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Policy Number: C21108-A

CNS Stimulants- IL Medicaid Only

PRODUCTS AFFECTED

Adderall (amphetamine/dextroamphetamine), Adderall XR (amphetamine/dextroamphetamine), Adhansia XR (methylphenidate), Adzenys XR-ODT (amphetamine), amphetamine ER, amphetamine sulfate, amphetamine/dextroamphetamine, Aptensio XR (methylphenidate), Azstarys (serdexmethylphenidate/dexmethylphenidate), Concerta (methylphenidate), Cotempla XR-ODT (methylphenidate), Daytrana (methylphenidate), Desoxyn (methamphetamine), Dexedrine (dextroamphetamine), dextroamphetamine sulfate, dextroamphetamine sulfate ER, dextroamphetamine soln, dexmethylphenidate, dexmethylphenidate ER, Dynavel XR (amphetamine), Evekeo (amphetamine), Evekeo ODT (amphetamine), Focalin (dexmethylphenidate), Focalin XR (dexmethylphenidate), Jornay PM (methylphenidate), methamphetamine, Methylin, methylphenidate, methylphenidate chew, methylphenidate CD/ER/LA/XR, methylphenidate soln, Mydayis (amphetamine/dextroamphetamine), Procentra (dextroamphetamine), QuilliChew ER (methylphenidate), Qullivant XR (methylphenidate), Relexxii (methylphenidate), Ritalin (methylphenidate), Ritalin LA (methylphenidate), Vyvanse (lisdexamfetamine), Xelstrym (dextroamphetamine), Zenzedi (dextroamphetamine)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:
See FDA approved uses

REQUIRED MEDICAL INFORMATION:
A. FOR ATTENTION DEFICIT DISORDER/ATTENTION DEFICIT HYPERACTIVITY DISORDER (IN ADDITION TO REQUIREMENTS BY AGE):
   1. Documentation that the requested drug, dose, and frequency is supported for

treatment of the member's diagnosis and age within FDA approved label OR compendia
AND

2. The member is receiving only one stimulant medication, except when using long- acting and short-acting formulations of the same drug.
AND
3. FOR JORNAY PM ONLY:
Documentation of the following:
   (a) Age is greater than or equal to 6
   AND
   (b) The member has failed to respond to at least TWO preferred ADHD agents in the past 18 months
AND
4. FOR NON-FORMULARY/NON-PREFERRED AGENTS (excluding JORNAY PM):
Documentation of the following:
   (a) Member has failed to respond to at least THREE formulary stimulants from both of the stimulant subclasses (e.g., amphetamine/dextroamphetamine AND methylphenidate/dexmethylphenidate)
   [Requests for a non-preferred, EXTENDED-RELEASE product requires a failure of extended release formulations of the preferred agents.
   Requests for a non-preferred, IMMEDIATE RELEASE product require failure of the immediate release formulations of the preferred agents.]
   OR
   (b) Documentation member has adverse reaction(s) or contraindication(s) to all preferred agents that is not expected to be experienced with the non-preferred drug
AND
5. ANY SPECIFIC POPULATION CRITERIA BELOW ARE ALSO APPLICABLE

B. ADHD FOR MEMBERS GREATER THAN 3 AND LESS THAN 6 YEARS
1. Documented diagnosis of Attention deficit hyperactivity disorder (ADHD).
AND
2. Prescriber attests that member's symptoms are not accounted for by another mental disorder and that the member's symptoms cause clinically significant impairment (social, academic or occupational functioning) and are present in two or more settings.
AND
3. One of the following is present:
   (a) For Inattentive Type at least FIVE of the following symptoms must have persisted for at least 6 months: lack of attention to details/careless mistakes; lack of sustained attention; poor listener; failure to follow through on tasks; poor organization; avoids tasks requiring sustained mental effort; loses things; easily distracted; forgetful.
   OR
   (b) For the Hyperactive-Impulsive Type, at least six of the following symptoms must have persisted for at least 6 months: fidgeting/squirming; leaving seat; inappropriate running/climbing; difficulty with quiet activities; "on the go;" excessive talking; blurting answers; can't wait turn; intrusive
   OR
   (c) The Combined Type requires both inattentive and hyperactive-impulsive criteria to be met.
4. Documentation that the requested drug is FDA approved for the member's age and diagnosis.
NOTE: If the member age and indication being requested is not found in the FDA label or appropriate compendia of literature (e.g. AHFS, Micromedex, current accepted guidelines, etc.), please refer to Molina Off-Label Policy for Review.

