

Drug Coverage Policy

Attention Deficit Hyperactivity Disorder (ADHD) Stimulants for Employer Group Plans

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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 and have discretion in making individual coverage determinations. 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)

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

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

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

Employer Group Medical Necessity Criteria and Preferred Covered Alternatives:

Product	Criteria
	Criteria 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/Legacy Drug List Plans: Documentation of BOTH of the following: A. Trial of amphetamine/dextroamphetamine salts
	Documentation of BOTH of the following:
	 B. Failure, contraindication, or intolerance to THREE of the following: dexmethylphenidate (generic for Focalin) dextroamphetamine sulfate (generic for Zenzedi) OR Procentra (dextroamphetamine solution) methamphetamine (generic for Desoxyn) methylphenidate chewable tablet OR methylphenidate tablet (generic for Ritalin) OR wethylphenidate oral solution (generic for Methylin) v. Vyvanse (lisdexamfetamine)
	Value/Advantage/Cigna Total Savings Drug List Plans: Documentation of BOTH of the following:

Product	Criteria
	 A. Trial of amphetamine/dextroamphetamine salts immediate-release tablets 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: dexmethylphenidate (generic for Focalin) dextroamphetamine sulfate (generic for Zenzedi) OR Procentra (dextroamphetamine solution) methylphenidate chewable tablet OR methylphenidate tablet (generic for Ritalin) OR
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: Individual is 18 years of age or older 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 Hypersonnolence and meets the following: Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders Individual meets the preferred covered alternatives criteria as indicated below: Standard/Performance/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):

Product	Criteria
	 Value/Advantage/Cigna Total Savings 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 BOTH of the following:
Adhansia XR (methylphenidate	Adhansia XR is considered medically necessary when the individual meets BOTH of the following:
extended-release capsules)	 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): Individual is 18 years of age or older 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:
	 Standard/Performance/Legacy Drug List Plans: Documentation of failure, contraindication, or intolerance to ALL of the following:

Product	Criteria
	 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) 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: Documented diagnosis of ONE of the following:
	 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)
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 and meets BOTH of the following: Individual is 18 years of age or older 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

Product	Criteria
	 Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders
amphetamine/ dextroamphetami ne salts immediate- release tablets <u>and</u> extended-release capsules (generic for <u>Adderall/Adderall</u> <u>XR</u>)	 Amphetamine/dextroamphetamine salts immediate-release tablets or 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 and meets BOTH of the following: Individual is 18 years of age or older 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: Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders
Aptensio XR (methylphenidate extended-release capsules)	 Aptensio XR is considered medically necessary when the individual meets BOTH of the following: Documented diagnosis of ONE of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) Narcolepsy Adjunctive/Augmentation Treatment for Depression and meets BOTH of the following: Individual is 18 years of age or older Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIS]) Fatigue Associated with Cancer and/or its Treatment Idiopathic Hypersomnolence and meets the following: Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders
	Standard/Performance/Legacy Drug List Plans:There is documentation of BOTH of the following:A. Trial of methylphenidate extended-releasecapsules(the bioequivalent generic product) AND cannottake due to a formulation difference in the inactive

Product	Criteria
	 ingredient(s) which would result in a significant allergy or serious adverse reaction B. Failure, contraindication, or intolerance to ALL of the following: dexmethylphenidate ER (generic for Focalin XR) dextroamphetamine/amphetamine ER (generic for Adderall XR) OR Mydayis (mixed amphetamine salts ER) or generic for Mydayis iii. Vyvanse (lisdexamfetamine)
	 Value/Advantage/Cigna Total Savings 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 mixed amphetamine salts ER (generic for Mydayis)
Azstarys (serdexmethylpheni date and dexmethylphenidate capsules)	 Azstarys is considered medically necessary when the individual meets BOTH of the following: Documented diagnosis of ONE of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) Narcolepsy Adjunctive/Augmentation Treatment for Depression and meets BOTH of the following: Individual is 18 years of age or older Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) Fatigue Associated with Cancer and/or its Treatment Idiopathic Hypersonnolence and meets the following: Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders
	Standard/Performance/Legacy Drug List Plans: Covered as a non-preferred brand [step therapy may apply]Value/Advantage/Cigna Total Savings Drug List Plans: Documentation of failure, contraindication, or intolerance to FOUR of the following: A. dexmethylphenidate ER capsules (generic for Focalin XR)

