)*

**Diagnosis:**

a. FDA-approved indication(s)

**Specialist:** No restriction

**Criteria:**

a. Confirmed diagnosis

**Formulary Status:** Formulary, Age-Edit applies (18 or older)

**B. Drugs:** Adzenys XR-ODT (amphetamine ER-ODT), Cotempla XR-ODT (methylphenidate ER-ODT), Daytrana (methylphenidate transdermal patch), Dyanavel XR suspension (amphetamine ER suspension), QuilliChew ER (methylphenidate ER chewable), Quillivant XR (methylphenidate ER oral suspension)

**Diagnosis:**

a. Diagnosis of ADHD

**Specialist:** No restriction

**Criteria:**

a. ONE of the following:

i. Administration via feeding tube or documented difficulty swallowing (i.e. dysphagia)

1. Failure or clinically significant adverse effects to one of the preferred sprinkling capsules: Metadate CD or Ritalin LA

OR

ii. Failure or clinically significant adverse effects to at least two formulary long-acting stimulants (e.g. Adderall XR, Concerta, Dexedrine Spansule SR, Focalin XR, Metadate CD, Metadate ER)

**Formulary Status:** Non-formulary, PA applies

**C. Drugs:** Aptensio XR (methylphenidate ER), Ritalin LA (methylphenidate)

**Diagnosis:**
a. Diagnosis of ADHD

**Specialist:** No restriction

**Criteria:**

a. Failure or clinically significant adverse effects to at least two formulary long-acting stimulants (e.g. Adderall XR, Concerta, Dexedrine Spansule SR, Focalin XR, Metadate CD, Metadate ER)

**Formulary Status:** Non-formulary, PA applies

**D. Drug: Desoxyn** (methamphetamine)*

**Diagnosis:**

a. Diagnosis of ADHD (pediatrics: children ≥ 6 years old and adolescents)  
OR
b. Diagnosis of Obesity

**Specialist:** Psychiatrist (ADHD only)

**Criteria:**

a. ADHD:
   i. Failure or clinically adverse effects to at least one long acting formulary stimulant (e.g. Adderall XR, Concerta, Dexedrine Spansule SR, Focalin XR, Metadate CD, Metadate ER) and two additional formulary stimulants  
   AND
   ii. Prescribed by a psychiatrist
b. Obesity:
   i. Must meet BMI criteria (please see the anti-obesity drug class prior authorization protocol)  
   AND
   ii. Failure or clinically adverse effects to orlistat, phentermine and diethylpropion

**Formulary Status:** Non-formulary, PA applies

**E. Drug: Evekeo** (amphetamine)

**Diagnosis:**

a. Diagnosis of ADHD or Narcolepsy  
OR
b. Diagnosis of Obesity

**Specialist:** No restriction

**Criteria:**

a. ADHD or Narcolepsy:
i. Failure or clinically adverse effects to at least two formulary stimulants (see part A)
b. Obesity:
   i. Must meet BMI criteria (please see the anti-obesity drug class prior authorization protocol) AND
   ii. Failure or clinically adverse effects to orlistat, phentermine and diethylpropion

Formulary Status: Non-formulary, PA applies

F. Drugs: Methylin (methylphenidate chewable, oral solution), Procentra (dextroamphetamine oral solution)*

Diagnosis:
   a. Diagnosis of ADHD

Specialist: No restriction

Criteria:
   a. ONE of following:
      i. Administration via feeding tube or documented difficulty swallowing (i.e. dysphagia)
      OR
      ii. Failure or clinically significant adverse effects to one of the preferred sprinkling capsule: Metadate CD or Ritalin LA
      OR
      iii. Failure or clinically significant adverse effects to two formulary stimulants (see part A)
   b. Diagnosis of Narcolepsy and ONE of following:
      i. Administration via feeding tube or documented difficulty swallowing (i.e. dysphagia)
      OR
      ii. Failure or clinically significant adverse effects to two formulary stimulants (see part A)

Formulary Status: Non-formulary, PA applies

G. Drug: Vyvanse (lisdexamfetamine)

Diagnosis:
   a. Diagnosis of ADHD OR
   b. Diagnosis of Binge Eating Disorder (adults only)

