UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for ADHD Products

Program	ADHD Products
Medication	ADHD Agents
Markets in Scope	Hawaii, Nevada, New Jersey, New York, California, Colorado, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2014
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	1/2021

1. Background:

The intent of the criteria is to ensure the appropriate utilization of ADHD agents within the appropriate FDA approved age limits, labeled indications, and consistent with current evidence in the literature.

A. Formulary Status

Preferred Products
Adderall* (amphetamine/dextroamphetamine salts) tablet Adderall XR* (amphetamine/dextroamphetamine salts) extended-release capsule Concerta* (methylphenidate) extended-release tablet Intuniv *(guanfacine) extended-release tablet Metadate CD* (methylphenidate) extended-release capsule Metadate ER* (methylphenidate) tablet Ritalin* (methylphenidate) tablet Ritalin LA* (methylphenidate) 20mg, 30mg, 40mg extended-release capsule Strattera* (atomoxetine) capsule
Non-Preferred Products
Adderall (amphetamine/dextroamphetamine) tablet Adderall XR (amphetamine/dextroamphetamine salts) extended-release capsule Adhansia XR (methylphenidate) extended-release capsule Adzenys XR-ODT (amphetamine) extended-release tablet/Adzenys ER (amphetamine) extended-release suspension Aptensio XR (methylphenidate) extended-release capsule 24 HR Concerta (methylphenidate) extended-release tablet Cotempla XR-ODT (methylphenidate) extended-release tablet Daytrana (methylphenidate) patch

Desoxyn (methamphetamine) tablet
Dexedrine (dextroamphetamine) tablet/extended-release capsule 24 HR
Dyanavel XR (amphetamine) extended-release suspension
Evekeo (amphetamine) tablet/Evekeo ODT (amphetamine) tablet
Focalin (dexmethylphenidate) tablet/Focalin XR (dexmethylphenidate) extended-release capsule 24 HR
Intuniv (guanfacine) extended-release tablet 24 HR
Jornay PM (methylphenidate) extended-release capsule
Kapvay (clonidine) extended-release tablet
Metadate CD (methylphenidate) extended-release capsule
Metadate ER (methylphenidate) controlled-release tablet
Methylin (methylphenidate) chewable tablet/solution
Methylphenidate ER (generic Ritalin LA) 10mg, 60mg extended-release capsule
Mydayis (mixed amphetamine salts) extended-release capsule
Procentra (dextroamphetamine) solution
Quillichew ER (methylphenidate) extended-release chewable tablet
Quillivant XR (methylphenidate) extended-release suspension
Relexxii (methylphenidate) extended-release tablet
Ritalin (methylphenidate) tablet
Ritalin LA (methylphenidate) extended-release capsule 24 HR
Strattera (atomoxetine) capsule
Vyvanse (lisdexamfetamine) capsule/Vyvanse (lisdexamfetamine) chewable tablet
Zenzedi (dextroamphetamine) tablet

*** Only generic versions are covered**

Off-labeled Use:
Drug therapies must be utilized in accordance with FDA approved indications OR the uses found within the compendia of literature† AND the drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program. Authorization for off-labeled use of medication will be evaluated on an individual basis. Review of an off-labeled request by the UnitedHealthcare Community & State Medical Staff will be predicated on the appropriateness of treatment, scientific evidence and full consideration of medical necessity.

†-Compendia of current literature: • American Hospital Formulary Service Drug Information • National Comprehensive Cancer Network Drugs and Biologics Compendium • Thomson Micromedex DrugDex • Clinical Pharmacology • United States Pharmacopoeia-National Formulary (USP-NF)

Age Edits

-All products have a **minimum age of 6 years** except for the following:
- Adderall (amphetamine/dextroamphetamine salts) - 3 years of age

- Dexedrine (dextroamphetamine) tablet – 3 years of age
- Evekeo (amphetamine) tablet – 3 years of age
-Mydayis (mixed amphetamine salts) ER capsule – 13 years of age
- ProCentra (dextroamphetamine) solution – 3 years of age
- Zenzedi (dextroamphetamine) tablet – 3 years of age

Products may contain black boxed warnings including but not limited to: drug dependence and potential for abuse. Please see full prescribing information for additional details.

