Drug Coverage Policy

Effective Date 07/01/2025
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Attention Deficit Hyperactivity Disorder (ADHD) Stimulants for Employer Group Plans

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Related Coverage Resources

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not

recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for the following Attention Deficit Hyperactivity Disorder (ADHD) stimulant products:

- **Adderall®** (dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine sulfate, amphetamine aspartate immediate-release tablets)
- **Adderall XR®** (mixed amphetamine salts [dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine sulfate, amphetamine aspartate] extended-release capsules)
- **Adhansia XR™** (methylphenidate extended-release capsules)
- **Adzenys XR-ODT™** (amphetamine extended-release orally disintegrating tablets)
- **amphetamine** immediate-release tablets
- **amphetamine/dextroamphetamine salts** immediate-release tablets and extended-release capsules (generic for Adderall/Adderall XR)
- **Aptensio XR™** (methylphenidate extended-release capsules)
- **Azstarys™** (serdexmethylphenidate and dexmethylphenidate capsules)
- **Concerta®** (methylphenidate extended-release tablets)
- **Cotempla XR-ODT™** (methylphenidate extended-release orally disintegrating tablets)
- **Daytrana®** (methylphenidate transdermal system)
- **Desoxyn®** (methamphetamine tablets)
- **Dexedrine® Spansules®** (dextroamphetamine sustained-release capsules)
- **dexmethylphenidate** immediate-release tablets and extended-release capsules
- **dextroamphetamine sulfate** immediate-release tablets and oral solution
- **Dyanavel® XR** (amphetamine extended-release tablets and oral suspension)
- **Evekeo™** (amphetamine sulfate tablets)
- **Evekeo ODT™** (amphetamine sulfate orally disintegrating tablets)
- **Focalin®** (dexmethylphenidate immediate-release tablets)
- **Focalin® XR** (dexmethylphenidate extended-release capsules)
- **Jornay PM™** (methylphenidate hydrochloride extended-release capsules)
- **lisdexamfetamine dimesylate** capsules and chewable tablets
- **Metadate CD** (methylphenidate hydrochloride extended-release capsules)
- **methamphetamine** immediate-release tablet
- **Methylin®** (methylphenidate tablets, chewable tablets, and oral solution)
- **methylphenidate** chewable tablets, oral solution, immediate-release tablets, and extended-release capsules and tablets
- **methylphenidate** extended-release tablets 45mg, 63mg, and 72 mg
- **methylphenidate** transdermal system/patch
- **mixed salts of a single-entity amphetamine product** extended-release capsules (generic for Mydayis)
- **Mydayis™** (mixed salts of a single-entity amphetamine product extended-release capsules)
- **Procentra®** (dextroamphetamine sulfate liquid)
- **QuilliChew ER™** (methylphenidate extended-release chewable tablets)
- **Quillivant™ XR** (methylphenidate extended-release oral suspension)
- **Relexxii®** (methylphenidate extended-release tablets)

- **Ritalin®** (methylphenidate immediate-release tablets)
- **Ritalin® LA** (methylphenidate extended-release capsules)
- **Ritalin SR®** (methylphenidate sustained-release tablets)
- **Vyvanse®** (lisdexamfetamine dimesylate capsules and chewable tablets)
- **Xelstrym™** (dextroamphetamine transdermal system)
- **Zenzedi™** (dextroamphetamine tablets)

Refer to **Appendix** for additional Attention-Deficit/Hyperactivity Disorder (ADHD) product information (such as dosage formulations, strengths, and durations of action)

When prior authorization applies, the diagnostic criteria below applies to the Complete Plan only. Not for the Essential or Limited plans.

Medical Necessity Criteria

Documentation: Documentation is required where noted in the criteria. Documentation may include, but not limited to, chart notes, laboratory tests, claims records, and/or other information.

Coverage criteria are listed for products **in below table:**

Employer Group Medical Necessity Criteria and Preferred Covered Alternatives:

Product	Criteria
Adderall (amphetamine/ dextroamphetamine salts immediate-release tablets)	**Adderall is considered medically necessary when the individual meets BOTH of the following**: 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following (i and ii): i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Individual meets the preferred covered alternatives criteria as indicated below: **Standard/Performance/Value/Advantage/Total Savings/Legacy Drug List Plans:** Documentation of **BOTH** of the following: A. Trial of **amphetamine/dextroamphetamine salts immediate-release tablets** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction

Product	Criteria
	B. Failure, contraindication, or intolerance to **THREE** of the following: i. dexmethylphenidate (generic for Focalin) ii. dextroamphetamine sulfate (generic for Zenzedi) **OR** Procentra (dextroamphetamine solution) iii. methamphetamine (generic for Desoxyn) iv. methylphenidate chewable tablet **OR** methylphenidate tablet (generic for Ritalin) **OR** methylphenidate oral solution (generic for Methylin) v. lisdexamfetamine capsules or chewable tablets (generic for Vyvanse)
Adderall XR (amphetamine/ dextroamphetamine salts extended-release capsules)	**Adderall XR is considered medically necessary when the individual meets BOTH of the following:** 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Individual meets the preferred covered alternatives criteria as indicated below: **Standard/Performance/Value/Advantage/Total Savings/Legacy Drug List Plans:** There is documentation of **BOTH** of the following: A. Trial of **amphetamine/dextroamphetamine salts extended-release capsules** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction B. Failure, contraindication, or intolerance to **ALL** of the following (i, ii, and iii): i. dexmethylphenidate ER (generic for Focalin XR) ii. methylphenidate ER capsules (generic for Ritalin LA or generic for Aptensio XR) **OR** methylphenidate ER tablet (generic for Concerta) iii. lisdexamfetamine capsules or chewable tablets (generic for Vyvanse)

