UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for ADHD Products - OHIO

Program	ADHD Products
Medication	ADHD Agents
Markets In Scope	Ohio

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) Adderall XR** (amphetamine/dextroamphetamine salts extended release) Concerta* (methylphenidate ER) Intuniv (guanfacine)* Metadate ER* (methylphenidate SR) Ritalin* (methylphenidate) Ritalin SR* (methylphenidate SR) Ritalin LA* (methylphenidate ER) Vyvanse (lisdexamfetamine)
Non-Preferred Products
Adderall (amphetamine/dextroamphetamine) tablet Adzenys XR (amphetamine ER) ODT amphetamine/dextroamphetamine salts extended release Aptensio XR (methylphenidate) capsule 24 HR Concerta (methylphenidate) tablet Cotempla XR (methylphenidate) ODT Daytrana (methylphenidate) patch Desoxyn (methamphetamine) tablet Dexedrine (dextroamphetamine) tablet/Spansule SR capsule 24HR Dyanavel XR (amphetamine) suspension Evekeo (amphetamine) tablet Focalin (dexmethylphenidate) tablet/XR capsule 24HR Intuniv (guanfacine) tablet 24HR Kapvay (clonidine SR) tablet Metadate ER (methylphenidate SR) tablet controlled release/CD capsule controlled release Methylin (methylphenidate) chewable tablet/solution Mydayis (mixed amphetamine salts) ER capsule

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Procentra (dextroamphetamine) solution
Quillichew ER (methylphenidate ER) chewable tablet
Quillivant (methylphenidate ER) suspension
Ritalin (methylphenidate) tablets/SR tablets controlled release/LA capsule 24HR
Strattera (atomoxetine) caps
Zenzedi (dextroamphetamine) tabs

*** Only generic versions are covered** ****Only brand version is 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

Drug Name	Min Member Age
Adderall (amphetamine/dextroamphetamine salts)	3
Adderall XR (amphetamine/dextroamphetamine salts extended release)	6
Concerta (methylphenidate ER)	6
Intuniv (guanfacine)	6
Metadate ER (methylphenidate SR)	6
Ritalin (methylphenidate)	6
Ritalin SR (methylphenidate SR)	6
Ritalin LA (methylphenidate ER)	6
Vyvanse (lisdexamfetamine)	6

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2. Coverage Criteria:

A. <u>Requests for Members Less than the FDA Approved Minimum Age</u>

1. **<u>All</u>** 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 parent- and/or teacher-administered 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 non-preferred product, the child has a history of failure, contraindication, or intolerance to a trial of at least one short-acting AND one long-acting preferred product.

   Authorization of therapy will be issued for 12 months.

B. <u>Requests for Members Greater than the Maximum Age Edit of 18 Years</u>

<u>One</u> of the following:

1. amphetamine/dextroamphetamine salts (generic Adderall), BRAND Adderall XR, methylphenidate ER (generic Concerta, generic Ritalin LA), methylphenidate SR (generic Metadate ER, generic Ritalin SR), methylphenidate (generic Ritalin)
   a. Patient has **<u>one</u>** 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.
- **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. Vyvanse (lisdexamfetamine)
   a. Patient has **one** of the following:
   - Attention Deficit Hyperactivity Disorder/Attention Deficit Disorders (ADHD/ADD)]
   - Narcolepsy
   - Binge Eating Disorder (BED)
   - 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.
   - **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-

3. guanfacine (generic Intuniv)
   i. Patient has **one** of the following:
   - Attention Deficit Hyperactivity Disorder/Attention Deficit Disorders (ADHD/ADD)]
   - Fatigue associated with medical illness in patients in palliative or end of life care.
   - **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.

C. Non-Preferred Criteria

One of the following:

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

    a. **All** of the following:

        i. **One** of the following:

            (a) Beneficiary 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.**

            -OR-

            (b) There are no preferred formulary alternatives for the requested drug.

            -AND-

        ii. **One** of the following:

            (a) 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

            -OR-

            (b) If the request is for **GENERIC** Adderall XR, **one** of the following:

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

b. **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.

-OR-

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

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

-AND-

b. History of failure, contraindication, or intolerance to Intuniv

Authorization of therapy will be issued for 12 months.

†Compendia: • American Hospital Formulary Service Drug Information • National Comprehensive Cancer Network Drugs and Biologics Compendium • Thomson Micromedex DrugDex • Clinical Pharmacology

4. References:

1. Adderall® Prescribing Information. Pamona, NY: Barr Laboratories, March 2007.
2. Adderall XR® Prescribing Information. Wayne, PA: Shire, August 2011.
3. Concerta® Prescribing Information. Titusville, NJ: Ortho-McNeil-Janssen Pharmaceuticals, November 2010.
4. Dexedrine® Prescribing Information. Pamona, NY: Barr Laboratories, March 2000.
5. Dexedrine Spansule® Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline, September 2009.
6. Intuniv® Prescribing Information. Wayne, PA: Shire, June 2011.
7. Metadate ER® Prescribing Information. Rochester, NY: Medeva Pharmaceuticals, July 1999.
8. Ritalin® Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals, December 2010.
9. Ritalin SR® Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals, December 2010.
10. Strattera® Prescribing Information. Indianapolis, IN: Eli Lilly, August 2011.
11. American Academy of Pediatrics: Clinical Practice Guideline: ADHD: Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents Subcommittee on Attention-Deficit/Hyperactivity Disorder, Steering Committee on Quality Improvement and Management. *Pediatrics.* 2011; 128:5 1007-1022; published ahead of print October 16, 2011, doi:10.1542/peds.2011-2654.
12. Greenhill L, Kollins S, Abikoff H, et al. Efficacy and Safety of Immediate-Release Methylphenidate Treatment for Preschoolers With ADHD. *J Am Acad Child Adolesc Psychiatry*. 2006; 45(11): 1284-93.
13. Vyvanse Prescribing Information. Wayne, PA: Shire, January 2015.

Program	Program type – ADHD Products
Change Control	
Date	Change
2/2018	Ohio specific policy created for 4/1/18 since Ohio will be moving to a Single PDL later in 2018.