UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1020-8
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), Adzenys XR-ODT (amphetamine)*, Concerta (methylphenidate extended-release*), Cotempla XR-ODT* (methylphenidate), Daytrana* (methyphenidate 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), Mydayis* (dextroamphetamine-amphetamine mixed salts), 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), Zenzedi*(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, 3/2017, 9/2017, 9/2018
Effective Date	12/1/2018; Oxford only: 12/1/2018

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:

A. **Adderall***, **Adderall XR, Adzenys XR-ODT*, Cotempla XR-ODT*, Desoxyn, Dexedrine, Dyanavel XR*, Evekeo, Focalin, Focalin XR*,**

Procentra, **Zenzedi***, **Aptensio XR*, Concerta, Daytrana*, Metadate CD, Metadate ER, Methylin, Methylin ER, Mydayis*, 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.

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

      -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

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 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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2. Adderall XR® Prescribing Information. Wayne, PA. Shire US Inc. July 2018.
3. Focalin® Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation. January 2017.
4. Focalin XR® Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation. January 2017.
5. Daytrana® Prescribing Information. Miami, FL: Noven Therapeutics, LLC;. January 2017.
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7. Desoxyn Prescribing Information. Barceloneta, PR. AbbVie LTD. May 2017.
8. ProCentra Prescribing Information. Independence Pharmaceuticals LLC. Newport, KY. February 2017.
9. Ritalin® and Ritalin-SR® Prescribing Information. East Hanover, NJ. Novartis Pharmaceuticals Corporation. January 2017.
10. Ritalin LA® Prescribing Information. East Hanover, NJ. Novartis Pharmaceuticals Corporation. January 2017.
11. Metadate CD® Prescribing Information. Smyrna, GA. UCB Manufacturing, Inc. October 2016.
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23. Evekeo Prescribing Information. Atlanta, GA. Arbor Pharmaceuticals, Inc. September 2016.
24. Aptensio XR Prescribing Information. Coventry, RI. Rhodes Pharmaceuticals L.P. October 2016.
25. 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.
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27. QuilliChew ER Prescribing Information. New York, NY. Pfizer Inc. July 2017.
28. Dyanavel XR Prescribing Information. Monmouth Junction, NJ. Tris Pharma, Inc. May 2017.
29. 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.
30. Howard R, Howard P. GP guides to drugs used in palliative care: psychostimulants. Drug Points. Available at: http://onlinelibrary.wiley.com/doi/10.1002/psb.984/pdf
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35. Cotempla XR-ODT Prescribing Information. Grand Prairie, TX. Neos Therapeutics, Inc. June 2017.
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Program	Prior Authorization/Notification – CNS Stimulants
Change Control	
8/2013	Added Zenzedi 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.
3/2017	Annual review. Added Adzenys XR to criteria. Consolidated sections A and B. Updated references.
9/2017	Added Cotempla XR-ODT and Mydayis to criteria.
9/2018	Annual review. Updated references.