Product	Criteria
Adhansia XR (methylphenidate extended-release capsules)	**Adhansia XR is considered medically necessary when the individual meets BOTH of the following:** 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following (i and ii): i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Individual meets the preferred covered alternatives criteria as indicated below: **Standard/Performance/Value/Advantage/Total Savings/Legacy Drug List Plans:** Documentation of failure, contraindication, or intolerance to **ALL** of the following: A. dexmethylphenidate ER (generic for Focalin XR) B. dextroamphetamine/amphetamine ER (generic for Adderall XR) **OR** Mydayis (mixed amphetamine salts ER) or generic for Mydayis C. methylphenidate ER capsules (generic for Ritalin LA or generic for Aptensio XR) **OR** methylphenidate ER tablet (generic for Concerta)
Adzenys XR-ODT (amphetamine extended-release orally disintegrating tablets)	**Adzenys XR-ODT is considered medically necessary when the individual meets ALL of the following:** 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following (i and ii): i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Documented inability to swallow capsules and tablets

Product	Criteria
	3. Individual meets the preferred covered alternatives criteria as indicated below: **<u>Value/Advantage/Total Savings Drug List Plans</u>:** Documentation of failure, contraindication, or intolerance to **ALL** of the following: A. dexmethylphenidate ER (generic for Focalin XR) B. dextroamphetamine/amphetamine ER (generic for Adderall XR) **OR** mixed amphetamine salts ER (generic for Mydayis) C. lisdexamfetamine capsules or chewable tablets (generic for Vyvanse) D. methylphenidate ER capsules (generic for Ritalin LA or generic for Aptensio XR)
amphetamine immediate-release tablets	**Amphetamine immediate-release tablet is considered medically necessary when the individual meets the following criteria:** Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression <u>and</u> meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence <u>and</u> meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders
amphetamine/ dextroamphetamine salts immediate-release tablets <u>and</u> extended-release capsules (generic for <u>Adderall/Adderall XR</u>)	**Amphetamine/dextroamphetamine salts immediate-release tablets <u>or</u> extended-release capsules (generic for <u>Adderall/Adderall XR</u>) are considered medically necessary when the individual meets the following criteria**: Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression <u>and</u> meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence <u>and</u> meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders

Product	Criteria
Aptensio XR (methylphenidate extended-release capsules)	**Aptensio XR is considered medically necessary when the individual meets BOTH of the following:** 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Individual meets the preferred covered alternatives criteria as indicated below: **Standard/Performance/Value/Advantage/Total Savings/Legacy Drug List Plans:** There is documentation of **BOTH** of the following: A. Trial of **methylphenidate extended-release capsules** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction B. Failure, contraindication, or intolerance to **BOTH** of the following: i. dexmethylphenidate ER (generic for Focalin XR) ii. dextroamphetamine/amphetamine ER (generic for Adderall XR) **OR** Mydayis (mixed amphetamine salts ER) or generic for Mydayis
Azstarys (serdexmethylphenidate and dexmethylphenidate capsules)	**Azstarys is considered medically necessary when the individual meets BOTH of the following:** 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following:

Product	Criteria
	i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Individual meets the preferred covered alternatives criteria as indicated below: **<u>Standard/Performance/Legacy Drug List Plans:</u>** Covered as a non-preferred brand [step therapy may apply] **<u>Value/Advantage/Total Savings Drug List Plans</u>:** Documentation of failure, contraindication, or intolerance to **FOUR** of the following: A. dexmethylphenidate ER capsules (generic for Focalin XR) B. methylphenidate ER tablets (generic for Concerta) C. methylphenidate CD capsules (generic for Metadate CD) D. methylphenidate LA capsules (generic for Ritalin LA) E. methylphenidate ER capsules (generic for Aptensio XR)
Concerta (methylphenidate extended-release tablets)	**Concerta is considered medically necessary when the individual meets BOTH of the following:** 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression <u>and</u> meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence <u>and</u> meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Individual meets the preferred covered alternatives criteria as indicated below: **<u>Standard/Performance/Value/Advantage/Total Savings/Legacy Drug List Plans:</u>** Documentation of **BOTH** of the following: A. Trial of **<u>methylphenidate extended-release tablets</u>** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction B. Failure, contraindication, or intolerance to **BOTH** of the following: i. dexmethylphenidate ER (generic for Focalin XR)

Product	Criteria
	ii. dextroamphetamine/amphetamine ER (generic for Adderall XR) **OR** Mydayis (mixed amphetamine salts ER) or generic for Mydayis
Cotempla XR ODT (methylphenidate extended-release orally disintegrating tablets)	**Cotempla XR ODT is considered medically necessary when the individual meets ALL of the following:** 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Documented inability to swallow capsules and tablets 3. Individual meets the preferred covered alternatives criteria as indicated below (does not apply to Legacy Drug List Plans): **Standard/Performance/Value/Advantage/Total Savings/Drug List Plans:** There is documentation failure, contraindication, or intolerance to **ALL** of the following: A. dexmethylphenidate ER (generic for Focalin XR) B. dextroamphetamine/amphetamine ER (generic for Adderall XR) **OR** Mydayis (mixed amphetamine salts ER) or generic for Mydayis C. methylphenidate ER capsules (generic for Ritalin LA or generic for Aptensio XR)
Daytrana (methylphenidate transdermal system/patch)	**Daytrana is considered medically necessary when the individual meets the following criteria:** Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following (i and ii): i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following:

Product	Criteria
	i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders
Desoxyn (methamphetamine tablets)	**Desoxyn is considered medically necessary when the individual meets BOTH of the following:** 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Individual meets the preferred covered alternatives criteria as indicated below: **Standard/Performance/Legacy/Value/Advantage/Total Savings Drug List Plans:** Documentation of **BOTH** of the following: A. Trial of **methamphetamine tablets** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction B. Failure, contraindication, or intolerance to **THREE** of the following: i. dexmethylphenidate (generic for Focalin) ii. dextroamphetamine/amphetamine (generic for Adderall) iii. dextroamphetamine tablet (generic for Zenzedi) **OR** Procentra (dextroamphetamine solution) iv. lisdexamfetamine capsules or chewable tablets (generic for Vyvanse) v. methylphenidate chewable tablet **OR** methylphenidate tablet (generic for Ritalin) **OR** methylphenidate oral solution (generic for Methylin)
Dexedrine (dextroamphetamine sustained-release capsules)	**Dexedrine is considered medically necessary when the individual meets BOTH of the following:** 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy

Product	Criteria
	C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Individual meets the preferred covered alternatives criteria as indicated below: **Standard/Performance/Value/Advantage/Total Savings/Legacy Drug List Plans:** Documentation of **BOTH** of the following: A. Trial of **dextroamphetamine sustained-release capsules** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction B. Failure, contraindication, or intolerance to **THREE** of the following: i. dextroamphetamine/amphetamine ER (generic for Adderall XR) **OR** Mydayis (mixed amphetamine salts ER) or generic for Mydayis ii. dexmethylphenidate ER (generic for Focalin XR) iii. methylphenidate ER capsules (generic for Ritalin LA or generic for Aptensio XR) **OR** methylphenidate ER tablets (generic for Concerta) iv. lisdexamfetamine capsules or chewable tablets (generic for Vyvanse)
dexmethylphenidate immediate-release tablets and extended-release capsules	**Dexmethylphenidate immediate-release tablets or extended-release capsules are considered medically necessary when the individual meets the following criteria:** Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following:

Product	Criteria
	i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders
dextroamphetamine immediate release tablets and oral solution	**Dextroamphetamine immediate release tablets or oral solution are considered medically necessary when the individual meets the following criteria:** Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders
Dyanavel XR (amphetamine extended-release oral suspension and tablets [may be chewed])	**Dyanavel XR is considered medically necessary when the individual meets ALL of the following:** 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Documented inability to swallow capsules and tablets 3. Individual meets the preferred covered alternatives criteria as indicated below: **Value/Advantage/Total Savings Drug List Plans:** Documentation of failure, contraindication, or intolerance to **ALL** of the following: A. dexmethylphenidate ER (generic for Focalin XR) B. dextroamphetamine/amphetamine ER (generic for Adderall XR) **OR** mixed amphetamine salts ER (generic for Mydayis)

Product	Criteria
	C. lisdexamfetamine capsules or chewable tablets (generic for Vyvanse) D. methylphenidate ER capsules (generic for Ritalin LA or generic for Aptensio XR)
Evekeo (amphetamine sulfate immediate-release tablets)	**Evekeo is considered medically necessary when the individual meets BOTH of the following:** 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Individual meets the preferred covered alternatives criteria as indicated below: **Standard/Performance/Value/Advantage/Total Savings/Legacy Drug List Plans:** Documentation of **BOTH** of the following: A. Trial of **amphetamine sulfate immediate-release tablets** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction B. Failure, contraindication, or intolerance to **THREE** of the following: i. dexmethylphenidate (generic for Focalin) ii. dextroamphetamine sulfate (generic for Zenzedi) **OR** Procentra (dextroamphetamine solution) iii. methamphetamine (generic for Desoxyn) iv. methylphenidate chewable tablet OR methylphenidate tablet (generic for Ritalin) **OR** methylphenidate oral solution (generic for Methylin) v. lisdexamfetamine capsules or chewable tablets (generic for Vyvanse)
Evekeo ODT (amphetamine sulfate orally disintegrating tablets)	**Evekeo ODT is considered medically necessary when the individual meets ALL of the following:** 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD)

Product	Criteria
	B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression <u>and</u> meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence <u>and</u> meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Documented inability to swallow capsules and tablets 3. Individual meets the preferred covered alternatives criteria as indicated below: **<u>Value/Advantage/Total Savings Drug List Plans</u>:** Documentation of failure, contraindication, or intolerance to **FOUR** of the following: A. amphetamine immediate-release tablets (generic for Evekeo) B. dexmethylphenidate (generic for Focalin) C. dextroamphetamine sulfate (generic for Zenzedi) **OR** Procentra (dextroamphetamine solution) D. lisdexamfetamine capsules or chewable tablets (generic for Vyvanse) E. methamphetamine (generic for Desoxyn) F. methylphenidate chewable tablet **OR** methylphenidate tablet (generic for Ritalin) **OR** methylphenidate oral solution (generic for Methylin)
Focalin (dexmethylphenidate immediate-release tablets)	**Focalin is considered medically necessary when the individual meets BOTH of the following:** 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression <u>and</u> meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence <u>and</u> meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Individual meets the preferred covered alternatives criteria as indicated below:

Product	Criteria
	Standard/Performance/Value/Advantage/Total Savings/Legacy Drug List Plans: Documentation of **BOTH** of the following: A. Trial of **dexmethylphenidate immediate-release tablets** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction B. Failure, contraindication, or intolerance to **THREE** of the following: i. amphetamine (generic for Evekeo) **OR** dextroamphetamine/amphetamine (generic for Adderall) ii. dextroamphetamine sulfate (generic for Zenzedi) **OR** Procentra (dextroamphetamine solution) iii. methamphetamine (generic for Desoxyn) iv. methylphenidate chewable tablet **OR** methylphenidate tablet (generic for Ritalin) **OR** methylphenidate oral solution (generic for Methylin)
Focalin XR (dexmethylphenidate extended-release capsules)	**Focalin XR is considered medically necessary when the individual meets BOTH of the following:** 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Individual meets the preferred covered alternatives criteria as indicated below: **Standard/Performance/Value/Advantage/Total Savings/Legacy Drug List Plans:** Documentation of **BOTH** of the following: A. Trial of **dexmethylphenidate extended-release capsules** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction B. Failure, contraindication, or intolerance to **BOTH** of the following:

Product	Criteria
	i. dextroamphetamine/amphetamine ER (generic for Adderall XR) **OR** Mydayis (mixed amphetamine salts ER) or generic for Mydayis ii. methylphenidate ER capsules (generic for Ritalin LA or generic for Aptensio XR) **OR** methylphenidate ER tablet (generic for Concerta)
Jornay PM (methylphenidate extended-release capsules)	**Jornay PM is considered medically necessary when the** individual meets **ALL** of the following: 1. Individual is 6 years of age or older 2. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 3. Individual meets the preferred covered alternatives criteria as indicated below: **Standard/Performance/Value/Advantage/Total Savings/Legacy Drug List Plans:** Documentation of failure, contraindication, or intolerance to **ALL** of the following: A. dexmethylphenidate ER (generic for Focalin XR) B. dextroamphetamine/amphetamine ER (generic for Adderall XR) **OR** Mydayis (mixed amphetamine salts ER) or generic for Mydayis C. methylphenidate ER capsules (generic for Ritalin LA or generic for Aptensio XR) **OR** methylphenidate ER tablet (generic for Concerta)
lisdexamfetamine dimesylate capsules and chewable tablets	**Lisdexamfetamine capsules or chewable tablets are considered medically necessary when the individual meets the following:** Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Binge-Eating Disorder in an Adult (18 years of age and older) C. Narcolepsy D. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following:

Product	Criteria
	i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) E. Fatigue Associated with Cancer and/or its Treatment F. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders
Metadate CD (methylphenidate hydrochloride extended-release capsules)	**Metadate CD is considered medically necessary when the individual meets BOTH of the following:** 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Individual meets the preferred covered alternatives criteria as indicated below: **Standard/Performance/Legacy/Value/Advantage/Total Savings Drug List Plans:** Documentation of **BOTH** of the following: A. Trial of **methylphenidate extended-release capsule** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction B. Failure, contraindication, or intolerance to **THREE** of the following: i. dexmethylphenidate ER capsules (generic for Focalin XR) ii. methylphenidate ER tablets (generic for Concerta) iii. methylphenidate LA capsules (generic for Ritalin LA) iv. methylphenidate ER capsules (generic for Aptensio XR

Product	Criteria
methamphetamine immediate-release tablets	**Methamphetamine immediate-release tablets are considered medically necessary when the Individual meets the following criteria:** Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders
Methylin (methylphenidate immediate-release oral solution)	**Methylin is considered medically necessary when the individual meets BOTH of the following:** 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Individual meets the preferred covered alternatives criteria as indicated below: **Standard/Performance/Value/Advantage/Total Savings/Legacy Drug List Plans:** Documentation of **BOTH** of the following: A. Trial of **methylphenidate immediate-release oral solution** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction B. Failure, contraindication, or intolerance to **THREE** of the following:

Product	Criteria
	i. amphetamine (generic for Evekeo) **OR** dextroamphetamine/amphetamine (generic for Adderall) ii. dexmethylphenidate (generic for Focalin) iii. dextroamphetamine sulfate (generic for Zenzedi) OR Procentra (dextroamphetamine solution) iv. methamphetamine (generic for Desoxyn)
methylphenidate • 5 mg/5 mL and 10 mg/5 mL oral solution • 5 mg, 10 mg and 20 mg IR tablets • 2.5 mg, 5 mg and 10 mg chewable tablets • 10 mg, 15mg, 20 mg, 30 mg, 40 mg, 50 mg and 60 mg ER capsules • 10 mg, 18 mg, 20 mg, 27 mg, 36 mg, 54 mg ER tablets	**Methylphenidate solution, immediate-release tablets, chewable tablets, or extended-release capsules/tablets are considered medically necessary when the individual meets the following criteria:** Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression <u>and</u> meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence <u>and</u> meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders
methylphenidate extended-release 45mg, 63mg, 72 mg tablets	**Methylphenidate extended-release 45mg, 63mg, or 72 mg tablets are considered medically necessary when the individual meets BOTH of the following:** 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression <u>and</u> meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence <u>and</u> meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Individual meets the preferred covered alternatives criteria as indicated below: **<u>Standard/Performance/Legacy/Value/Advantage/Total Savings Drug List Plans:</u>**

Product	Criteria
	Documentation of failure, contraindication, or intolerance to **ALL** of the following: A. dexmethylphenidate extended-release capsules (generic for Focalin XR) B. methylphenidate extended-release tablets (generic for Concerta) C. methylphenidate CD capsules (generic for Metadate CD) or methylphenidate LA capsules (generic for Ritalin LA) D. methylphenidate extended-release capsules (generic for Aptensio XR)
methylphenidate transdermal system/patch	**Methylphenidate transdermal system/patch is considered medically necessary when the individual meets the following criteria:** Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders
mixed salts of a single-entity amphetamine product extended-release capsules (generic for Mydayis)	**Mixed salts of a single-entity amphetamine product extended-release capsules (generic for Mydayis) is considered medically necessary when the individual meets BOTH of the following:** 1. Age 13 years or older 2. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders

Product	Criteria
Mydayis (mixed salts of a single-entity amphetamine product extended-release capsules)	**Mydayis is considered medically necessary when the individual meets ALL of the following:** 1. Age 13 years or older 2. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 3. Individual meets the preferred covered alternatives criteria as indicated below: **Value/Advantage/Total Savings Drug List Plans:** Documentation of failure, contraindication, or intolerance to **ALL** of the following: A. dexmethylphenidate ER (generic for Focalin XR) B. dextroamphetamine/amphetamine ER (generic for Adderall XR) C. lisdexamfetamine capsules or chewable tablets (generic for Vyvanse) D. methylphenidate ER capsules (generic for Ritalin LA or generic for Aptensio XR) **OR** methylphenidate ER tablet (generic for Concerta)
Procentra (dextroamphetamine sulfate liquid)	**Procentra is considered medically necessary when the individual meets the following criteria:** Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders

Product	Criteria
Quillichew ER (methylphenidate extended-release chewable tablets)	**Quillichew ER is considered medically necessary when the individual meets ALL of the following:** 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Documented inability to swallow capsules or tablets 3. Individual meets the preferred covered alternatives criteria as indicated below: **Value/Advantage/Total Savings Drug List Plans:** Documentation of failure, contraindication, or intolerance to **ALL** of the following: A. dexmethylphenidate ER (generic for Focalin XR) B. dextroamphetamine/amphetamine ER (generic for Adderall XR) **OR** mixed amphetamine salts ER (generic for Mydayis) C. methylphenidate ER capsules (generic for Ritalin LA or generic for Aptensio XR)
Quillivant XR (methylphenidate extended-release oral suspension)	**Quillivant XR is considered medically necessary when the individual meets BOTH of the following:** 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Documented inability to swallow capsules or tablets
Relexxii (methylphenidate	**Relexxii is considered medically necessary when the individual meets BOTH of the following:**

Product	Criteria
extended-release 18mg, 27mg, 36mg, 45mg, 54mg, 63mg, 72 mg tablets)	1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Individual meets the preferred covered alternatives criteria as indicated below: **Standard/Performance/Legacy/Value/Advantage/Total Savings Drug List Plans:** Documentation of failure, contraindication, or intolerance to **ALL** of the following: A. dexmethylphenidate extended-release capsules (generic for Focalin XR) B. methylphenidate extended-release tablets (generic for Concerta) C. methylphenidate CD capsules (generic for Metadate CD) or methylphenidate LA capsules (generic for Ritalin LA) D. methylphenidate extended-release capsules (generic for Aptensio XR)
Ritalin (methylphenidate immediate-release tablets)	**Ritalin immediate-release tablets are considered medically necessary when the individual meets BOTH of the following:** 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Individual meets the preferred covered alternatives criteria as indicated below:

Product	Criteria
	Standard/Performance/Value/Advantage/Total Savings/Legacy Drug List Plans: Documentation of **BOTH** of the following: A. Trial of **methylphenidate immediate-release tablets** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction B. Failure, contraindication, or intolerance to **THREE** of the following: i. amphetamine (generic for Evekeo) **OR** dextroamphetamine/amphetamine (generic for Adderall) ii. dexmethylphenidate (generic for Focalin) iii. dextroamphetamine sulfate (generic for Zenzedi) **OR** Procentra (dextroamphetamine solution) iv. methamphetamine (generic for Desoxyn)
Ritalin LA (methylphenidate extended-release capsules)	**Ritalin LA capsules are considered medically necessary when the individual meets BOTH of the following:** 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Individual meets the preferred covered alternatives criteria as indicated below: **Standard/Performance/Value/Advantage/Total Savings/Legacy Drug List Plans:** Documentation of **BOTH** of the following: A. Trial of **methylphenidate extended-release capsules** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction B. Failure, contraindication, or intolerance to **BOTH** of the following: i. dexmethylphenidate ER (generic for Focalin XR)

Product	Criteria
	ii. dextroamphetamine/amphetamine ER (generic for Adderall XR) **OR** Mydayis (mixed amphetamine salts ER) or generic for Mydayis
Vyvanse capsules (lisdexamfetamine dimesylate)	**Vyvanse capsules are considered medically necessary when the patient meets BOTH of the following (1 and 2):** 1. Documented diagnosis of **ONE** of the following (A, B, C, D, E, or F): A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Binge-Eating Disorder in an Adult (18 years of age and older) C. Narcolepsy D. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) E. Fatigue Associated with Cancer and/or its Treatment F. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Preferred product criteria is met as listed below: **Standard/Performance/Legacy/Value/Advantage/Total Savings Drug List Plans:** Patient meets **ONE** of the following (A or B): A. Patient has tried **lisdexamfetamine capsules** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction B. Patient is currently receiving Vyvanse capsules
Vyvanse chewable tablets (lisdexamfetamine dimesylate)	**Vyvanse chewable tablets are considered medically necessary when the patient meets ALL of the following (1, 2 and 3):** 1. Documented inability to swallow capsules and tablets 2. Documented diagnosis of **ONE** of the following (A, B, C, D, E, or F): A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Binge-Eating Disorder in an Adult (18 years of age and older) C. Narcolepsy D. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) E. Fatigue Associated with Cancer and/or its Treatment F. Idiopathic Hypersomnolence and meets the following:

Product	Criteria
	i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 3. Preferred product criteria is met as listed below: **<u>Standard/Performance/Legacy/Value/Advantage/Total Savings Drug List Plans</u>:** Patient meets **ONE** of the following (A <u>or</u> B): A. Patient has tried **<u>lisdexamfetamine chewable tablets</u>** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction B. Patient is currently receiving Vyvanse chewable tablets
Xelstrym (dextroamphetamine transdermal system)	**Xelstrym is considered medically necessary when the individual meets BOTH of the following:** 1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression <u>and</u> meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence <u>and</u> meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Individual meets the preferred covered alternatives criteria as indicated below: **<u>Standard/Performance/Value/Advantage/Total Savings/Legacy Drug List Plans:</u>** Documentation of failure, contraindication, or intolerance to **FOUR** of the following: A. dexmethylphenidate ER (generic for Focalin XR) B. dextroamphetamine/amphetamine ER (generic for Adderall XR) **OR** Mydayis (mixed amphetamine salts ER) or generic for Mydayis C. dextroamphetamine ER capsules (generic for Dexedrine) D. lisdexamfetamine capsules or chewable tablets (generic for Vyvanse) E. methylphenidate ER capsules (generics for Metadate CD, Ritalin LA, or Aptensio XR)
Zenzedi (dextroamphetamine tablets)	**Zenzedi is considered medically necessary when the individual meets BOTH of the following:**