Product	Criteria
	 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	Concerta is considered medically necessary when the individual meets BOTH of the following:
extended-release tablets)	 Documented diagnosis of ONE of the following: A ttention Deficit Hyperactivity Disorder (ADD/ADHD) Narcolepsy Adjunctive/Augmentation Treatment for Depression and meets BOTH of the following:

Product	Criteria
	ii. dextroamphetamine/amphetamine ER (generic for Adderall XR) OR mixed amphetamine salts ER (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: Documented diagnosis of ONE of the following:
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

Product	Criteria
	C. Adjunctive/Augmentation Treatment for Depression <u>and</u> meets BOTH of the following (i <u>and</u> 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: Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders
Desoxyn	Desoxyn is considered medically necessary when the individual
(methamphetamine	meets BOTH of the following:
tablets)	 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: Individual is 18 years of age or older 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
	Standard/Performance/Legacy/Value/Advantage/Cigna
	<u>Total Savings Drug List Plans:</u> 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)
	 in. dextroampletamine tablet (generic for Zenzedi) OR Procentra (dextroampletamine solution) iv. methylphenidate chewable tablet OR methylphenidate tablet (generic for Ritalin) OR methylphenidate oral solution (generic for Methylin)

Product	Criteria
Dexedrine (dextroamphetamine sustained-release	Dexedrine is considered medically necessary when the individual meets BOTH of the following:
sustained-release capsules)	 Documented diagnosis of ONE of the following: A Attention Deficit Hyperactivity Disorder (ADD/ADHD) Narcolepsy Adjunctive/Augmentation Treatment for Depression and meets BOTH of the following: Individual is 18 years of age or older Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) Fatigue Associated with Cancer and/or its Treatment
	iv. Vyvanse (lisdexamfetamine) <u>Value/Advantage/Cigna Total Savings Drug List Plans</u> : There is documentation of BOTH of the following:
	 A. Trial of <u>dextroamphetamine sustained-release</u> <u>capsules</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 ALL of the following: dextroamphetamine/amphetamine ER (generic for Adderall XR) OR mixed amphetamine salts ER (generic for Mydayis)

Product	Criteria
	 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)
dexmethylphenida te immediate- release tablets <u>and</u> extended-release capsules	Dexmethylphenidate immediate-release tablets <u>or</u> 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: i. Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders
dextroamphetami ne immediate release	Dextroamphetamine immediate release tablets <u>or</u> oral solution are considered medically necessary when the individual meets the following criteria:
tablets <u>and</u> oral solution	 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 <u>and</u> 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

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
	 Documented inability to swallow capsules and tablets Individual meets the preferred covered alternatives criteria as indicated below:
	 Value/Advantage/Cigna 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)
Evekeo (amphetamine	Evekeo is considered medically necessary when the individual meets BOTH of the following:
sulfate immediate- release tablets)	 Documented diagnosis of ONE of the following: Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets BOTH of the following: Individual is 18 years of age or older 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
	Standard/Performance/Legacy Drug List Plans:Documentation of BOTH of the following:A. Trial of amphetamine sulfate immediate-releasetabletstablets(the bioequivalent generic product) AND cannottake due to a formulation difference in the inactive

Product	Criteria
	 ingredient(s) which would result in a significant allergy or serious adverse reaction B. Failure, contraindication, or intolerance to THREE of the following: dexmethylphenidate (generic for Focalin) dextroamphetamine sulfate (generic for Zenzedi) OR Procentra (dextroamphetamine solution) methamphetamine (generic for Desoxyn) methylphenidate tablet OR methylphenidate tablet (generic for Ritalin) OR v. Wyvanse (lisdexamfetamine)
	 Value/Advantage/Cigna Total Savings Drug List Plans: Documentation of BOTH of the following: A. Trial of <u>amphetamine sulfate immediate-release</u> <u>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 THREE of the following: dexmethylphenidate (generic for Focalin) dextroamphetamine sulfate (generic for Zenzedi) OR Procentra (dextroamphetamine solution) methamphetamine (generic for Desoxyn) methylphenidate tablet (generic for Ritalin) OR methylphenidate oral solution (generic for Methylin)
Evekeo ODT (amphetamine sulfate orally disintegrating tablets)	 Evekeo ODT is considered medically necessary when the individual meets ALL of the following: Documented diagnosis of ONE of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy Adjunctive/Augmentation Treatment for Depression and meets BOTH of the following: Individual is 18 years of age or older Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) Fatigue Associated with Cancer and/or its Treatment Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders Documented inability to swallow capsules and tablets Individual meets the preferred covered alternatives criteria as indicated below:

Product	Criteria
	Value/Advantage/Cigna Total Savings Drug List Plans: 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. methamphetamine (generic for Desoxyn) E. methylphenidate chewable tablet OR methylphenidate tablet (generic for Ritalin) OR methylphenidate oral solution (generic for Methylin)
Focalin (dexmethylphenidat	Focalin is considered medically necessary when the individual meets BOTH of the following:
e immediate-release tablets)	 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: Individual is 18 years of age or older 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
	 Standard/Performance/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:

Product	Criteria
Product	 iv. methylphenidate chewable tablet OR methylphenidate tablet (generic for Ritalin) OR methylphenidate oral solution (generic for Methylin) v. Vyvanse (lisdexamfetamine) Value/Advantage/Cigna Total Savings 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: amphetamine (generic for Evekeo) OR
Focalin XR	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 is considered medically necessary when the individual
(dexmethylphenidat e extended-release capsules)	 meets BOTH of the following: Documented diagnosis of ONE of the following: Attention Deficit Hyperactivity Disorder (ADD/ADHD) Narcolepsy Adjunctive/Augmentation Treatment for Depression and meets BOTH of the following: Individual is 18 years of age or older Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) Fatigue Associated with Cancer and/or its Treatment Idiopathic Hypersomnolence and meets the following: Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders
	<u>Standard/Performance/Legacy Drug List Plans:</u> Documentation of BOTH of the following: A. Trial of <u>dexmethylphenidate extended-release</u> <u>capsules</u> (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive

Product	Criteria
Jornay PM (methylphenidate extended-release capsules)	 ingredient(s) which would result in a significant allergy or serious adverse reaction B. Failure, contraindication, or intolerance to ALL of the following: dextroamphetamine/amphetamine ER (generic for Adderall XR) OR Mydayis (mixed amphetamine salts ER) or generic for Mydayis methylphenidate ER capsules (generic for Ritalin LA or generic for Aptensio XR) OR methylphenidate ER tablet (generic for Concerta) Vyvanse (lisdexamfetamine) Value/Advantage/Cigna Total Savings 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 Failure, contraindication, or intolerance to BOTH of the following:
	 Individual meets the preferred covered alternatives criteria as indicated below:
	Standard/Performance/Legacy Drug List Plans:

Product	Criteria
	 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) D. Vyvanse (lisdexamfetamine) Value/Advantage/Cigna 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 Adderall XR) OR mixed amphetamine salts ER (generic for Mydayis) C. methylphenidate ER capsules (generic for Ritalin LA or generic for Aptensio XR) OR mixed amphetamine ER (generic for Adderall XR) OR mixed amphetamine salts ER (generic for Adderall XR) OR mixed amphetamine salts ER (generic for Adderall XR) OR mixed amphetamine salts ER (generic for Adderall XR) OR mixed amphetamine salts ER (generic for Ritalin LA or generic for Aptensio XR) OR methylphenidate ER tablet (generic for Concerta)
lisdexamfetamine dimesylate capsules <u>and</u> chewable tablets	 Lisdexamfetamine capsules <u>or</u> 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: Individual is 18 years of age or older 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: 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

Product	Criteria
	 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: 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 <u>capsule</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 THREE of the following: dexmethylphenidate ER capsules (generic for Focalin XR) methylphenidate LA capsules (generic for Ritalin LA) iv. methylphenidate ER capsules (generic for Aptensio XR
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: Individual is 18 years of age or older 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: Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders
Methylin (methylphenidate	Methylin is considered medically necessary when the individual meets BOTH of the following:

Product	Criteria
immediate-release oral solution)	 Documented diagnosis of ONE of the following: A Attention Deficit Hyperactivity Disorder (ADD/ADHD) Narcolepsy Adjunctive/Augmentation Treatment for Depression and meets BOTH of the following: Individual is 18 years of age or older Individual is concurrently receiving other medication therapy for depression (for example, selective serotonin reuptake inhibitors [SSRIs]) Fatigue Associated with Cancer and/or its Treatment
	 Value/Advantage/Cigna Total Savings 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: amphetamine (generic for Evekeo) OR dextroamphetamine/amphetamine (generic for Focalin) ii. dexmethylphenidate (generic for Focalin)

