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 Policy Number: C4191-A

CNS Stimulants

PRODUCTS AFFECTED

Adderall (amphetamine-dextroamphetamine), Adderall XR (amphetamine-dextroamphetamine ER), Adzenys ER (amphetamine ER susp), Adzenys XR-ODT (amphetamine tab extended release disintegrating), amphetamine extended release susp, amphetamine sulfate tabs, amphetamine-dextroamphetamine 3-Bead, Desoxyn (methamphetamine), Dexedrine Spansule (dextroamphetamine sulfate cap), dextroamphetamine sulfate tab, dextroamphetamine sulfate SOLN, dextroamphetamine sulfate ER, Dyanavel XR (amphetamine extended release), Evekeo (amphetamine sulfate), Evekeo ODT (amphetamine sulfate ODT), lisdexamfetamine, methamphetamine HCl tabs, Mydayis CP24 (amphetamine-dextroamphetamine 3-bead cap ER), Procentra (dextroamphetamine sulfate oral solution), Vyvanse (lisdexamfetamine), Xelstrym patch (dextroamphetamine), Zenzedi tabs (dextroamphetamine sulfate tab)

Adhansia XR (methylphenidate HCl cap ER), Aptensio XR (methylphenidate HCl cap ER), Azstarys CAPS (serdexmethylphenidate-dexmethylphenidate), Cotempla XR-ODT (methylphenidate tab extended release disintegrating), Concerta (methylphenidate HCl tab ER osmotic release), Daytrana PTCH (methylphenidate TD patch), dexmethylphenidate HCl ER, Focalin (dexmethylphenidate HCl tab), Focalin XR (dexmethylphenidate HCl cap ER), Jornay PM (methylphenidate HCl cap delayed ER), Methylin SOLN (methylphenidate HCl soln), methylphenidate HCl chew, methylphenidate HCl ER, methylphenidate TD patch, QuilliChew ER (methylphenidate HCl chew tab extended release), Quillivant XR SRER (methylphenidate HCl for ER susp), Relexxii TBCR (methylphenidate HCl tab ER osmotic release), Ritalin (methylphenidate), Ritalin LA (methylphenidate ER)

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.

Drug and Biologic Coverage Criteria

DIAGNOSIS:

Attention deficit hyperactivity disorder (ADHD), Binge eating disorder (BED), Narcolepsy, Shift work sleep disorder, Depressive disorders, Excessive fatigue/sleepiness

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

ALL INDICATIONS (EXCEPT BINGE EATING DISORDER):

1. Documentation member is receiving only one stimulant medication, except when using ONE long-acting and ONE short-acting formulations
AND
2. FOR NON-FORMULARY/NON-PREFERRED AGENTS:
 - (a) Member has failed to respond to at least THREE formulary stimulants from both of the stimulant subclasses if indicated for the requested diagnosis (e.g., amphetamine/dextroamphetamine AND methylphenidate/dexmethylphenidate)
MOLINA REVIEWER NOTE: 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
3. ANY SPECIFIC POPULATION CRITERIA BELOW ARE ALSO APPLICABLE

A. ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD):

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 member's symptoms cause clinically significant impairment (social, academic, or occupational functioning) and are present in two or more settings
AND
3. FOR MEMBERS 18 YEARS OF AGE AND OLDER: ONE of the following must be met:
 - (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

Drug and Biologic Coverage Criteria

B. BINGE EATING DISORDER (BED) (VYVANSE, LISDEXAMFETAMINE ONLY):

1. Documented diagnosis of binge eating disorder
AND
2. Documentation of member's baseline number of binge eating days per week and member's treatment plan
AND
3. Prescriber attests member is receiving concurrent psychotherapy (e.g., cognitive- behavioral therapy [CBT], self-help CBT, family therapy, interpersonal therapy, etc.) – recommended first-line treatment (ref. 44) 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 risk for substance abuse
AND
7. Member is 18 years of age and older