Product	Criteria
	1. Documented diagnosis of **ONE** of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets **BOTH** of the following: i. Individual is 18 years of age or older ii. Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 2. Individual meets the preferred covered alternatives criteria as indicated below: **Standard/Performance/Value/Advantage/Total Savings/Legacy Drug List Plans:** Documentation of **BOTH** of the following: A. Trial of **dextroamphetamine tablets** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction B. Failure, contraindication, or intolerance to **THREE** of the following: i. amphetamine (generic for Evekeo) **OR** dextroamphetamine/amphetamine (generic for Adderall) ii. dexmethylphenidate (generic for Focalin) iii. lisdexamfetamine capsules or chewable tablets (generic for Vyvanse) iv. methamphetamine (generic for Desoxyn) v. methylphenidate chewable tablet **OR** methylphenidate tablet (generic for Ritalin) **OR** methylphenidate oral solution (generic for Methylin)

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Attention Deficit Hyperactivity Disorder (ADHD) stimulants are considered medically necessary for continued use when initial criteria are met **AND** there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

1. **Fatigue associated with Multiple Sclerosis (MS).** There are no published studies supporting this use. In addition, neither recent review articles nor the 2007 practice parameters for the treatment of narcolepsy and other hypersomnias of central origin mention stimulants (only modafinil). Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin, updated in 2007, state that modafinil may be effective for the treatment of daytime sleepiness due to MS.[27] Agents that have been studied for the treatment of fatigue due to MS include amantadine, modafinil, pemoline, aminopyridines, antidepressants, and aspirin.[41]

2. **Long-term Combination Therapy (i.e., > 2 months) with Strattera and Central Nervous System (CNS) Stimulants for the treatment of ADD/ADHD (for example, mixed amphetamine salts extended-release capsules [Adderall XR, Mydayis, or generics], methylphenidate extended-release tablets, methylphenidate immediate-release tablets).** Currently, data do not support using Strattera and CNS stimulant medications concomitantly.[42] Short-term drug therapy (≤ 2 months) with both Strattera and CNS stimulant medications are allowed for transitioning the patient to only one drug. Intuniv and clonidine extended-release tablets (Kapvay, generics) are indicated for use as monotherapy, or as adjunctive therapy to CNS stimulant medications; therefore, long-term combination therapy with either agent and CNS stimulants is appropriate.[35-36]

3. **Neuroenhancement.** The use of prescription medication to augment cognitive or affective function in otherwise healthy individuals (also known as neuroenhancement) is increasing in adult and pediatric populations.[37] A 2013 Ethics, Law, and Humanities Committee position paper, endorsed by the American Academy of Neurology (AAN) indicates that based on available data and the balance of ethics issues, neuroenhancement in legally and developmentally nonautonomous children and adolescents without a diagnosis of a neurologic disorder is not justifiable. In nearly autonomous adolescents, the fiduciary obligation of the physician may be weaker, but the prescription of neuroenhancements is inadvisable due to numerous social, developmental, and professional integrity issues.

4. **Weight Loss.** Of the CNS stimulants, only amphetamine and methamphetamine are indicated for exogenous obesity, as a short-term (i.e., a few weeks) adjunct in a regimen of weight reduction based on caloric restriction, for patients in whom obesity is refractory to alternative therapy (e.g., repeated diets, group programs, and other drugs).[4,41] However, guidelines on the management of obesity do not address or recommend use of amphetamine or methamphetamine (or any other CNS stimulants).[38-40]

Background

OVERVIEW

The central nervous system (CNS) stimulant medications in this policy are indicated for the following uses:[1-24,43,44,48-53]

- **Attention deficit hyperactivity disorder (ADHD)**, treatment. All of the stimulant medications in this policy are indicated for the treatment of ADHD.
- **Binge eating disorder**, treatment. Vyvanse is the only stimulant medication indicated for the treatment of binge eating disorder.
- **Narcolepsy**, treatment. Several methylphenidate and amphetamine-containing products are also indicated for the treatment of narcolepsy.
- **Exogenous obesity**, treatment. Evekeo is indicated as adjunctive therapy for the short-term (i.e., a few weeks) treatment of exogenous obesity.

Dextroamphetamine sulfate tablets, Zenzedi, and Adderall (generics) are indicated in patients ≥ 3 years of age; the other products are indicated in patients ≥ 6 years of age, except for Mydayis which is indicated in patients ≥ 13 years of age.[1,2,6,19,43] Adderall XR (generics), Adzenys ER, Adzenys XR-ODT, Mydayis, Vyvanse, Concerta (generics), and several methylphenidate products are indicated for use in adults with ADHD.[2,5,9,24,43,48] Jornay PM is the only stimulant taken in the evening.[49]

Other Uses with Supportive Evidence
Idiopathic hypersomnia: A condition similar to narcolepsy, idiopathic hypersomnia is characterized by constant or recurrent daytime sleepiness with no other cause of sleepiness, prolonged nocturnal sleep, difficulty awakening with sleep drunkenness, and long unrefreshing naps with no history of cataplexy.[29-32]

Guidelines
Eating disorders: The American Psychiatric Association (APA) guideline on the treatment of patients with eating disorders (2006 with a Guideline Watch in 2012) suggests treatment with antidepressant medications, particularly selective serotonin reuptake inhibitors (SSRIs), is associated with at least a short-term reduction in binge eating behavior but, in most cases, not with substantial weight loss (recommended with substantial clinical confidence); topiramate is effective for binge reduction and weight loss (recommended with moderate clinical confidence); and zonisamide may produce similar effects regarding weight loss (may be recommended on the basis of individual circumstances).[39,40] The 2012 Guideline Watch references a 2011 literature review by a multinational task force on eating disorders which concluded that Grade A evidence supports the use of imipramine (with moderate risk-benefit ratio), sertraline and citalopram/escitalopram (all with good risk-benefit ratios), and topiramate (with moderate risk-benefit ratio), and Grade D evidence for fluvoxamine and fluoxetine (i.e., inconsistent results).