Product	Criteria
	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 and meets BOTH of the following: Individual is 18 years of age or older 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: 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 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:
	Total Savings Drug List Plans:Documentation of failure, contraindication, or intolerance to ALLof the following:A. dexmethylphenidate extended-release capsules (generic for Focalin XR)

Product	Criteria
	 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	Mixed salts of a single-entity amphetamine product extended- release capsules (generic for <u>Mydayis</u>) is considered medically necessary when the individual meets BOTH of the following:
product extended- release capsules (generic for <u>Mydayis</u>)	 Age 13 years or older Documented diagnosis of ONE of the following: Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets BOTH of the following: Individual is 18 years of age or older 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:
Mydayis (mixed salts of a single-entity	Mydayis is considered medically necessary when the individual meets ALL of the following:
amphetamine	 Age 13 years or older Documented diagnosis of ONE of the following:

Product	Criteria
product extended- release capsules)	 A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) B. Narcolepsy C. Adjunctive/Augmentation Treatment for Depression and meets BOTH of the following: Individual is 18 years of age or older 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: 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/Cigna 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. 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: Individual is 18 years of age or older 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: Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders
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 Humanativity Disorder (ADD(ADHD))
	A. Attention Deficit Hyperactivity Disorder (ADD/ADHD)B. Narcolepsy

Product	Criteria				
	 C. Adjunctive/Augmentation Treatment for Depression and meets BOTH of the following: Individual is 18 years of age or older 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: 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: 				
	 <u>Value/Advantage/Cigna 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. 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: 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: Individual is 18 years of age or older 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: Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 				
Relexxii (methylphenidate extended-release 18mg, 27mg, 36mg, 45mg, 54mg, 63mg, 72 mg tablets)	Relexxii 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:				

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]) D. Fatigue Associated with Cancer and/or its Treatment E. Idiopathic Hypersomnolence and meets the following: Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders Individual meets the preferred covered alternatives criteria as indicated below: 			
	 <u>Standard/Performance/Legacy/Value/Advantage/Cigna</u> <u>Total Savings Drug List Plans:</u> 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: Documented diagnosis of ONE of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) Narcolepsy Adjunctive/Augmentation Treatment for Depression and meets BOTH of the following: Individual is 18 years of age or older 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: Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders 			
	 Individual meets the preferred covered alternatives criteria as indicated below: <u>Standard/Performance/Legacy Drug List Plans:</u> Documentation of BOTH of the following: A. Trial of <u>methylphenidate immediate-release</u> <u>tablets</u> (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive 			

Product	Criteria			
	 Documentation of BOTH of the following: A. Trial of methylphenidate extended-release <u>capsules</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 ALL of the following: dexmethylphenidate ER (generic for Focalin XR) dextroamphetamine/amphetamine ER (generic for Adderall XR) OR Mydayis (mixed amphetamine salts ER) or generic for Mydayis			
	 Vyvanse (IIsdexametamine) Value/Advantage/Cigna Total Savings 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:			
Vyvanse capsules (lisdexamfetamine dimesylate)	 Vyvanse capsules are considered medically necessary when the individual meets BOTH of the following: Documented diagnosis of ONE of the following: A. Attention Deficit Hyperactivity Disorder (ADD/ADHD) Binge-Eating Disorder in an Adult (18 years of age and older) Narcolepsy Adjunctive/Augmentation Treatment for Depression and meets BOTH of the following: Individual is 18 years of age or older 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 Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders Individual meets the preferred covered alternatives criteria as indicated below [does NOT apply to a diagnosis of binge-eating 			

Product	Criteria				
	 Value/Advantage/Cigna 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) OR methylphenidate ER tablets (generic for Concerta) 				
Vyvanse chewable tablets (lisdexamfetamine dimesylate)	 Vyvanse chewable tablets are considered medically necessary when the individual meets ALL of the following: Documented inability to swallow capsules and tablets Documented diagnosis of ONE of the following (A or B):				
Xelstrym (dextroamphetamine transdermal system)	generic for Aptensio XR) 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				

