

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2016 P 1020-5
Program	Prior Authorization/Notification – CNS Stimulants
Medication	Adderall* (amphetamine-dextroamphetamine mixed salts), Adderall XR (amphetamine-dextroamphetamine mixed salts extended-release), Aptensio XR* (methylphenidate extended-release), Concerta (methylphenidate extended-release*), Daytrana* (methylphenidate transdermal), Desoxyn (methamphetamine), Dexedrine (dextroamphetamine), Dyanavel XR* (amphetamine extended-release), Focalin (dexmethylphenidate), Evekeo (amphetamine sulfate), Focalin XR* (dexmethylphenidate extended-release), Metadate (methylphenidate), Metadate CD (methylphenidate extended-release*), Methylin (methylphenidate), Methylin ER (methylphenidate extended-release), Procentra (dextroamphetamine), QuilliChew ER* (methylphenidate extended-release), Quillivant XR* (methylphenidate extended-release), Ritalin (methylphenidate), Ritalin SR (methylphenidate extended-release), Ritalin LA* (methylphenidate extended-release), Vyvanse (lisdexamfetamine), Zenedi*(dextroamphetamine)
P&T Approval Date	4/09, 1/2010, 1/2011, 1/2012, 2/2013, 8/2013, 8/2014, 10/2014, 4/2015, 2/2016
Effective Date	5/1/2016; Oxford only: 5/1/2016

**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 hypersomnolence, 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:**

<p><b>A. Adderall*, Adderall XR, Desoxyn, Dexedrine, Dyanavel XR*, Evekeo, Focalin, Focalin XR*, Procentra and Zenedi* will be approved based on <u>one</u> of the following:</b></p>
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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.

**Authorization will be issued for 12 months.**

**B. Aptensio XR\*, Concerta, Daytrana\*, Metadate CD, Metadate ER, Methylin, Methylin ER, QulliChew ER\*, Quillivant XR\*, Ritalin, Ritalin SR, and Ritalin LA\* 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.

**Authorization will be issued for 12 months.**

### C. 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

**-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 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.

**-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**

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 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.

**-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:**

\*Typically excluded from coverage.

Supply Limits may also be in place.

**4. References:**

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7. Desoxyn Prescribing Information. Barceloneta, PR. AbbVie LTD. February 2015.
8. ProCentra Prescribing Information. Charlotte, NC. FSC Laboratories. June 2010.
9. Ritalin® and Ritalin-SR® Prescribing Information. East Hanover, NJ. Novartis Pharmaceuticals Corporation. July 2015.
10. Ritalin LA® Prescribing Information. East Hanover, NJ. Novartis Pharmaceuticals Corporation. July 2015.
11. Metadate CD® Prescribing Information. Smyrna, GA. UCB Manufacturing, Inc. February 2015.
12. Metadate® ER Prescribing Information. Smyrna, GA. UCB Manufacturing, Inc. January 2014.
13. Concerta® Prescribing Information. Titusville, NJ. McNeil Pediatrics. September 2015.
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24. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. 5th ed. Washington, DC: 2013.
25. Evekeo Prescribing Information. Atlanta, GA. Arbor Pharmaceuticals, Inc. February 2015.

26. Aptensio Prescribing Information. Coventry, RI. Rhodes Pharmaceuticals L.P. May 2015.
27. Johansson B, et al. Methylphenidate reduces mental fatigue and improves processing speed in persons suffered a traumatic brain injury. *Brain Inj.* 2015; 29(6): 758-65.
28. Lee, MA, Fine B. Adolescent Concussions. *Connecticut Medicine.* 2010; 74(3): 149-56.
29. QuilliChew ER Prescribing Information. New York, NY. Pfizer Inc. December 2015.
30. Dyanavel XR Prescribing Information. Monmouth Junction, NJ. Tris Pharma, Inc. November 2015.
31. Kaminki, M, Sjogren P. The use of psychostimulants in palliative and supportive treatment of cancer patients. *Advances in Palliative Medicine.* 2007; 6(1): 23-31.
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Program	Prior Authorization/Notification – CNS Stimulants
<b>Change Control</b>	
8/2013	Added Zenedi to coverage criteria. Changed Liquadd to Procentra
8/2014	Updated references, formatting changes.
10/2014	Added Autism Spectrum Disorder to list of covered indications.
4/2015	Added Binge Eating Disorder to the list of covered indications for Vyvanse due to new FDA approved indication. Added Evekeo to coverage criteria.
2/2016	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.