C. NARCOLEPSY/SHIFT WORK SLEEP DISORDER:

1. (a) Documented diagnosis of narcolepsy confirmed by polysomnography and multiple sleep latency test (MSLT) [DOCUMENTATION REQUIRED]
OR
(b) Documented diagnosis of shift work 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

D. DEPRESSIVE DISORDERS:

1. Documented diagnosis of depressive condition
AND
2. Prescribed product's 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

E. 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

Drug and Biologic Coverage Criteria

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 concurrent psychotherapy while on pharmacologic agents
AND
3. The dose requested does not exceed 70 mg/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
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 with provider rationale for a break in treatment
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 DISORDER: Initial authorization: 3 months, Continuation of Therapy: 6 months

ALL OTHER INDICATIONS: Initial authorization: 12 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:

Dose and frequency must be supported by FDA label or compendia supported dosing for prescribed indication. See Appendix for dosing/quantity limits.

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, 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, Adzenys ER, Adzenys XR-ODT, Azstarys, Dexmethylphenidate ER, Focalin XR, Jornay PM, and Xelstryl are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older.

Cotempla XR-ODT, Evekeo ODT are 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 13 years 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 is 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) in adults and pediatric patients 6 years and older, Moderate to Severe Binge-Eating Disorder (BED) in adults

COMPENDIAL APPROVED OFF-LABELED USES:

Fatigue, severe, cancer related or in palliative care setting; Major depressive disorder in medically ill, palliative care, terminal illness, or elderly patients

APPENDIX

APPENDIX:

Reserved for State specific information. Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.

State Specific Information

State Marketplace

Illinois (Source: [Illinois General Assembly](#))

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“(215 ILCS 200/60) Sec. 60. Length of prior authorization approval. *A prior authorization approval shall be valid for the lesser of 6 months after the date the health care professional or health care provider receives the prior authorization approval or the length of treatment as determined by the patient’s health care professional or the renewal of the plan, and the approval period shall be effective regardless of any changes, including any changes in dosage for a prescription drug prescribed by the health care professional. All dosage increases must be based on established evidentiary standards and nothing in this Section shall prohibit a health insurance issuer from having safety edits in place. This Section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids. Except to the extent required by medical exceptions processes for prescription drugs set forth in Section 45.1 of the Managed Care Reform and Patient Rights Act, nothing in this Section shall require a policy to cover any care, treatment, or services for any health condition that the terms of coverage otherwise completely exclude from the policy’s covered benefits without regard for whether the care, treatment, or services are medically necessary. (Source: P.A. 102-409, eff. 1-1-22.)*”

“(215 ILCS 200/65) Sec. 65. Length of prior authorization approval for *treatment for chronic or long-term conditions*. If a health insurance issuer requires a prior authorization for a recurring health care service or maintenance medication for the treatment of a chronic or long-term condition, *the approval shall remain valid for the lesser of 12 months from the date the health care professional or health care provider receives the prior authorization approval or the length of the treatment as determined by the patient’s health care professional*. This Section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids. Except to the extent required by medical exceptions processes for prescription drugs set forth in Section 45.1 of the Managed Care Reform and Patient Rights Act, nothing in this Section shall require a policy to cover any care, treatment, or services for any health condition that the terms of coverage otherwise completely exclude from the policy’s covered benefits without regard for whether the care, treatment, or services are medically necessary. (Source: P.A. 102-409, eff. 1-1-22.)”

Kentucky (Source: [Kentucky Revised Statutes](#))

