UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

<table>
<thead>
<tr>
<th>Program Number</th>
<th>2019 P 1020-10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program</td>
<td>Prior Authorization/Notification – CNS Stimulants</td>
</tr>
<tr>
<td>Medication</td>
<td>Adderall* (amphetamine-dextroamphetamine mixed salts), Adderall XR (amphetamine-dextroamphetamine mixed salts extended-release), Adhansia XR (methylphenidate extended-release), Aptsensio XR* (methylphenidate extended-release), Adzenys XR-ODT (amphetamine)<em>, Concerta (methylphenidate extended-release</em>), Cotempla XR-ODT* (methylphenidate), Daytrana* (methylphenidate transdermal), Desoxyn (methylamphetamine), Dexedrine (dextroamphetamine), Dyanavel XR* (amphetamine extended-release), Evekeo (amphetamine sulfate)<em>, Evekeo ODT (amphetamine sulfate)</em>, Focalin (dexamphetamine), Focalin XR* (dexamphetamine extended-release), Jornay PM (methylphenidate)<em>, Metadate (methylphenidate), Metadate CD (methylphenidate extended-release</em>), Methylphenidate, Methylphenidate ER (methylphenidate extended-release), Mydayis* (dextroamphetamine-amphetamine mixed salts), Procentra (dextroamphetamine), QuillChe ER* (methylphenidate extended-release), Quillivant XR* (methylphenidate extended-release), Ritalin (methylphenidate), Ritalin SR (methylphenidate extended-release), Ritalin LA* (methylphenidate extended-release), Vyvanse (lisdexamfetamine), Zenzedi*(dextroamphetamine)</td>
</tr>
<tr>
<td>Effective Date</td>
<td>11/1/2019; Oxford only: 11/1/2019</td>
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1. **Background:**  
   This program will allow coverage for diagnoses supported by FDA labeling and clinical evidence. The CNS stimulants have a variety of FDA approved labeled indications, such as Attention Deficit Hyperactivity Disorder (ADHD), Attention Deficit Disorder (ADD), and narcolepsy. In addition, Vyvanse is indicated for Moderate to Severe Binge Eating Disorder (BED). There is evidence for off-label use for the stimulants in idiopathic hypersomnia, fatigue associated with multiple sclerosis, mental fatigue secondary to traumatic brain injury, and depression. The potential use of these agents for weight loss is not a covered benefit. Because of the high abuse potential for this class of medications, their use should be closely monitored in certain age groups. In addition, if the member is less than 12 years of age, the prescription will automatically process without a coverage review.

2. **Coverage Criteria:**

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A. Adderall*, Adderall XR, Adhansia XR*, Adzenys XR-ODT*, Aptensio XR*, Concerta, Cotempla XR-ODT*, Daytrana*, Desoxyn, Dexamphetamine, Dyanavel XR*, Evekeo*, Evekeo ODT*, Focalin, Focalin XR*, Jornay PM*, Metadate CD, Metadate ER, Methylin, Methylin ER, Mydayis*, Procentra, QuilliChew ER*, Quillivant XR*, Ritalin, Ritalin SR, Ritalin LA*, and Zenzedi* will be approved based on one of the following:

1. The patient is less than 12 years of age

-OR-

2. Both of the following:

   a. The patient is 12 years of age or older

   -AND-

   b. The patient has one of the following diagnoses:

      (1) Attention-deficit hyperactivity disorder (ADHD) or attention-deficit disorder (ADD)
      (2) Depression
      (3) Narcolepsy
      (4) Other hypersomnia of central origin
      (5) Autism Spectrum Disorder
      (6) Mental fatigue secondary to traumatic brain injury (e.g. post-concussion syndrome)
      (7) Fatigue associated with medical illness in patients in palliative or end of life care.
      (8) Fatigue associated with multiple sclerosis

Authorization will be issued for 12 months.

