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Attention Deficit Hyperactivity Disorder (ADHD) Stimulants

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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. 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) stimulants:

- **Immediate-release Attention Deficit Hyperactivity Disorder (ADHD) Stimulant Medications** (refer to [Appendix 1](#) for products)
- **Extended-release Attention Deficit Hyperactivity Disorder (ADHD) Stimulant Medications** (refer to [Appendix 2](#) for products)

Note: When Prior Authorization applies, the diagnostic criteria below applies to the Complete Plan only. Not for the Essential or Limited plans.

Medical Necessity Criteria

Attention Deficit Hyperactivity Disorder (ADHD) stimulants are considered medically necessary when the following are met:

1. Individual meets the following, drug specific criteria:

Product	Criteria for Use
Adderall® (mixed amphetamine salts) Adderall XR® (mixed amphetamine salts) Adhansia XR™ (methylphenidate) amphetamine 5 mg and 10 mg IR tablets Aptensio XR™ (methylphenidate) Azstarys™ (serdexmethylphenidate and dexamethylphenidate capsule) Concerta® (methylphenidate) Daytrana® (methylphenidate) Desoxyn® (methamphetamine) Dexedrine® (dextroamphetamine) dexamethylphenidate: <ul style="list-style-type: none"> • 2.5 mg, 5mg and 10 mg IR tablets • 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 35 mg and 40 mg ER capsules dextroamphetamine: <ul style="list-style-type: none"> • 5 mg / 5mL oral solution • 2.5 mg, 5 mg, 7.5 mg 10 mg, 15 mg, 20 mg 30 mg IR tablets Evekeo® (amphetamine) Focalin® (dexamethylphenidate) Focalin XR® (dexamethylphenidate) methamphetamine 5 mg IR tablets Methylin® (methylphenidate) methylphenidate: <ul style="list-style-type: none"> • 5 mg/5 mL and 10 mg/5 mL oral solution • 5 mg, 10 mg and 20 mg IR tablets 	Diagnosis of ONE of the following: <ul style="list-style-type: none"> • Attention Deficit/Hyperactivity Disorder (ADD/ADHD) • Narcolepsy • Adjunctive/Augmentation Treatment for Depression and BOTH of the following: <ul style="list-style-type: none"> ○ 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 where confirmed by a sleep specialist physician or at an institution that specializes in sleep disorders

Product	Criteria for Use
<ul style="list-style-type: none"> • 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 and 72 mg ER tablets • Relexxii (methylphenidate ER) 72 mg • Methylphenidate ER 72 mg <p>mixed amphetamine salts (generic for Adderall/Adderall XR):</p> <ul style="list-style-type: none"> • 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 20 mg and 30 mg IR tablets • 5 mg, 10 mg, 15 mg, 20 mg, 25 mg and 30 mg ER capsules <p>Procentra (dextroamphetamine) Ritalin® (methylphenidate) Ritalin LA® (methylphenidate) Zenzedi™ (dextroamphetamine)</p>	
<p>Adzenys ER® (amphetamine) Adzenys XR ODT® (amphetamine) Cotempla XR ODT™ (methylphenidate) Dyanavel XR® (amphetamine) Evekeo ODT® (amphetamine) Quillichew ER™ (methylphenidate) Quillivant XR® (methylphenidate)</p>	<p>ONE of the following:</p> <ul style="list-style-type: none"> • Individual is less than 13 years of age • Attestation that the individual is unable to swallow capsules and tablets
<p>Jornay PM™ (methylphenidate)</p>	<p>BOTH of the following:</p> <ul style="list-style-type: none"> • Individual is 6 years of age or older • Diagnosis of ONE of the following: <ul style="list-style-type: none"> ○ Attention Deficit/Hyperactivity Disorder (ADD/ADHD) ○ Narcolepsy ○ Adjunctive/Augmentation Treatment for Depression and BOTH of the following: <ul style="list-style-type: none"> ▪ 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 where confirmed by a sleep specialist physician or at an institution that specializes in sleep disorders
<p>Mydayis™ (mixed amphetamine salts)</p>	<p>BOTH of the following:</p> <ul style="list-style-type: none"> • Individual is 13 years of age or older • Diagnosis of ONE of the following:

Product	Criteria for Use
	<ul style="list-style-type: none"> ○ Attention Deficit/Hyperactivity Disorder (ADD/ADHD) ○ Narcolepsy ○ Adjunctive/Augmentation Treatment for Depression and BOTH of the following: <ul style="list-style-type: none"> ▪ 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
Vyvanse® (lisdexamphetamine) capsule	Diagnosis of ONE of the following: <ul style="list-style-type: none"> ● 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 BOTH of the following: <ul style="list-style-type: none"> ○ 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 where confirmed by a sleep specialist physician or at an institution that specializes in sleep disorders
Vyvanse® (lisdexamphetamine) chewable tablet	BOTH of the following: <ul style="list-style-type: none"> ● ONE of the following: <ol style="list-style-type: none"> 1. Treatment of Attention Deficit Hyperactivity Disorder (ADHD) 2. Treatment of binge-eating disorder in an adult (18 years of age and older) ● ONE of the following: <ul style="list-style-type: none"> ○ Individual is less than 13 years of age ○ Attestation that the individual is unable to swallow capsules and tablets

Coverage for Attention Deficit Hyperactivity Disorder (ADHD) stimulants varies across plans and may require the use of preferred products. Refer to the customer's benefit plan document for coverage details.