Specialist: No restriction

Criteria:
a. ADHD:
   i. ONE of following:
      1. History of substance abuse;
         OR
      2. Failure or clinically significant adverse effects to at least two formulary long-acting stimulants (e.g. Adderall XR, Concerta, Dextedrine Spansule SR, Focalin XR, Metadate CD, Metadate ER)

b. Binge Eating Disorder:
   i. Confirmed diagnosis

**Formulary Status:** Non-formulary, PA applies

**Clinical Justification:**

*2011 American Academy of Pediatrics: Clinical Practice Guideline for the Diagnosis, Evaluation and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents*

- For elementary school-aged children (6-11 years of age), the primary care clinician should prescribe FDA approved medications for ADHD and/or evidence based parent-and/or teacher administered behavior therapy as treatment for ADHD, preferably both (Evidence A)
  - The evidence is particularly strong for stimulant medications and sufficient but less strong for atomoxetine, extended release guanfacine, and extended release clonidine (in that order) (Evidence A).

- For adolescents (12-18 years of age), the primary care clinician should prescribe FDA-approved medications for ADHD with the assent of the adolescents (Evidence A) and may prescribe behavior therapy as treatment for ADHD.

- All approved stimulant medications are methylphenidate or amphetamine compounds, which have similar effects and adverse effects. Given the extensive evidence of efficacy and safety, they remain the first choice of medication treatment.
  - Decision regarding which compound a clinician first prescribes should be made on the basis of individual preferences of the clinician and family.
  - If a trial with 1 group is unsuccessfully (poor efficacy or adverse effects), a trial on a medication from the other group should be undertaken.

- For cases in which there is concern about possible abuse or diversion of the medication or there is a strong preference against stimulant medication, an FDA-approved non stimulant medication may be considered as first choice of medication.

- The medications that use a microbead technology can be opened and sprinkled on food for patients who have difficulty swallowing tablets or capsules. Immediate-release
methylphenidate, which comes in liquid and chewable forms, and a methylphenidate transdermal patch are also available as alternatives to tablets or capsules.

- Atomoxetine is a selective norepinephrine-reuptake inhibitor and might result in maximum response after approximately 4 to 6 weeks. Extended-release guanfacine and extended-release clonidine are alpha2-adrenergic agonists and might result in maximum response in approximately 2 to 4 weeks.

- Atomoxetine might cause gastrointestinal tract symptoms, appetite suppression and sedation early in treatment.

- Both alpha2-adrenergic agonists can cause the adverse effect of somnolence. In addition, it is recommended that the medications be tapered when discontinued to prevent a possible rebound in blood pressure.

**Abuse Potential of Lisdexamfetamine**

Overall, data evidence is limited on abuse potential of lisdexamfetamine. For patients with a history of amphetamine or stimulant abuse, lisdexamfetamine may be considered as a treatment option, when stimulants are clinically indicated.

A small study consisted of nine subjects evaluated the abuse liability of single intravenous doses of lisdexamfetamine and intravenous immediate-release dextroamphetamine compared to placebo in adult stimulant abusers. As a result, the 20mg dextroamphetamine showed significantly increase abuse-related liking scores compared with placebo (p < 0.05), whereas the liking effects of 50mg lisdexamfetamine did not significantly differ from placebo. The authors concluded that 25mg or 50mg lisdexamfetamine intravenous dose did not associate with significant abuse-related liking scores.

**References:**


<table>
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<th>Date</th>
<th>Change</th>
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<tbody>
<tr>
<td>08/16/2017</td>
<td>• Added Quantity Limit to Dexamethasone</td>
</tr>
<tr>
<td></td>
<td>• Added Quantity Limit to Dextroamphetamine (generic Dexedrine)</td>
</tr>
<tr>
<td></td>
<td>• Added Quantity Limit to Dextroamphetamine-amphetamine</td>
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<tr>
<td></td>
<td>• Added Quantity Limit to Dextroamphetamine-amphetamine ER</td>
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</table>

Change Control

Dosing varies by strength and FDA max dose. Please see the formulary table (www.iehp.org)