B. Vyvanse Initial Authorization

1. Vyvanse will be approved based on one of the following:

   a. The patient is less than 12 years of age

   -OR-

   b. Both of the following:

      (1) The patient is 12 years of age or older
(2) The patient has **one** of the following diagnoses:

(a) Attention-deficit hyperactivity disorder (ADHD) or attention-deficit disorder (ADD)
(b) Depression
(c) Narcolepsy
(d) Other hypersomnia of central origin
(e) Autism Spectrum Disorder
(f) Mental fatigue secondary to traumatic brain injury (e.g. post-concussion syndrome)
(g) Fatigue associated with medical illness in patients in palliative or end of life care.
(i) Fatigue associated with multiple sclerosis

-OR-

c. **All** of the following:

(1) The patient is 12 years of age or older

-AND-

(2) The patient has Moderate to Severe Binge Eating Disorder (BED)

-AND-

(3) The patient meets **both** of the following:

(a) Patient has had binge eating disorder for 3 months or longer
(b) Patient has between 4 and 13 binge-eating episodes per week

-AND-

(4) The patient meets **three (3)** or more of the following:

(a) Patient eats much more rapidly than normal
(b) Patients eats until feeling uncomfortably full
(c) Patient eats large amounts of food when not feeling physically hungry
(d) Patient eats alone because of feeling embarrassed by how much one is eating
(e) Patient feels disgusted with oneself, depressed, or very guilty after binge-eating
Authorization will be issued for 3 months for Moderate to Severe Binge Eating Disorder and 12 months for all other approved indications

C. Reauthorization for Vyvanse

1. Vyvanse will be reauthorized based on one of the following:

   a. The patient is less than 12 years of age

   -OR-

   b. Both of the following:

      (1) The patient is 12 years of age or older

      -AND-

      (2) The patient has one of the following diagnoses:

          (a) Attention-deficit hyperactivity disorder (ADHD) or attention-deficit disorder (ADD)
          (b) Depression
          (c) Narcolepsy
          (d) Other hypersonmia of central origin
          (e) Autism Spectrum Disorder
          (f) Mental fatigue secondary to traumatic brain injury (e.g. post-concussion syndrome)
          (g) Fatigue associated with medical illness in patients in palliative or end of life care.
          (h) Fatigue associated with multiple sclerosis

      -OR-

   c. All of the following:

      (1) The patient is 12 years of age or older

      -AND-

      (2) The patient has Moderate to Severe Binge Eating Disorder (BED)

      -AND-

      (3) Documentation of positive clinical response (e.g., meaningful
reduction in the number of binge eating episodes or binge days per week from baseline, improvement in the signs and symptoms of binge eating disorder) to Vyvanse therapy.

Reauthorization will be issued for 12 months for all approved indications

3. Additional Clinical Programs:
   • Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
   • Supply Limits may also be in place
   *Typically excluded from coverage.

4. References:

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<thead>
<tr>
<th>Program</th>
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<tbody>
<tr>
<td>Change Control</td>
<td></td>
</tr>
<tr>
<td>8/2013</td>
<td>Added Zenzedi to coverage criteria. Changed Liquadd to Procentra</td>
</tr>
<tr>
<td>8/2014</td>
<td>Updated references, formatting changes.</td>
</tr>
<tr>
<td>10/2014</td>
<td>Added Autism Spectrum Disorder to list of covered indications.</td>
</tr>
<tr>
<td>4/2015</td>
<td>Added Binge Eating Disorder to the list of covered indications for Vyvanse due to new FDA approved indication. Added Evekeo to coverage criteria.</td>
</tr>
<tr>
<td>2/2016</td>
<td>Added Aptensio XR, QuilliChew and Dyanavel XR to criteria. Added indication for mental fatigue secondary to traumatic brain injury. Changed criteria for end of life fatigue associated with cancer to fatigue associated with medical illness in patients in palliative or end of life care. Updated references.</td>
</tr>
<tr>
<td>3/2017</td>
<td>Annual review. Added Adzenys XR to criteria. Consolidated sections A and B. Updated references.</td>
</tr>
<tr>
<td>9/2017</td>
<td>Added Cotempla XR-ODT and Mydayis to criteria.</td>
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<tr>
<td>9/2018</td>
<td>Annual review. Updated references.</td>
</tr>
<tr>
<td>7/2019</td>
<td>Added Jornay PM to criteria. Added criteria for fatigue due to MS. Updated references.</td>
</tr>
<tr>
<td>8/2019</td>
<td>Added Adhansia XR and Evekeo ODT to criteria.</td>
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