Product	Criteria				
	 C. Adjunctive/Augmentation Treatment for Depression and meets BOTH of the following: Individual is 18 years of age or older 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 Idiopathic Hypersomnolence and meets the following: Diagnosis is confirmed by a sleep specialist physician or at an institution (sleep center) that specializes in sleep disorders Individual meets the preferred covered alternatives criteria as indicated below: 				
	 Standard/Performance/Legacy Drug List Plans: Documentation of failure, contraindication, or intolerance to FOUR of the following:				
	 Value/Advantage/Cigna Total Savings Drug List Plans: 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 mixed amphetamine salts ER (generic for Mydayis) C. dextroamphetamine ER capsules (generic for Dexedrine). D. 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: Documented diagnosis of ONE of 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: 				
	 Standard/Performance/Legacy Drug List Plans: Documentation of BOTH of the following: A. Trial of <u>dextroamphetamine 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 THREE of the following: i. amphetamine (generic for Evekeo) OR dextroamphetamine/amphetamine (generic for Focalin) ii. dexmethylphenidate (generic for Focalin) iii. methamphetamine (generic for Desoxyn) iv. methylphenidate chewable tablet OR methylphenidate oral solution (generic for Methylin) v. Vyvanse (lisdexamfetamine) 				
	 Value/Advantage/Cigna Total Savings 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: amphetamine (generic for Evekeo) OR dextroamphetamine/amphetamine (generic for Adderall) dexmethylphenidate (generic for Desoxyn) methylphenidate 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.

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):

- 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 \geq 3 years of age; the other products are indicated in patients \geq 6 years of age, except for Mydayis which is indicated in patients \geq 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:

Trade Name (Generic Name)	Formulation	Strengths (mg)	Comments on Dosing/ Duration of Action
Adderall [®] (mixed amphetamine	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.
salts*, generics)			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™ (amphetamin e)	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™ (amphetamin e)	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,	IR tablet	5	Total daily dose may be given in two divided doses daily Duration of Action: 3 to 5 hours
generics) Dexedrine [®]	Sustained-release	5, 10, 15	Sustained-release can be used QD. An initial dose
Spansule [®] (dextro-	capsule	-,,	is released and remainder is gradually released.

Amphetamine Dosage Forms and Dosing.^{1-24, 43-44, 48-53}

amphetamine sulfate, generics)			Duration of Action: 8 to 10 hours
Dextro- amphetamine sulfate	IR tablet, scored	5, 10	First dose upon awakening; additional doses (1 or 2) at intervals of 4 to 6 hours.
(generics)			Duration of Action: 4 to 5 hours
Dyanavel [®] XR (amphetamin	ER oral suspension and	Suspension: 2.5 mg/ mL	Take in the a.m. with or without food.
e)	tablet	Tablet: 5, 10, 15, 20	Duration of Action: Up to 13 hours
Evekeo [®] (amphetamin e 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 [®] (amphetamin e 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 [®] (methylphenid ate)	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 [®] (methylphenid ate)	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	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.

and dexmethylphe			
nidate) Concerta [®] (methylphenid ate, 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 [™] (methylphenid ate)	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 [®] (methylphenid ate)	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 [®] (dexmethylph	IR tablets	2.5, 5, 10	Doses given at least 4 hours apart.
enidate, generics)			Duration of Action: 3-5 hours
Focalin XR [®] (dexmethylph enidate, 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® (methylphenid ate)	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 [®] (methylphenid ate, 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 (methylphenid	ER tablets (8-hour duration)	10, 20	Swallow whole. Do not crush or chew.
ate, generics)	_		Duration of Action:3 to 8 hours; variable
Methylin [®] , Ritalin [®] (methylphenid ate, 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 prefer- ably 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 (methylphenid ate, generics)	ER tablets (8-hour duration)	10, 20	Swallow whole. Do not crush or chew. Duration of Action: 7 to 8 hours
QuilliChew ER [®] (methylphenid ate)	ER chewable tablets	20 and 30 (scored), 40	Chew tablet(s). Take with or without food.

Quillivant XR [®] (methylphenid ate)	ER oral suspension	5 mg/mL	Vigorously shake the bottle for at least 10 seconds prior to administering the dose.
Ritalin LA [®] (methylphenid ate, 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 [®] (methylphenid		20	Swallow whole. Do not crush or chew.
ate, generics)	duration)		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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