KY304.17A-167 Time span of authorizations

(Subsection 2) “Unless otherwise provided in subsection (3) of this section or prohibited by state or federal law, if a provider receives a prior authorization for a drug prescribed to a covered person with a condition that requires ongoing medication therapy, and the provider continues to prescribe the drug, and the drug is used for a condition that is within the scope of use approved by the United States Food and Drug Administration or has been proven to be a safe and effective form of treatment for the patient’s specific underlying condition based on clinical practice guidelines that are developed from peer-reviewed publications, the prior authorization received shall: (a) Be valid for the lesser of: 1. One (1) year from the date the provider receives the prior authorization; or 2. Until the last day of coverage under the covered person’s health benefit plan during a single plan year; and (b) Cover any change in dosage prescribed by the provider during the period of authorization.” (Subsection 3) “Except as provided in paragraph (b) of this subsection, the provisions of subsection (2) of this section shall not apply to: 1. Medications that are prescribed for a non-maintenance condition; 2. Medications that have a typical treatment period of less than twelve (12) months; 3. Medications where there is medical or scientific evidence that does not support a twelve (12) month approval; or 4. Medications that are opioid analgesics or benzodiazepines. (b) Paragraph (a) of this subsection shall not apply to any medication that is prescribed to a patient in a community-based palliative care program.”

Re-authorization (approved authorization previously issued by Molina Healthcare) for maintenance medications within this policy shall be approved for a 12 month duration when request meets policy requirements, unless exceptions noted above have been met.

Mississippi (Source: Mississippi Legislature)

“SECTION 13. Length of approvals. (1) A prior authorization approval shall be valid for the lesser of six (6) months after the date the health care professional or health care provider receives the prior authorization approval or the length of treatment as determined by the patient’s health care professional or the renewal of the policy or plan, and the approval period shall be effective regardless of any changes, including any changes in dosage for a prescription drug prescribed by the health care professional. Notwithstanding the foregoing, a health insurer and an enrollee or his/her health care professional may extend a prior authorization approval for a longer period, by agreement. All dosage increases must be based on established evidentiary standards, and nothing in this section shall prohibit a health insurance

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issuer from having safety edits in place. This section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids.

(2) Nothing in this section shall require a policy or plan to cover any care, treatment, or services for any health condition that the terms of coverage otherwise completely exclude from the policy's or plan's covered benefits without regard for whether the care, treatment or services are medically necessary.

SECTION 14. Approvals for chronic conditions. (1) If a health insurance issuer requires a prior authorization for a recurring health care service or maintenance medication for the treatment of a chronic or long-term condition, including, but not limited to, chemotherapy for the treatment of cancer, the approval shall remain valid for the lesser of twelve (12) months from the date the health care professional or health care provider receives the prior authorization approval or the length of the treatment as determined by the patient's health care professional. Notwithstanding the foregoing, a health insurer and an enrollee or his or her health care professional may extend a prior authorization approval for a longer period, by agreement. This section shall not apply to the prescription of benzodiazepines or Schedule II narcotic drugs, such as opioids.

(2) Nothing in this section shall require a policy or plan to cover any care, treatment or services for any health condition that the terms of coverage otherwise completely exclude from the policy's or plan's covered benefits without regard for whether the care, treatment, or services are medically necessary.”

Nevada (Source: Nevada Legislature)

“Chapter 689A of Nevada Revised Statutes (NRS) is hereby amended by adding thereto a new section to read as follows:

1. A policy of health insurance which provides coverage for prescription drugs must not require an insured to submit to a step therapy protocol before covering a drug approved by the Food and Drug Administration that is prescribed to treat a psychiatric condition of the insured, if:
 - a. The drug has been approved by the Food and Drug Administration with indications for the psychiatric condition of the insured or the use of the drug to treat that psychiatric condition is otherwise supported by medical or scientific evidence;
 - b. The drug is prescribed by:
 - i. A psychiatrist
 - ii. A physician assistant under the supervision of a psychiatrist;
 - iii. An advanced practice registered nurse who has the psychiatric training and experience prescribed by the State Board of Nursing pursuant to NRS 632.120; or
 - iv. A primary care provider that is providing care to an insured in consultation with a practitioner listed in subparagraph (1), (2) or (3), if the closest practitioner listed in subparagraph (1), (2) or (3) who participates in the network plan of the insurer is located 60 miles or more from the residence of the insured; and
 - c. The practitioner listed in paragraph (b) who prescribed the drug knows, based on the medical history of the insured, or reasonably expects each alternative drug that is required to be used earlier in the step therapy protocol to be ineffective at treating the psychiatric condition...
3. As used in this section:
 - c. *‘Step therapy protocol’ means a procedure that requires an insured to use a prescription drug or sequence of prescription drugs other than a drug that a practitioner recommends for treatment of a psychiatric condition of the insured before his or her policy of health insurance provides coverage for the recommended drug.*

Molina Reviewer Note: Medical necessity review for a psychiatric condition cannot require trial of other medications first. This is applicable to formulary medications that require prior authorization and non-formulary medications and is not limited to only medications designated ‘ST’. If the requested drug is a brand name and the generic is on formulary, request can be reviewed for specific medical reason generic cannot be used.

