Select Drugs for Attention Deficit Hyperactivity Disorder (ADHD)

Policy # 00601
Original Effective Date: 01/17/2018
Current Effective Date: 01/11/2021

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider select drugs for attention deficit hyperactivity disorder (ADHD), including but not limited to Cotempla XR-ODT™‡ (methylphenidate), Adzenys ER™‡ oral suspension (amphetamine), Relexxii™‡ (methylphenidate), branded Methylphenidate ER, Jornay PM™‡ (methylphenidate), Adhansia XR™‡ (methylphenidate), and Evekeo ODT™‡ (amphetamine), to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for select drugs for ADHD, including but not limited to Cotempla XR-ODT (methylphenidate), Adzenys ER oral suspension (amphetamine), Relexxii (methylphenidate), branded Methylphenidate ER, Jornay PM (methylphenidate), Adhansia XR (methylphenidate), and Evekeo ODT (amphetamine), will be considered when the following criteria are met for the requested drug:

- Cotempla XR-ODT:
    - Patient has a diagnosis of ADHD; AND
    - Patient is 6 to 17 years of age; AND
    - Patient has tried and failed (e.g., intolerance or inadequate response) TWO of the following generic products for ADHD: methylphenidate ER or CD capsules, dexmethylphenidate ER capsules, or dextroamphetamine-amphetamine mixed salt ER capsules unless there is clinical evidence or patient history that suggests the alternatives will be ineffective or cause an adverse reaction to the patient.

*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

- Adzenys ER oral suspension:
  - Patient has a diagnosis of ADHD; AND
  - Patient is 6 to 17 years of age; AND
    *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
  - Patient has tried and failed (e.g., intolerance or inadequate response) TWO of the following generic products for ADHD: dextroamphetamine oral solution, dextroamphetamine/amphetamine mixed salts immediate release tablet, dextroamphetamine/amphetamine mixed salts extended release capsule, methylphenidate oral solution, methylphenidate chewable tablet, or methylphenidate ER or CD capsules unless there is clinical evidence or patient history that suggests the alternatives will be ineffective or cause an adverse reaction to the patient.
    *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Relexxii, branded Methylphenidate ER:
  - Patient has a diagnosis of ADHD; AND
  - Patient is 6 to 65 years of age; AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) TWO of the following generic products for ADHD: methylphenidate ER or CD capsules, dexmethylphenidate ER capsules, or dextroamphetamine-amphetamine mixed salt ER capsules unless there is clinical evidence or patient history that suggests the alternatives will be ineffective or cause an adverse reaction to the patient.
    *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Jornay PM, Adhansia XR:
  - Patient has a diagnosis of ADHD; AND
  - Patient is 6 years of age or older; AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) TWO of the following generic products for ADHD: methylphenidate ER or CD capsules, dexmethylphenidate ER capsules, or dextroamphetamine-amphetamine mixed salt ER capsules unless there is clinical evidence or patient history that suggests the alternatives will be ineffective or cause an adverse reaction to the patient.

*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

- Evekeo ODT:
  - Patient has a diagnosis of ADHD; AND
  - Patient is 6 to 17 years of age; AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) TWO of the following generic products for ADHD: dextroamphetamine oral solution, dextroamphetamine/amphetamine mixed salts immediate release tablet, dextroamphetamine/amphetamine mixed salts extended release capsule, methylphenidate oral solution, methylphenidate chewable tablet, or methylphenidate ER or CD capsules unless there is clinical evidence or patient history that suggests the alternatives will be ineffective or cause an adverse reaction to the patient.
    *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of select drugs for ADHD, including but not limited to Cotempla XR-ODT (methylphenidate), Adzenys ER oral suspension (amphetamine), Relexxii (methylphenidate), branded Methylphenidate ER, Jornay PM (methylphenidate), Adhansia XR (methylphenidate), and Evekeo ODT (amphetamine, when at least TWO of the listed generic alternatives for the requested ADHD drug have NOT been tried and failed to be **not medically necessary.****