2. Coverage Criteria:

A. Diagnosis to Drug Match

NOTE: This program applies to only the following markets: California, Hawaii, New Jersey, New York, Pennsylvania- CHIP, Rhode Island

One of the following:

1. amphetamine/dextroamphetamine salts (generic Adderall), amphetamine/dextroamphetamine salts extended-release (generic Adderall XR), methylphenidate ER tablet (generic Concerta), generic Ritalin LA 20mg, 30mg, 40mg), methylphenidate SR (generic Metadate ER), methylphenidate (generic Ritalin), methylphenidate CD (generic Metatdate CD)
    a. Patient has **one** of the following:
        - Attention Deficit Hyperactivity Disorder/Attention Deficit Disorders (ADHD/ADD)
        - Narcolepsy
        - Mental fatigue secondary to traumatic brain injury (e.g. post-concussion syndrome)
        - Fatigue associated with medical illness in patients in palliative or end of life care.
        - Fatigue associated with multiple sclerosis
        - **Both** of the following:
            - The use of this drug is supported by information from the appropriate compendia†.
            - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program.

-OR-

2. guanfacine ER (generic Intuniv) and atomoxetine (generic Strattera)
    a. Patient has **one** of the following:
        - Attention Deficit Hyperactivity Disorder/Attention Deficit Disorders (ADHD/ADD)

- **Both** of the following:
  - The use of this drug is supported by information from the appropriate compendia†.
  - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program.

Authorization of therapy will be issued for 12 months

B. Requests for Members Less than the FDA Approved Minimum Age

1. **All** of the following:

   a. One of the following:
   - Diagnosis of Attention Deficit Hyperactivity Disorder/Attention Deficit Disorders (ADHD/ADD)
   - The use of this drug is supported by information from the appropriate compendia†.

-AND-

   b. The child is unresponsive to, or has had an inadequate response to behavioral therapy

-AND-

   c. The child is experiencing moderate-severe continuing disturbance in function despite behavioral therapy

-AND-

   d. If the request is for a preferred product: The Patient has a history of failure, contraindication, or intolerance to at least **three** preferred alternatives. - **Prior trials of formulary/PDL alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request.**
   NOTE: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to **all** of the preferred products for the patient's age. NOTE: Non-preferred requests- please proceed to section D. Nonpreferred Criteria

Authorization of therapy will be issued for 12 months

C. Requests for Members Greater than the Maximum Age Edit of 18 years
Note: This edit applies to only Nevada

One of the following:

1. amphetamine/dextroamphetamine salts (generic Adderall), amphetamine/dextroamphetamine salts extended-release (generic Adderall XR), methylphenidate ER tablet (generic Concerta), methylphenidate SR (generic Metadate ER), methylphenidate (generic Ritalin), methylphenidate CD (generic Metatdate CD)
    a. Patient has **one** of the following:
        - Attention Deficit Hyperactivity Disorder/Attention Deficit Disorders (ADHD/ADD)
        - Narcolepsy
        - Mental fatigue secondary to traumatic brain injury (e.g. post-concussion syndrome)
        - Fatigue associated with medical illness in patients in palliative or end of life care.
        - Fatigue associated with multiple sclerosis
        - **Both** of the following
            - The use of this drug is supported by information from the appropriate compendia†.
            - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program.

-OR-

2. guanfacine ER (generic Intuniv) and atomoxetine (generic Strattera)
    i. Patient has **one** of the following:
        - Attention Deficit Hyperactivity Disorder/Attention Deficit Disorders (ADHD/ADD)
        - **Both** of the following:
            - The use of this drug is supported by information from the appropriate compendia†.
            - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program.