C. ADHD FOR MEMBERS 19 YEARS OF AGE AND OLDER:
1. Documented diagnosis of Attention deficit hyperactivity disorder (ADHD)
AND

2. One of the following is present:
   (a) For Inattentive Type at least FIVE of the following symptoms must have persisted for at least 6 months: lack of attention to details/careless mistakes; lack of sustained attention; poor listener; failure to follow through on tasks; poor organization; avoids tasks requiring sustained mental effort; loses things; easily distracted; forgetful.
   OR
   (b) For the Hyperactive-Impulsive Type, at least five of the following symptoms must have persisted for at least 6 months: fidgeting/squirming; leaving seat; inappropriate running/climbing; difficulty with quiet activities; "on the go;" excessive talking; blurting answers; can't wait turn; intrusive
   OR
   (c) For Combined Type requires both inattentive and hyperactive-impulsive criteria to be met

D. BINGE EATING DISORDER(BED)- (VYVANSE ONLY):
1. Documented diagnosis of binge eating disorder
   AND
2. Documentation of all of the following: (a) Member is 18 years of age or older; (b) member's baseline number of binge-eating days per week; and (c) member's treatment plan
   AND
3. Prescriber attests member is receiving concurrent psychotherapy (e.g., cognitive- behavioral therapy [CBT], self-help CBT, family therapy, etc.) – recommended first-line treatment OR will be starting psychotherapy along with drug, AND member has agreed to be compliant with concurrent method of psychotherapy treatment
   AND
4. Documentation member has had an inadequate response or intolerance to at least TWO formulary medications used for BED such as SSRI's, imipramine, desipramine, topiramate, or zonisamide.
   AND
5. Prescriber attests that member has NOT taken monoamine oxidase inhibitors in the past 14 days AND member is NOT concurrently taking other stimulants
   AND
6. Prescriber attests to a review of member's risk for substance abuse

E. NARCOLEPSY:
1. (a) Documented diagnosis of narcolepsy confirmed by polysomnography and multiple sleep latency test (MSLT)
   OR
   (b) Documentation of shiftwork sleep disorder.
   AND
2. Prescriber attests requested agent will not be used concurrently with modafinil or armodafinil
   AND
3. Member is 18 years of age and older

F. DEPRESSIVE DISORDERS:
1. Documented diagnosis of depressive condition
   AND
2. Prescribed products utilization is supported by FDA label or compendia for indication, dosage and age
   AND
3. Prescriber attests that the stimulant being used will be utilized as adjunct to standard antidepressant therapy unless as noted below.

Note: Use as monotherapy only in patients with anticipated short remaining lifetime that would preclude onset of effect of an antidepressant; otherwise use as adjunct to antidepressant

AND

4. Member is 18 years of age and older

G. EXCESSIVE FATIGUE/SLEEPINESS:
   1. Documented diagnosis of a chronic condition associated with severe fatigue or excessive sleepiness (e.g. Chronic fatigue syndrome, Multiple sclerosis, Organic brain disorder, Obstructive Sleep Apnea/Hypopnea Syndrome, Parkinson's Disease)
      AND
   2. Member is 18 years of age and older

CONTINUATION OF THERAPY:

A. BINGE EATING DISORDER (VYVANSE ONLY):
   1. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms (e.g. Improvement from baseline in the number of binge days per week, weight loss etc.)
      AND
   2. Prescriber attests member is continuing to receive psychotherapy while on pharmacologic agents
      AND
   3. The dose requested is not exceeding 70mg/day
      AND
   4. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation (documentation required)
      AND
   5. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

B. FOR ALL OTHER INDICATIONS:
   1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation (documentation required)
      AND
   2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
      AND
   3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms
      AND
   4. FOR MDD ONLY: Prescriber attests that the stimulant being used will be utilized as adjunct to standard antidepressant therapy unless as noted below.
      Note: Use as monotherapy only in patients with anticipated short remaining lifetime that would preclude onset of effect of an antidepressant; otherwise use as adjunct to antidepressant

DURATION OF APPROVAL:

BINGE EATING DISODER: Initial authorization: 3 months, Continuation of Therapy: 6 months
ADHD- Initial authorization: 12 months, Continuation of Therapy: 12 months
ALL OTHER INDICATIONS: Initial authorization: 3 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
No Requirement

AGE RESTRICTIONS:
Age of member limited to the product specific FDA labeled indication or compendia supported indication by age.

QUANTITY:
See Illinois Formulary for Product specific quantity limit requirements

PLACE OF ADMINISTRATION:
The recommendation is that oral and transdermal medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral, Transdermal

DRUG CLASS:
Amphetamines-Methylphenidates

FDA-APPROVED USES:
Adderall XR, Aptensio XR, Daytrana, Dyanavel XR, Focalin, Methylphenidate patch, QuilliChew ER, Quillivant XR, and Ritalin LA are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

Concerta and Methylphenidate Extended-Release and Relexxii are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children 6 years of age and older, adolescents, and adults up to the age of 65.

Adhansia XR, Focalin XR, , Adzenys XR-ODT, Aptensio XR, Dexmethylphenidate ER, Jornay PM and Xelstrym, are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.
Cotempla XR-ODT is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.

Mydayis is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 13years and older.

Adderall, Dexedrine Spansules, Dextroamphetamine, Methylin, methylphenidate, methylphenidate extended-release, ProCentra, Ritalin, Zenzedi are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy.

Desoxyn, Methamphetamine are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD)

Evekeo, Amphetamine is indicated for Narcolepsy, Attention Deficit Disorder with Hyperactivity, and Exogenous Obesity.

Vyvanse is indicated for the treatment of: Attention Deficit Hyperactivity Disorder (ADHD), Moderate to Severe Binge-Eating Disorder (BED) in adults

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of CNS Stimulants are considered experimental/investigational and therefore will follow Molina's Off-Label policy.