Ohio (Source: [Ohio Revised Code](#))

Chapter 3923 Sickness And Accident Insurance Section 3923.041 Policies with prior authorization requirement provisions “(B)(6)(a) For policies issued on or after January 1, 2017, *for a prior approval related to a chronic condition*, the insurer or plan shall honor a prior authorization approval for an approved drug for the lesser of the following from the date of the approval: (i) Twelve months; (ii) The last day of the covered person’s eligibility

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under the policy or plan. (b) The duration of all other prior authorization approvals shall be dictated by the policy or plan.”

State Medicaid

Kentucky (Source: [Kentucky Revised Statutes](#)) KY304.17A-167 Time span of authorizations

(Subsection 2) “Unless otherwise provided in subsection (3) of this section or prohibited by state or federal law, if a provider receives a prior authorization for a drug prescribed to a covered person with a condition that requires ongoing medication therapy, and the provider continues to prescribe the drug, and the drug is used for a condition that is within the scope of use approved by the United States Food and Drug Administration or has been proven to be a safe and effective form of treatment for the patient’s specific underlying condition based on clinical practice guidelines that are developed from peer-reviewed publications, the prior authorization received shall: (a) Be valid for the lesser of: 1. One (1) year from the date the provider receives the prior authorization; or 2. Until the last day of coverage under the covered person’s health benefit plan during a single plan year; and (b) Cover any change in dosage prescribed by the provider during the period of authorization.” (Subsection 3) “Except as provided in paragraph (b) of this subsection, the provisions of subsection (2) of this section shall not apply to: 1. Medications that are prescribed for a non-maintenance condition; 2. Medications that have a typical treatment period of less than twelve (12) months; 3. Medications where there is medical or scientific evidence that does not support a twelve (12) month approval; or 4. Medications that are opioid analgesics or benzodiazepines. (b) Paragraph (a) of this subsection shall not apply to any medication that is prescribed to a patient in a community-based palliative care program.”

Re-authorization (approved authorization previously issued by Molina Healthcare) for maintenance medications within this policy shall be approved for a 12 month duration when request meets policy requirements, unless exceptions noted above have been met.

Use the lowest number/amount of tablets/capsules/liquid to achieve the prescribed dose and frequency. Quantity limit/dose is cumulative across strengths and dosage forms of the drug regimen.

Brand Name (CNS Stimulants)	Generic Name	Quantity Limitations
		QL/dose is cumulative across strengths and dosage forms
Adderall IR	Amphetamine/dextroamphetamine IR tablets	60 mg/day
Adderall XR	Amphetamine/dextroamphetamine ER capsules	60 mg/day
Mydayis	Amphetamine/dextroamphetamine 3-Bead ER capsule	1 capsule per day or 30 per 30 days
Dyanavel XR	Amphetamine ER oral suspension Amphetamine ER tablets	20 mg/day
Adzenys XR-ODT	Amphetamine ER orally disintegrating tab	18.8 mg/day
Evekeo	Amphetamine tablet	60 mg/day
Evekeo ODT	Amphetamine oral disintegrating tablet	40 mg/day
Desoxyn	Methamphetamine tablets	25 mg/day
Vyvanse	Lisdexamfetamine	1 capsule per day or 30 per 30 days 1 chew tab per day or 30 per 30 days
Daytrana	Methylphenidate transdermal	1 patch/day or 30 per 30 days
Metadate CD 10 mg	Methylphenidate ER (CD)	1 capsule/day or 30 per 30 days