Narcolepsy and other hypersomnias: The practice parameters from the American Academy of Sleep Medicine for the treatment of narcolepsy and other hypersomnias of central origin, updated in 2007, state that amphetamine, methamphetamine, dextroamphetamine, and methylphenidate are effective for treatment of daytime sleepiness due to narcolepsy.[25] The parameters also state that amphetamine, methamphetamine, dextroamphetamine, methylphenidate and modafinil may be effective for the treatment of daytime sleepiness due to idiopathic hypersomnia. As there may be underlying causes/behaviors associated with excessive daytime sleepiness, a sleep specialist physician has the training to correctly recognize and diagnose this condition.

Major depressive disorder (MDD): The 2010 APA practice guidelines for the treatment of patients with MDD state that many clinicians find augmentation of antidepressants with low doses of stimulants such as methylphenidate or dextroamphetamine may help ameliorate otherwise suboptimally responsive depression, although not all clinical trials have shown benefits from this strategy.[26] There are no clear guidelines regarding the length of time stimulants should be co-administered. A 16-week randomized, double-blind, placebo-controlled trial in patients with

geriatric depression in older (mean age of 70 years) outpatients diagnosed with major depression (n = 143) found that combined treatment with citalopram and methylphenidate demonstrated an enhanced clinical response profile in mood and wellbeing, as well as a higher rate of remission, compared with either drug alone.[45]

Cancer-related fatigue: The National Comprehensive Cancer Network (NCCN) guidelines on cancer-related fatigue (version 1.2021 – December 1, 2020) state to consider use of psychostimulants (i.e., methylphenidate) after other causes of fatigue have been ruled out and/or other management strategies have been attempted.[27] The NCCN guidelines on adult cancer pain (version 2.2021 – June 3, 2021) state that sedation may hinder the achievement of dose titration of opioids to levels that provide adequate analgesia.[28] If opioid-induced sedation develops and persists for greater than 2 to 3 days, it may be managed by administration of a psychostimulant, such as methylphenidate, dextroamphetamine, modafinil, armodafinil, or by adding caffeine. A meta-analysis of treatments for fatigue associated with palliative care showed a superior effect for methylphenidate in cancer-related fatigue.[46] A review of methylphenidate for cancer-related fatigue found a small but significant improvement in fatigue over placebo (P = 0.005).[47]

Appendix

Attention-Deficit/Hyperactivity Disorder (ADHD) Product Information:

Amphetamine Dosage Forms and Dosing.[1-24, 43-44, 48-53]

Trade Name (Generic Name)	Formulation	Strengths (mg)	Comments on Dosing/ Duration of Action
Adderall® (mixed amphetamine salts*, generics)	IR tablet, scored	5, 7.5, 10, 12.5, 15, 20, 30	First dose upon awakening; additional doses (1 or 2) at 4 to 6 hour intervals. Duration of Action: 4 to 6 hours
Adderall XR® (mixed amphetamine salts*, generics)	ER capsule	5, 10, 15, 20, 25, 30	Take upon awakening. Capsule may be taken whole or opened and contents sprinkled on applesauce and consumed immediately without chewing. Duration of Action: 10 hours
Adzenys ER™ (amphetamine)	ER oral suspension	1.25 mg/mL	Take in the morning with or without food. Do not mix with food or other liquids.
Adzenys XR-ODT™ (amphetamine)	ER ODT	3.1, 6.3, 9.4, 12.5, 15.7, 18.8	Take in the morning with or without food. The tablet will disintegrate in saliva so that it can be swallowed.
Desoxyn® (meth-amphetamine hydrochloride, generics)	IR tablet	5	Total daily dose may be given in two divided doses daily Duration of Action: 3 to 5 hours
Dexedrine® Spansule® (dextro-amphetamine sulfate, generics)	Sustained-release capsule	5, 10, 15	Sustained-release can be used QD. An initial dose is released and remainder is gradually released. Duration of Action: 8 to 10 hours

Dextro-amphetamine sulfate (generics)	IR tablet, scored	5, 10	First dose upon awakening; additional doses (1 or 2) at intervals of 4 to 6 hours. Duration of Action: 4 to 5 hours
Dyanavel® XR (amphetamine)	ER oral suspension and tablet	Suspension: 2.5 mg/ mL Tablet: 5, 10, 15, 20	Take in the a.m. with or without food. Duration of Action: Up to 13 hours
Evekeo® (amphetamine sulfate)	IR tablet, scored	5, 10	Total daily dose may be given in two divided doses daily Duration of Action: 4 to 6 hours
Evekeo ODT® (amphetamine sulfate)	ODT	2.5, 5, 10, 15, 20	Administer in the a.m. with or without food or liquid. Duration of Action: 4 to 6 hours
Mydayis® (mixed amphetamine salts*)	ER capsule	12.5, 25, 37.5, 50	Take upon awakening with or without food. Capsule may be taken whole or opened and sprinkled on applesauce and consumed immediately without chewing. Duration of Action: Up to 16 hours
Vyvanse® (lisdex-amfetamine dimesylate)	Capsule, chewable tablet	Capsules: 10, 20, 30,40, 50, 60, 70 Chewable tablets: 10, 20, 30, 40, 50, 60	Capsules may be swallowed whole or opened and mixed with yogurt, water, or orange juice. Capsules and chewable tablets are interchangeable on a mg-per-mg basis. Duration of Action: 10 hours, 14 hours (adults)

IR – Immediate-release; ADHD – Attention-deficit; hyperactivity disorder; QD – Once daily; BID – Twice daily; ER – Extended-release; ODT – Orally disintegrating tablet; NA – Not available.