Authorization of therapy will be issued for 12 months

D. Non-Preferred Criteria

One of the following:

1. A request for a non-preferred medication will be approved based on **one** of the following:

    a. If the request is for **Vyvanse**, **one** of the following:
    i. The patient is new to Vyvanse therapy and **one** of the following:

        (a) **Both** of the following:
            (i) Diagnosis of Attention Deficit Hyperactivity Disorder/Attention Deficit Disorders (ADHD/ADD)

        -AND-

            (ii) **One** of the following:
                a) History of failure, contraindication, or intolerance to **both** of the following:
                - amphetamine/dextroamphetamine salts extended-release (generic Adderall XR)
                - methylphenidate extended-release tablet or capsule (generic Concerta or Metadate CD)

        -OR-

                b) **Both** of the following:
                - History of or potential for a substance abuse disorder
                - History of failure, contraindication, or intolerance to atomoxetine (Strattera)

        -OR-

        (b) **Both** of the following:

            (i) **One** of the following diagnoses:
            - Narcolepsy
            - Mental fatigue secondary to traumatic brain injury (e.g. post-concussion syndrome)
            - Fatigue associated with medical illness in patients in palliative or end of life care
            - Fatigue associated with multiple sclerosis
            - **Both** of the following:
                - The use of this drug is supported by information from the appropriate compendia†
                - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

-AND-

(ii) **<u>One</u>** of the following:
- History of failure, contraindication, or intolerance to **<u>both</u>** of the following:
  - amphetamine/dextroamphetamine salts extended-release (generic Adderall XR)
  - methylphenidate extended-release tablet or capsule (generic Concerta or Metadate CD)
- History of or potential for a substance abuse disorder

-OR-

(c) Diagnosis of Binge Eating Disorder (BED)

-OR-

ii. The patient is ongoing on previously approved Vyvanse therapy and **<u>one</u>** of the following:
[NOTE: With the exception of Transition of Care authorizations, previous approval refers to any approval authorization given. Examples include (but are not limited to): previous fills received via the automated DX2RX process, prior authorization/appeals processes, and authorizations entered during the proactive review period. Transition of Care authorizations are the only authorizations that should NOT be considered a previous approval.]

(a) Vyvanse was initially approved **prior to 8/1/20**
(i) **<u>One</u>** of the following:
a. **<u>Both</u>** of the following:
i. Diagnosis of Attention Deficit Hyperactivity Disorder/Attention Deficit Disorders (ADHD/ADD)
ii. **<u>One</u>** of the following:
a) History of failure, contraindication, or intolerance to amphetamine/dextroamphetamine salts extended-release (generic Adderall XR)
b) **<u>Both</u>** of the following:
- History of or potential for a substance abuse disorder
- History of failure, contraindication, or intolerance to atomoxetine (Strattera)

c) Physician has provided rationale for needing to continue the patient on Vyvanse therapy

-OR-

b. **Both** of the following:
   i. **One** of the following diagnoses:
      - Narcolepsy
      - Mental fatigue secondary to traumatic brain injury (e.g. post-concussion syndrome)
      - Fatigue associated with medical illness in patients in palliative or end of life care
      - Fatigue associated with multiple sclerosis
      - **Both** of the following:
        - The use of this drug is supported by information from the appropriate compendia†
        - The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

-AND-

   ii. **One** of the following:
      a) History of failure, contraindication, or intolerance to amphetamine/dextroamphetamine salts extended-release (generic Adderall XR)
      b) History of or potential for a substance abuse disorder
      c) Physician has provided rationale for needing to continue the patient on Vyvanse therapy

-OR-

c. Diagnosis of Binge Eating Disorder (BED)

-OR-

(b) Vyvanse was initially approved **after 8/1/20**

(i) Documentation of positive clinical response to Vyvanse therapy

-OR-

b. If the request is for another non-preferred stimulant, **all** of the following:

i. Patient must demonstrate failure or intolerance to a majority (not more than three (3)) of the preferred formulary/PDL alternatives for the given diagnosis - **Prior trials of formulary/PDL alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request.**
NOTE: In instances where there are fewer than three preferred alternatives, the patient must have a history of failure, contraindication, or intolerance to **all** of the preferred products for the patient's age.