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Metadate ER 20 mg	Methylphenidate ER	3 tablets/day 90 per 30 days
Concerta	Methylphenidate ER osmotic release	72 mg/day
Relexxii	Methylphenidate ER osmotic release	72 mg/day
Methylin Solution 5 mg/5 ml	Methylphenidate oral solution	450 ml/month
Methylin Solution 10 mg/5 ml	Methylphenidate oral solution	900 ml/month
Aptensio XR	Methylphenidate ER capsule	60 mg/day
Adhansia XR	Methylphenidate ER capsule	85 mg/day
Ritalin	Methylphenidate tab	60 mg/day
Ritalin LA	Methylphenidate ER cap (LA)	60 mg/day
QuilliChew ER	Methylphenidate ER chew tabs	60 mg/day
Quillivant XR	Methylphenidate ER oral suspension	60 mg/day
Cotempla XR-ODT	Methylphenidate ER orally disintegrating tab	51.8 mg/day
Jornay PM	Methylphenidate ER capsule	100 mg/day
Dexedrine ER	Dextroamphetamine ER capsules	60 mg/day
Zenzedi	Dextroamphetamine IR tablets	60 mg/day
Procentra 5 mg/5 ml	Dextroamphetamine oral solution	60 mg/day
Xelstrym PTCH	Dextroamphetamine TD Patch	1 patch/day or 30 per 30 days
Focalin	Dexmethylphenidate IR tablets	20 mg/day
Focalin XR	Dexmethylphenidate ER capsule	40 mg/day
Azstarys	Serdexmethylphenidate/dexmethylphenidate	1 capsule/day or 30/30 days

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Off-label Supported Use for Narcolepsy:

At the time of this policy update, there are no CNS stimulant agents with off-label supported use for narcolepsy.

Off-label Supported Use for Depressive Disorders:

At the time of this policy update, there is off-label supported use for IR methylphenidate for depressive disorders.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

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

Contraindications to methylphenidate products (including dexmethylphenidate) include: hypersensitivity to methylphenidate, and concurrent treatment with monoamine oxidase (MAO) inhibitors, and also within a minimum of 14 days following discontinuation of a MAO inhibitor (hypertensive crises may result).

Additional contraindications to Relexxii (methylphenidate ER osmotic release), Daytrana (methylphenidate patch) include: patients with marked anxiety, tension, and agitation, patients with glaucoma, and patients with motor tics or with a family history or diagnosis of Tourette's syndrome.

Contraindications to amphetamine products (including lisdexamfetamine, dextroamphetamine, methamphetamine) include: hypersensitivity to amphetamine products, and concurrent use of monoamine oxidase (MAO) inhibitors or within 14 days of the last MAOI dose.

Additional contraindications to Evekeo (amphetamine tablets) include: Advanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism, known

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hypersensitivity or idiosyncrasy to the sympathomimetic amines, agitated states, and patients with a history of drug abuse.

Additional contraindications to Desoxyn (methamphetamine) include: patients with glaucoma, advanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism or known hypersensitivity or idiosyncrasy to sympathomimetic amines, patients in an agitated state, and patients who have a history of drug abuse.

Additional contraindications to Adderall, Adderall XR (amphetamine/dextroamphetamine), Dexedrine (dextroamphetamine), ProCentra (dextroamphetamine) and Zenzedi (dextroamphetamine) include: advanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism, known hypersensitivity or idiosyncrasy to the sympathomimetic amines, glaucoma, agitated states, patients with a history of drug abuse.

Contraindications to Azstarys (serdexmethylphenidate and dexmethylphenidate) include: known hypersensitivity to serdexmethylphenidate, methylphenidate, or product components, and concurrent treatment with a monoamine oxidase inhibitor (MAOI), or use of an MAOI within the preceding 14 days.

OTHER SPECIAL CONSIDERATIONS:

CNS stimulants have a black box warning for abuse and dependence.

CNS stimulants are schedule II controlled substances.