Methylphenidate/Dexmethylphenidate Dosage Forms and Dosing. [1-24, 43-44, 48-53]

Generic Name (Trade Name)	Formulation	Strengths (mg)	Comments on Dosing/ Duration of Action
Adhansia XR® (methylphenidate)	ER capsules	25, 35, 45, 55, 70, 85	Take with or without food. May be taken whole or opened and sprinkled onto applesauce or yogurt. Duration of Action: Up to 16 hours
Aptensio XR® (methylphenidate)	ER capsules	10, 15, 20, 30, 40, 50, 60	Take with or without food. May be taken whole or opened and the entire contents sprinkled onto applesauce. Duration of Action: Up to 12 hours
Azstarys™ (serdexmethyl-phenidate and dexmethylphenidate)	capsules	26.1 mg/ 5.2 mg, 39.2 mg/ 7.8 mg, 52.3 mg/ 10.4 mg	Take with or without food. Swallow capsules whole or open and sprinkle onto applesauce or add to water.

Concerta® (methylphenidate, generics)	ER tablets (12-hour duration)	18, 27, 36, 54	Take with or without food. Must be swallowed whole with liquid. Do not chew, divide or crush. Duration of Action: Up to 12 hours
Cotempla XR-ODT™ (methylphenidate)	ER orally disintegrating tablets	8.6, 17.3, 25.9	Take with or without food. Place the whole tablet on the tongue and allow it to disintegrate without chewing or crushing. No liquid is needed to take the tablet. Duration of Action: Up to 12 hours
Daytrana® (methylphenidate)	Transdermal Patch (12-hour duration)	10, 15, 20, 30	Patch may be removed earlier than 9 hours to avoid unwanted side effects or for shorter duration of effect. Duration of Action: 12 hours
Focalin® (dexmethylphenidate, generics)	IR tablets	2.5, 5, 10	Doses given at least 4 hours apart. Duration of Action: 3-5 hours
Focalin XR® (dexmethylphenidate, generics)	ER capsules	5, 10, 15, 20, 25, 30, 35, 40	Must be swallowed whole with liquid. Capsules can be opened and sprinkled on applesauce. Do not crush, chew, or divide capsule beads. Duration of Action: Up to 12 hours
Jornay PM® (methylphenidate)	ER capsules	20, 40. 60, 80, 100	Take only in the evening. May be swallowed whole or opened and sprinkled onto applesauce. Duration of Action: Peak concentration occurs 14 hours after dose with gradual decline thereafter
Metadate CD® (methylphenidate, generics)	IR 30% and ER 70% capsules	10, 20, 30, 40, 50, 60	Take before breakfast. May be opened and contents sprinkled on applesauce and consumed immediately without chewing or crushing. Duration of Action:8 to 9 hours
Metadate® ER (methylphenidate, generics)	ER tablets (8-hour duration)	10, 20	Swallow whole. Do not crush or chew. Duration of Action:3 to 8 hours; variable
Methylin®, Ritalin® (methylphenidate, generics)	Oral solution, IR tablets, chewable tablets	5, 10, 20 tablets, 2.5, 5, 10 chewable tablets, 5 mg/5 mL, 10 mg/5 mL	Give in divided doses 2 or 3 times daily preferably 30 to 45 minutes before meals. Chewable tablets should be administered with water to avoid choking. Duration of Action: 3 to 4 hours
Methylin® ER (methylphenidate, generics)	ER tablets (8-hour duration)	10, 20	Swallow whole. Do not crush or chew. Duration of Action: 7 to 8 hours
QuilliChew ER® (methylphenidate)	ER chewable tablets	20 and 30 (scored), 40	Chew tablet(s). Take with or without food.
Quillivant XR® (methylphenidate)	ER oral suspension	5 mg/mL	Vigorously shake the bottle for at least 10 seconds prior to administering the dose.

Ritalin LA® (methylphenidate, generics)	IR 50% and delayed release 50% capsules	10, 20, 30, 40	Give QD in the morning. Swallow whole. Do not crush or chew. Capsule may be opened and beads sprinkled on applesauce. Duration of Action: 7 to 9 hours
Ritalin-SR® (methylphenidate, generics)	Sustained-release tablets (8-hour duration)	20	Swallow whole. Do not crush or chew. Duration of Action: 3 to 8 hours; variable

ER – Extended-release; IR – Immediate-release; BID – Twice daily; QD – Once daily; NA – Not available.

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Revision Details

Type of Revision	Summary of Changes	Date
Selected Revision	**Vyvanse capsules** **Updated** the preferred product requirements to multi-source brand criteria. **Extended** the preferred product criteria to the Standard, Performance and Legacy formularies. **Vyvanse chewable tablets** **Updated** the preferred product requirements to multi-source brand criteria. **Extended** the preferred product criteria to the Standard, Performance and Legacy formularies. **Updated** the preferred product requirements for Adderall, Adderall XR, Adhansia XR, Adzenys XR-ODT, Aptensio XR, Concerta, Cotempla XR ODT, Desoxyn, Dexedrine, Dyanavel XR, Evekeo, Evekeo ODT, Focalin, Focalin XR, Jornay PM, Methylin, Mydayis, Ritalin, Ritalin LA, Xelstrym and Zenzedi.	07/01/2025