OTHER SPECIAL CONSIDERATIONS:
None.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Adderall TABS 10MG
Adderall TABS 12.5MG
Adderall TABS 15MG
Adderall TABS 20MG
Adderall TABS 30MG
Adderall TABS 5MG
Adderall TABS 7.5MG
Adderall XR CP24 10MG
Adderall XR CP24 15MG
Adderall XR CP24 20MG
Adderall XR CP24 25MG
Adderall XR CP24 30MG
Adderall XR CP24 5MG
Adhansia XR CP24 25MG
Adhansia XR CP24 35MG
Adhansia XR CP24 45MG
Adhansia XR CP24 55MG
Adhansia XR CP24 70MG
Adhansia XR CP24 85MG
Adzenys ER SUER 1.25MG/ML
Adzenys XR-ODT TBED 12.5MG
Adzenys XR-ODT TBED 15.7MG
Adzenys XR-ODT TBED 18.8MG
Adzenys XR-ODT TBED 3.1MG
Adzenys XR-ODT TBED 6.3MG
Adzenys XR-ODT TBED 9.4MG
Amphetamine ER SUER 1.25MG/ML
Amphetamine Sulfate TABS 10MG
Amphetamine Sulfate TABS 5MG
Amphetamine-Dextroamphet ER CP24 10MG
Amphetamine-Dextroamphet ER CP24 15MG
Amphetamine-Dextroamphet ER CP24 20MG
Amphetamine-Dextroamphet ER CP24 25MG
Amphetamine-Dextroamphet ER CP24 30MG
Amphetamine-Dextroamphet ER CP24 5MG
Amphetamine-Dextroamphetamine TABS 10MG
Amphetamine-Dextroamphetamine TABS 12.5MG
Amphetamine-Dextroamphetamine TABS 15MG
Amphetamine-Dextroamphetamine TABS 20MG
Amphetamine-Dextroamphetamine TABS 30MG
Amphetamine-Dextroamphetamine TABS 5MG
Amphetamine-Dextroamphetamine TABS 7.5MG
Aptensio XR CP24 10MG
Aptensio XR CP24 15MG
Aptensio XR CP24 20MG
Aptensio XR CP24 30MG
Aptensio XR CP24 40MG
Aptensio XR CP24 50MG
Aptensio XR CP24 60MG
Azstarys CAPS 26.1-5.2MG
Azstarys CAPS 39.2-7.8MG
Azstarys CAPS 52.3-10.4MG
Concerta TBCR 18MG
Concerta TBCR 27MG
Concerta TBCR 36MG
Concerta TBCR 54MG
Cotempla XR-ODT TBED 17.3MG
Cotempla XR-ODT TBED 25.9MG
Cotempla XR-ODT TBED 8.6MG
Daytrana PTCH 10MG/9HR
Daytrana PTCH 15MG/9HR
Daytrana PTCH 20MG/9HR
Daytrana PTCH 30MG/9HR
Desoxyn TABS 5MG
Dexedrine CP24 10MG
Dexedrine CP24 15MG
Dexedrine CP24 5MG
Dexmethylphenidate HCl ER CP24 10MG
Dexmethylphenidate HCl ER CP24 15MG
Dexmethylphenidate HCl ER CP24 20MG
Dexmethylphenidate HCl ER CP24 25MG
Dexmethylphenidate HCl ER CP24 30MG
Dexmethylphenidate HCl ER CP24 35MG
Dexmethylphenidate HCl ER CP24 40MG
Dexmethylphenidate HCl ER CP24 5MG
Dexmethylphenidate HCl TABS 10MG
Dexmethylphenidate HCl TABS 2.5MG
Dexmethylphenidate HCl TABS 5MG
Dextroamphetamine Sulfate ER CP24 10MG
Dextroamphetamine Sulfate ER CP24 15MG
Dextroamphetamine Sulfate ER CP24 5MG
Dextroamphetamine Sulfate SOLN 5MG/5ML
Dextroamphetamine Sulfate TABS 10MG
Dextroamphetamine Sulfate TABS 15MG
Dextroamphetamine Sulfate TABS 20MG
Dextroamphetamine Sulfate TABS 30MG
Dextroamphetamine Sulfate TABS 5MG
Dyanavel XR SUER 2.5MG/ML
Evekeo ODT TBDP 10MG
Evekeo ODT TBDP 15MG
Evekeo ODT TBDP 20MG
Evekeo ODT TBDP 5MG
Evekeo TABS 10MG
Evekeo TABS 5MG Focalin
TABS 10MG Focalin TABS
2.5MG Focalin TABS 5MG
Focalin XR CP24 10MG
Focalin XR CP24 15MG
Focalin XR CP24 20MG
Focalin XR CP24 25MG
Focalin XR CP24 30MG
Focalin XR CP24 35MG
Focalin XR CP24 40MG
Focalin XR CP24 5MG
Jornay PM CP24 100MG
Jornay PM CP24 20MG