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, 12.5MG, 15MG, 20MG, 30MG, 5MG, 7.5MG

Adderall XR CP24 10MG, 15MG, 20MG, 25MG, 30MG, 5MG

Adhansia XR CP24 25MG, 35MG, 45MG, 55MG, 70MG, 85MG

Adzenys ER SUER 1.25MG/ML

Adzenys XR-ODT TBED 12.5MG, 15.7MG, 18.8MG, 3.1MG, 6.3MG, 9.4MG

Amphetamine Sulfate TABS 10MG, 5MG

Amphet-Dextroamphet 3-Bead ER CP24 12.Gmg, 25mg, 37.5mg, 50mg

Aptensio XR CP24 10MG,15MG, 20MG, 30MG, 40MG, 50MG, 60MG

Azstarys CAPS 26.1-5.2MG, 39.2-7.8MG, 52.3-10.4MG

Concerta TBCR 18MG, 27MG, 36MG, 54MG

Cotempla XR-ODT 17.3MG, 25.9MG, 8.6MG

Daytrana PTCH 10MG/9HR, 15MG/9HR, 20MG/9HR, 30MG/9HR

Desoxyn TABS 5MG

Dexedrine CP24 10MG, 15MG, 5MG

Dexmethylphenidate HCl ER CP24 10MG, 15MG, 20MG, 25MG,30MG, 35MG, 40MG, 5MG

Dextroamphetamine Sulfate SOLN 5MG/5ML

Dextroamphetamine Sulfate TABS 15MG, 20MG, 30MG,2.5MG, 7.5MG

Dextroamphetamine Sulfate ER CP24 10MG, 15MG, 5MG

Dyanavel XR CHER 5MG. 10MG, 15MG, 20MG

Dyanavel XR SUER 2.5MG/ML

Evekeo TABS 10MG, 5MG

Evekeo ODT TBDP 10MG, 15MG, 20MG, 5MG

Focalin TABS 10MG, 2.5MG, 5MG

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Focalin XR CP24 10MG, 15MG, 20MG, 25MG, 30MG, 35MG, 40MG, 50MG, 5MG
Jornay PM CP24 100MG, 20MG, 40MG, 60MG, 80MG
Lisdexamfetamine Dimesylate CAPS 10MG, 20MG, 30MG, 40MG, 50MG, 60MG, 70MG
Lisdexamfetamine Dimesylate CHEW 10MG, 20MG, 30MG, 40MG, 50MG, 60MG
Methamphetamine HCl TABS 5MG
Methylin SOLN 10MG/5ML, 5MG/5ML
Methylphenidate HCl CHEW 10MG, 2.5MG, 5MG
Methylphenidate HCl ER (LA) CP24 60MG
Methylphenidate HCl ER (OSM) TBCR 45MG, 63MG, 72MG
Methylphenidate HCl ER (XR) CP24 10MG, 15MG, 20MG, 30MG, 40MG, 50MG, 60MG
Methylphenidate PTCH 10MG/9HR, 15MG/9HR, 20MG/9HR, 30MG/9HR
Mydayis CP24 12.5MG, 25MG, 37.5MG, 50MG
ProCentra SOLN 5MG/5ML
QuilliChew ER CHER 20MG, 30MG, 40MG
Quillivant XR SRER 25MG/5ML
Relexxii TBCR 18MG, 27MG, 36MG, 54MG, 63MG, 72MG
Ritalin TABS 10MG, 20MG, 5MG
Ritalin LA CP24 10MG, 20MG, 30MG, 40MG
Vyvanse CAPS 10MG, 20MG, 30MG, 40MG, 50MG, 60MG, 70MG
Vyvanse CHEW 10MG, 20MG, 30MG, 40MG, 50MG, 60MG
Xelstrym PTCH 4.5MG/9HR, 9MG/9HR, 13.5MG/9HR, 18MG/9HR
Zenzedi TABS 15MG, 2.5MG, 20MG, 30MG, 7.5MG