-AND-

ii. If the request is for a multi-source brand medication, **one** of the following:

- The multi-source brand is being requested because of an adverse reaction, allergy or sensitivity to a generic equivalent
- The multi-source brand is being requested due to a therapeutic failure with the generic equivalent
- The multi-source brand is being requested because transition to a generic equivalent could result in destabilization of the patient
- Special clinical circumstances exist that preclude the use of a generic version of the multi-source brand medication for the patient

-AND-

iii. **One** of the following:

(a) The requested drug must be used for an FDA-approved indication

-OR-

(b) **Both** of the following:

- The use of this drug is supported by information from the appropriate compendia of current literature†.
- The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program.

-OR-

c. A request for **Kapvay** will be approved based on **both** of the following:

i. Diagnosis of Attention Deficit Hyperactivity Disorder/Attention Deficit Disorders (ADHD/ADD)

-AND-

ii. History of failure, contraindication, or intolerance to **both** of the following:
- Guanfacine ER (generic Intuniv)
- Atomoxetine (generic Strattera)

-OR-

d. **ONE** of the following:

i. The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

-OR-

ii. The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge.

Authorization of therapy will be issued for 12 months.

†Compendia of current literature: • American Hospital Formulary Service Drug Information • National Comprehensive Cancer Network Drugs and Biologics Compendium • Thomson Micromedex DrugDex • Clinical Pharmacology • United States Pharmacopoeia-National Formulary (USP-NF)

3. Additional Clinical Rules:

- 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 be in place.

4. References:

1. Adderall® [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; March 2020.

2. Adderall XR® [package insert]. Lexington, MA: Shire US Inc.; July 2019.
3. Adhansia XR [package insert]. Wilson, NC: Purdue Pharmaceuticals LP; July 2019.
4. Adzenys ER [package insert]. Grand Prairie, TX: Neos Therapeutics LP.; September 2017.
5. Adzenys XR-ODT [package insert]. Grand Prairie, TX: Neos Therapeutics LP; February 2018.
6. Aptensio XR [package insert]. Coventry, RI: Rhodes Pharmaceuticals L.P.; June 2019.
7. Concerta® [package insert]. Titusville, NJ: Janssen Pharmaceuticals Inc.; January 2017.
8. Cotempla XR-ODT [package insert]. Grand Prairie, TX: Neos Therapeutics LP; June 2017.
9. Daytrana [package insert]. Miami, FL: Noven Therapeutics, LLC.; October 2019.
10. Dexedrine Spansule® [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; March 2019.
11. Desoxyn [package insert]. Lebanon, NJ: Recordati Rare Diseases Inc.; March 2019.
12. Dyanavel XR [package insert]. Monmouth Junction ,NJ: Tris Pharma, Inc.; February 2019.
13. Evekeo [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC.; April 2019.
14. Evekeo ODT [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC.; March 2019.
15. Focalin [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; November 2019.
16. Focalin XR [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; November 2019.
17. Intuniv® [package insert]. Lexington, MA: Shire US Inc.; December 2019.
18. Jornay PM [package insert]. Cherry Hill, NJ: Ironshore Pharmaceuticals, Inc.; April 2019.
19. Kapvay [package insert]. Oakville, Ontario: Concordia Pharmaceuticals Inc.; February 2020.
20. Metadate CD [package insert]. Smyrna, GA: UCB, Inc.; January 2017.
21. Metadate ER® [package insert]. Philadelphia, PA: Lannett Company, Inc.; April 2018.
22. Methylin [package insert]. Florham Park, NJ: Shionogi Inc.; August 2017.
23. Mydayis [package insert]. Lexington, MA: Shire US Inc.; September 2019.
24. Procentra [package insert]. Charlotte, NC: FSC Laboratories, Inc.; June 2010.
25. Quillichew ER [package insert]. New York, NY: Pfizer Inc.; March 2018.
26. Quillivant XR [package insert]. New York, NY: Pfizer Inc. ; October 2017.
27. Relexxii [package insert]. Bridgewater, NJ: Vertical Pharmaceuticals, LLC; November 2019.
28. Ritalin® [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; November 2019.
29. Ritalin LA [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; November 2019.
30. Strattera® [package insert]. Indianapolis, IN: Eli Lilly USA, LLC; February 2020.
31. Vyvanse® [package insert]. Lexington, MA: Shire US Inc.; January 2018.
32. Zenzedi [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC.; January 2019.
33. American Academy of Pediatrics: Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents *Pediatrics.* 2019; 144(4): e20192528.