Based on review of available data, the Company considers the use of Adzenys ER oral suspension (amphetamine) when a member is 18 years of age or older to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of select drugs for ADHD, including but not limited to Cotempla XR-ODT (methylphenidate), Adzenys ER oral suspension (amphetamine), Relexxii (methylphenidate), branded Methylphenidate ER, Jornay PM

(methylphenidate), Adhansia XR (methylphenidate), and Evekeo ODT (amphetamine, for any non-FDA approved request (e.g. indication) to be **investigational.***

Background/Overview

The treatment of ADHD includes using medications such as methylphenidate, dexmethylphenidate, dextroamphetamine/amphetamine salts, or some variant of those ingredients. Medications may vary based on product release, formulations etc. Multiple generic products exist in this class of medications, including methylphenidate ER or CD capsules, dexmethylphenidate ER capsules, or dextroamphetamine-amphetamine mixed salt ER capsules. Typically, new medications in this class that are FDA approved (such as those targeted in this policy) as branded products do not show superior efficacy to the existing generic products on the market. Note that generic methylphenidate extended release capsules and extended release dextroamphetamine-amphetamine capsules may be opened and sprinkled on 1 tablespoon of applesauce for those that may have issues swallowing. If a member is over 17 years of age, they should be able to use an alternative generic drug in tablet, capsule, or solution form in lieu of requesting Adzenys ER suspension. The generic products offer a more economical, yet equally efficacious, option over the brand name products in this class.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Cotempla XR-ODT is approved for the treatment of ADHD in patients 6 to 17 years of age.

Adzenys ER oral suspension is approved for the treatment of ADHD in patients 6 years of age or older.

Both Relexxii and branded Methylphenidate ER are indicated for the treatment of ADHD in children 6 years of age and older, adolescents, and adults up to the age of 65.

Both Jornay PM and Adhansia XR are indicated for the treatment of ADHD in patients 6 years of age and older.

Evekeo ODT is indicated for the treatment of ADHD in patients 6 to 17 years of age.

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Rationale/Source

This policy is in place to ensure that the targeted drugs in this policy are used according to their FDA label, and this policy is also intended to ensure that efficacious and economically sensible options are utilized prior to branded products.

References

1. Cotempla XR-ODT [package insert]. Neos Therapeutics Brands, LLC. Grand Prairie, TX. Updated June 2017.
2. Adzenys ER oral suspension [package insert]. Neos Therapeutics Brand, LLC. Grand Prairie, TX Updated September 2017.
3. Relexxii [package insert]. Vertical Pharmaceuticals, LLC. Bridgewater, New Jersey. Updated June 2018.
4. Methylphenidate ER [package insert]. Trigen Laboratories, LLC. Bridgewater, New Jersey. Updated February 2018.
5. Jornay PM [package insert]. Ironshore Pharmaceuticals, Inc. Cherry Hill, New Jersey. April 2019.
6. Adhansia XR [package insert]. Purdue Pharmaceuticals. Wilson, North Carolina. July 2019.
7. Evekeo ODT [package insert]. Arbor Pharmaceuticals. Atlanta, Georgia. January 2019.

Policy History

Original Effective Date: 01/17/2018
Current Effective Date: 01/11/2021

01/04/2018	Medical Policy Committee review
01/17/2018	Medical Policy Implementation Committee approval. New policy.
07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. Added new product, Adzenys ER suspension, to the policy.
02/07/2019	Medical Policy Committee review
02/20/2019	Medical Policy Implementation Committee approval. Added Relexxii and branded Methylphenidate ER to the policy. Updated relevant sections.
12/05/2019	Medical Policy Committee review

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12/11/2019 Medical Policy Implementation Committee approval. Added three new products, Jornay PM, Adhansia XR, and Evekeo ODT, to the policy.
12/03/2020 Medical Policy Committee review
12/09/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 12/2021

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.