REFERENCES

1. Adderall (Dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate and amphetamine sulfate tablets (Mixed salts of a single entity amphetamine product)) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals; September 2023.
2. Adderall XR (mixed salts of a single-entity amphetamine product) extended release capsules [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; October 2023.
3. Adhansia XR (methylphenidate hydrochloride) extended-release capsules [prescribing information]. Wilson, NC: Purdue Pharmaceuticals L.P.; June 2021.
4. Adzenys XR-ODT (amphetamine) extended-release orally disintegrating tablets [prescribing information]. Grand Prairie, TX: Neos Therapeutics Brands LLC; October 2023.
5. Amphetamine Sulfate Tablets [prescribing information]. Brookhaven, NY: Amneal Pharmaceuticals of New York, LLC; June 2023.
6. Aptensio XR (methylphenidate hydrochloride extended-release) capsules [prescribing information]. Coventry, RI: Rhodes Pharmaceuticals L.P.; October 2023.
7. Azstarys (serdexmethylphenidate and dexmethylphenidate) capsules [prescribing information]. Grand Rapids, MI: Corium, Inc.; October 2023.
8. Cotempla XR-ODT (methylphenidate extended-release orally disintegrating tablets) [prescribing information]. Grand Prairie, TX: Neos Therapeutics Brands, LLC; October 2023.
9. Daytrana (methylphenidate transdermal system) [prescribing information]. Miami, FL: Noven Pharmaceuticals, Inc.; October 2023.
10. Desoxyn (methamphetamine hydrochloride tablets) [prescribing information]. Flowood, MS: Key Therapeutics, LLC.; July 2022.
11. Dexedrine (dextroamphetamine sulfate) SPANSULE sustained-release capsules [prescribing information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; October 2023.
12. Dyanavel XR (amphetamine) extended-release oral suspension, DYANAVEL XR (amphetamine) extended-release tablets [prescribing information]. Monmouth Junction, NJ: Tris Pharma, Inc.; October 2023.
13. Evekeo ODT (amphetamine sulfate) orally disintegrating tablets [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals, LLC; September 2022.

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14. Evekeo (amphetamine sulfate tablets) [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2023.
15. Focalin (dexamethylphenidate hydrochloride) tablets [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2023.
16. Focalin XR (dexamethylphenidate hydrochloride) extended-release capsules [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2023.
17. Jornay PM (methylphenidate hydrochloride) extended-release capsules [prescribing information]. Morrisville, NC: Ironshore Pharmaceuticals Inc.; October 2023.
18. Methylin (methylphenidate hydrochloride) oral solution [prescribing information]. Florham Park, NJ: Shionogi Inc.; June 2023.
19. Mydayis (mixed salts of a single-entity amphetamine product) extended-release capsules [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; October 2023.
20. ProCentra (dextroamphetamine sulfate) Oral Solution [prescribing information]. Newport, KY: Independence Pharmaceuticals, LLC; July 2023.
21. QuilliChew ER (methylphenidate hydrochloride) extended-release chewable tablets [prescribing information]. Monmouth Junction, NJ: Tris Pharma, Inc.; October 2023.
22. Quillivant XR (methylphenidate hydrochloride) for extended-release oral suspension [prescribing information]. Monmouth Junction, NJ: Tris Pharma, Inc.; October 2023.
23. Relexxii (methylphenidate hydrochloride extended-release tablets) [prescribing information]. Alpharetta, GA: Vertical Pharmaceuticals, LLC; November 2021.
24. Ritalin LA (methylphenidate hydrochloride) extended-release capsules [prescribing information]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; October 2023.
25. Ritalin (methylphenidate hydrochloride) tablets [prescribing information]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; October 2023.
26. Vyvanse (lisdexamfetamine dimesylate) capsules, VYVANSE® (lisdexamfetamine dimesylate) chewable tablets [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; October 2023.
27. Xelstrym (dextroamphetamine) transdermal system [prescribing information]. Miami, FL: Noven Pharmaceuticals, Inc.; October 2023.
28. Zenzedi (dextroamphetamine sulfate) [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2023.
29. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, 5th edition. Arlington, VA., American Psychiatric Association, 2013.
30. Cantwell DP. Attention deficit disorder: A review of the past 10 years. J Am Acad Child Adolesc Psychiatry. 1996;35:978-87.
31. Dulcan M. Practice parameters for the assessment and treatment of children, adolescents, and adults with attention deficit/hyperactivity disorder. American Academy of Child and Adolescent Psychiatry. J Am Acad Child Adolesc Psychiatry. 1997;36(10Suppl):85S-121S.
32. Gibbons, C, Weiss, M. Clinical recommendations in current practice guidelines for diagnosis and treatment of ADHD in adults. Curr Psychiatry Rep. 2007 Oct;9(5):420-6.
33. Pliszka S; AACAP Work Group on Quality Issues. Practice parameter for the assessment and treatment of children and adolescents with attention-deficit/hyperactivity disorder. J Am Acad Child Adolesc Psychiatry. 2007;46(7):894-921
34. The American Academy of Pediatrics: Subcommittee on Attention-Deficit/Hyperactivity Disorder and Committee on Quality Improvement. Clinical practice guideline: treatment of the school-aged child with attention-deficit/hyperactivity disorder. Pediatrics. 2001 Oct;108(4):1033-44.
35. The American Academy Of Pediatrics: Subcommittee On Attention-Deficit/Hyperactivity Disorder, Steering Committee On Quality Improvement And Management ADHD: Clinical Practice Guideline for the diagnosis, evaluation, and treatment of attention deficit/ hyperactivity disorder in children and adolescents. Pediatrics. 2011Nov;128(5):1-16.
36. American Academy of Sleep Medicine. Central disorders of hypersomnolence. In: The International Classification of Sleep Disorders – Third Edition (ICSD-3) Online Version. Darien,