34. American Academy of Sleep Medicine. Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin. Standards of Practice Committee. Sleep. 2007; 30(12): 1706-11
35. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. 5th ed. Washington, DC: 2013.
36. 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.
37. Sysko, R., & Devlin, M. (2018). Binge Eating Disorder in Adults: Overview of treatment. In UpToDate, Yager, J (Ed.), *UpToDate*. Retrieved February 10, 2020, from https://www.uptodate.com/contents/binge-eating-disorder-in-adults-overview-of-treatment

Program	Program type – ADHD Products
Change Control	
Date	Change
12/2011	New clinical policy. Age edit limits (minimum and maximum) on the ADHD agents were previously in place. New portion of this guideline is section III.B, requests for immediate release methylphenidate for members less than 6 years old.
12/2012	Renamed policy to “ADHD Products” from “ADHD Age Edit” Changed the methylphenidate IR criteria for patients less than 6 years old to all preferred methylphenidate products. Changed max age edit criteria from covering patients 21 years of age or older to applying to patients 18 years of age or older. Renamed “Stimulant Max Age Edit” to now be named “Preferred ADHD Products – Max Age Edit”
2/2013	Added Vyvanse to the preferred product list, to the FDA approved indications list, and to the minimum age edit list in section III.A.1. Added Vyvanse prescribing information to reference list.
3/2015	Added Ritalin LA to preferred product grid. Added Ritalin LA to minimum age edit grid. Added new Vyvanse criteria in section II.C to address Vyvanse for binge eating disorder indication.
9/2016	Removed Strattera and Dexedrine products from formulary status grid and added note about formulary status. (non-preferred products are not included in the formulary status grid). Added non-preferred criteria for methylphenidate products.

	Added non-preferred criteria to maximum age edit section Added Strattera criteria to age edit section Added non-preferred product criteria Updated policy template.
12/2016	Updated Strattera section to include Kapvay and changed the step to a step through Intuniv. Added Intuniv criteria to maximum age edit section. Added a non-preferred non-stimulants section.
3/2017	Updated maximum age edit and Vyvanse sections to allow for compendia supported diagnoses.
6/2017	Added therapeutic duplication review criteria
7/2017	Updated age edit criteria to remove maximum age edit language.
9/2017	Removed all operational edits (age edits, therapeutic duplication) from this policy. The policy applies to only clinical edits.
2/2018	Added non-preferred medications to the policy. Minimum age criteria added back in and revised so that it is no longer specific to just methylphenidate. Revised non-preferred criteria to match the Atypical Antipsychotics policy. Added criteria for requests for generic Adderall XR. Rearranged the policy so it is in the same order as the Atypical Antipsychotics policy. Updated preferred products for 4/1/18 changes.
2/2018v2	Updated preferred products for 4/1/18 changes.
2/2018 v3	Updated auth duration in minimum age section.
2/2018 v4	Updated policy to account for California using Dx2Rx program starting in 4/17/18.
4/2018	Removed Ritalin SR since there are no active GPIs. Corrected minimum ages in the background.
5/2018	Added clarification regarding methylphenidate ER (generic Concerta) products. Updated step therapy language in non-preferred section.
7/2018	Added generic Strattera (atomoxetine) to the Dx2RX program for 10/1/18 go-live. Updated references.
7/2019	Added generic methylphenidate ER tablet (generic Concerta-AB rated) to preferred product. Updated references.
10/2019	Added Adhansia XR and Jornay PM. Added fatigue associated with multiple sclerosis as an approvable condition for stimulants. Updated references.

1/2020	Moved Adderall XR generic into a preferred position.
4/2020	Moved brand Adderall XR and Vyvanse into a non-preferred position.
11/2020	Added language to clarify “previously approved” Vyvanse therapy. Updated references.