Jornay PM CP24 40MG
Jornay PM CP24 60MG
Jornay PM CP24 80MG
Methamphetamine HCl TABS 5MG
Methylin SOLN 10MG/5ML
Methylin SOLN 5MG/5ML
Methylphenidate HCl CHEW 10MG
Methylphenidate HCl CHEW 2.5MG
Methylphenidate HCl CHEW 5MG
Methamphetamine HCl TABS 5MG
Methylin SOLN 10MG/5ML
Methylin SOLN 5MG/5ML
Methylphenidate HCl CHEW 10MG
Methylphenidate HCl CHEW 2.5MG
Methylphenidate HCl CHEW 5MG
Methylphenidate HCl ER (CD) CPCR 10MG
Methylphenidate HCl ER (CD) CPCR 20MG
Methylphenidate HCl ER (CD) CPCR 30MG
Methylphenidate HCl ER (CD) CPCR 40MG
Methylphenidate HCl ER (CD) CPCR 50MG
Methylphenidate HCl ER (CD) CPCR 60MG
Methylphenidate HCl ER (LA) CP24 10MG
Methylphenidate HCl ER (LA) CP24 20MG
Methylphenidate HCl ER (LA) CP24 30MG
Methylphenidate HCl ER (LA) CP24 40MG
Methylphenidate HCl ER (LA) CP24 60MG
Methylphenidate HCl ER (XR) CP24 10MG
Methylphenidate HCl ER (XR) CP24 15MG
Methylphenidate HCl ER (XR) CP24 20MG
Methylphenidate HCl ER (XR) CP24 30MG
Methylphenidate HCl ER (XR) CP24 40MG
Methylphenidate HCl ER (XR) CP24 50MG
Methylphenidate HCl ER (XR) CP24 60MG
Methylphenidate HCl ER TB24 18MG
Methylphenidate HCl ER TB24 27MG
Methylphenidate HCl ER TB24 36MG
Methylphenidate HCl ER TB24 54MG
Methylphenidate HCl ER TBCR 10MG
Methylphenidate HCl ER TBCR 18MG
Methylphenidate HCl ER TBCR 20MG
Methylphenidate HCl ER TBCR 27MG
Methylphenidate HCl ER TBCR 36MG
Methylphenidate HCl ER TBCR 54MG
Methylphenidate HCl ER TBCR 72MG
Methylphenidate HCl SOLN 10MG/5ML
Methylphenidate HCl SOLN 5MG/5ML
Methylphenidate HCl TABS 10MG
Methylphenidate HCl TABS 20MG
Methylphenidate HCl TABS 5MG
Mydayis CP24 12.5MG
Mydayis CP24 25MG
Mydayis CP24 37.5MG
Mydayis CP24 50MG
QuilliChew ER CHER 40MG
Quillivant XR SRER 25MG/5ML
Relexxii TBCR 72MG
Ritalin LA CP24 10MG
Ritalin LA CP24 20MG
Ritalin LA CP24 30MG
Ritalin LA CP24 40MG
Ritalin TABS 10MG
Ritalin TABS 20MG
Ritalin TABS 5MG
Vyvanse CAPS 10MG
Vyvanse CAPS 20MG
Vyvanse CAPS 30MG
Vyvanse CAPS 40MG
Vyvanse CAPS 50MG
Vyvanse CAPS 60MG
Vyvanse CAPS 70MG
Vyvanse CHEW 10MG
Vyvanse CHEW 20MG
Vyvanse CHEW 30MG
Vyvanse CHEW 40MG
Vyvanse CHEW 50MG
Vyvanse CHEW 60MG
Zenzedi TABS 10MG
Zenzedi TABS 15MG
Zenzedi TABS 2.5MG
Zenzedi TABS 20MG
Zenzedi TABS 30MG
Zenzedi TABS 5MG
Zenzedi TABS 7.5MG

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SUMMARY OF REVIEW/REVISIONS	DATE
ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q2/2022
Annual review. Updated for IL stipulated language	7/2023