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- IL: American Academy of Sleep Medicine; 2014. <http://www.aasmnet.org/ebooks/icsd3>.
37. American Psychiatric Association. Sleep-wake disorders. In: Diagnostic and Statistical Manual of Mental Disorders. 5th ed. Arlington, VA: American Psychiatric Association; 2013:361-422.
 38. Post RE, Kurlansik SL. Diagnosis and Management of Attention-Deficit/Hyperactivity Disorder in Adults. *Am Fam Physician* 2012 May 1;85(9):890-896
 39. Dopheide JA, Pliszka SR. Chapter 46. Attention Deficit/Hyperactivity Disorder. In: DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach*, 9e. New York, NY: McGraw-Hill; 2014.
 40. Binge-Eating Disorder in Adults: A Systematic Review and Meta-analysis. Brownley KA, Berkman ND, Peat CM, Lohr KN, Cullen KE, Bann CM, Bulik CM *Ann Intern Med*. 2016;165(6):409. Epub 2016 Jun 28.
 41. Wolraich, M. L., Hagan, J. F., Allan, C., Chan, E., Davison, D., Earls, M., . . . Zurhellen, W. (2019). Clinical practice guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents. *Pediatrics*, 144(4). Doi:10.1542/peds.2019-2528
 42. Treatment of patients with eating disorders, third edition. (2006). *APA Practice Guidelines for the Treatment of Psychiatric Disorders: Comprehensive Guidelines and Guideline Watches*, 1-128. Doi:10.1176/appi.books.9780890423363.138660
 43. Yager, J., Devlin, M. J., Halmi, K. A., Herzog, D. B., Mitchell, J. E., Powers, P., & Zerbe, K. J. (2014). Guideline watch (August 2012): Practice guideline for the treatment of patients with eating disorders, 3rd Edition. *FOCUS*, 12(4), 416-431. Doi:10.1176/appi.focus.120404
 44. American Psychiatric Association. (2023). *The American Psychiatric Association Practice Guideline for the Treatment of Patients with Eating Disorders, Fourth Edition*. American Psychiatric Pub.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Available Dosage Forms References	Q1 2024
REVISION- Notable revisions: Products Affected Diagnosis Required Medical Information Continuation of Therapy Quantity Route of Administration FDA-Approved Uses Compendial Approved Off-Labeled Uses Appendix Background Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file