Non-covered drugs are considered medically necessary when there is documentation of ONE of the following:

A. The individual has had inadequate efficacy to the number of covered alternatives according to the table below

OR

B. The individual has a contraindication according to FDA label, significant intolerance, or is not a candidate* for the covered alternatives according to the table below

**Note: Not a candidate due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], other attributes/conditions, or is unable to administer and requires this dosage formulation)*

Employer Group Non-Covered Products and Preferred Covered Alternatives by Drug List:

Non-Covered Product	Standard/Performance/Legacy	Value/Advantage/Cigna Total Savings
<p>Adderall (mixed salts of a single-entity amphetamine product immediate-release 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 20 mg, and 30 mg tablets)</p>	<p>BOTH of the following:</p> <ul style="list-style-type: none"> • amphetamine/dextroamphetamine salts (generic Adderall)[‡] • THREE of the following: <ul style="list-style-type: none"> ○ dexamethylphenidate (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 methylphenidate oral solution (generic for Methylin) ○ Vyvanse (lisdexamphetamine) 	<p>BOTH of the following:</p> <ul style="list-style-type: none"> • amphetamine/dextroamphetamine salts (generic Adderall)[‡] • THREE of the following: <ul style="list-style-type: none"> ○ dexamethylphenidate (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 methylphenidate oral solution (generic for Methylin)
<p>Adderall XR (mixed salts of a single-entity amphetamine product extended-release 5 mg, 10 mg, 15 mg, 20 mg, 25 mg and 30 mg capsules)</p>	<p>BOTH of the following:</p> <ul style="list-style-type: none"> • amphetamine/dextroamphetamine salts extended-release (generic Adderall XR)[‡] • ALL of the following: <ul style="list-style-type: none"> ○ dexamethylphenidate ER (generic for Focalin XR) ○ methylphenidate ER capsules (generic for Ritalin LA or generic for Aptensio XR) OR methylphenidate ER tablet (generic for Concerta) ○ Vyvanse (lisdexamphetamine) 	<p>BOTH of the following:</p> <ul style="list-style-type: none"> • amphetamine/dextroamphetamine salts extended-release (generic Adderall XR)[‡] • BOTH of the following: <ul style="list-style-type: none"> ○ dexamethylphenidate ER (generic for Focalin XR) ○ methylphenidate ER capsules (generic for Ritalin LA or generic for Aptensio XR) OR methylphenidate ER tablet (generic for Concerta)
<p>Adhansia XR (methylphenidate extended-release 25 mg, 35 mg, 45 mg, 55 mg, 70 mg and 85 mg capsules)</p>	<p>ALL of the following:</p> <ul style="list-style-type: none"> • dexamethylphenidate ER (generic for Focalin XR) • dextroamphetamine/amphetamine ER (generic for Adderall XR) OR Mydayis (mixed amphetamine salts) • methylphenidate ER capsules (generic for Ritalin LA OR generic for Aptensio XR) OR methylphenidate ER tablet (generic for Concerta) • Vyvanse (lisdexamphetamine) 	<p>ALL of the following:</p> <ul style="list-style-type: none"> • dexamethylphenidate ER (generic for Focalin XR) • dextroamphetamine/amphetamine ER (generic for Adderall XR) • methylphenidate ER capsules (generic for Ritalin LA OR generic for Aptensio XR) OR methylphenidate ER tablet (generic for Concerta)
<p>Adzenys ER (amphetamine extended-release 1.25mg/ mL oral suspension)</p>	<p>Covered as a Non-Preferred Brand</p>	<p>ALL of the following:</p> <ul style="list-style-type: none"> • dexamethylphenidate ER (generic for Focalin XR) • dextroamphetamine/amphetamine ER (generic for Adderall XR) • methylphenidate ER capsules (generic for Ritalin LA OR generic for Aptensio XR)
<p>Adzenys XR ODT (amphetamine extended-release 3.1 mg, 6.3 mg, 9.4 mg,</p>	<p>Covered as a Non-Preferred Brand</p>	<p>ALL of the following:</p> <ul style="list-style-type: none"> • dexamethylphenidate ER (generic for Focalin XR)

Non-Covered Product	Standard/Performance/Legacy	Value/Advantage/Cigna Total Savings
12.5 mg, 15.7 mg and 18.8 mg orally disintegrating tablets)		<ul style="list-style-type: none"> dextroamphetamine/amphetamine ER (generic for Adderall XR) methylphenidate ER capsules (generic for Ritalin LA OR generic for Aptensio XR)
Aptensio XR (methylphenidate extended-release 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg and 60 mg capsules)	ALL of the following: <ul style="list-style-type: none"> methylphenidate extended-release (generic Aptensio XR)[±] dexmethylphenidate ER (generic for Focalin XR) dextroamphetamine/amphetamine ER (generic for Adderall XR) OR Mydayis (mixed amphetamine salts) Vyvanse (lisdexamphetamine) 	ALL of the following: <ul style="list-style-type: none"> methylphenidate extended-release (generic Aptensio XR)[±] dexmethylphenidate ER (generic for Focalin XR) dextroamphetamine/amphetamine ER (generic for Adderall XR)
Azstarys™ (serdexmethylphenidate/dexmethylphenidate 26.1-5.2 mg, 39.2-7.8 mg, 52.3-10.4 mg oral capsules)	Covered as a Non-Preferred Brand <i>Note: Step therapy may apply</i>	ALL of the following: <ul style="list-style-type: none"> dexmethylphenidate ER capsules (generic for Focalin XR) methylphenidate ER tablets (generic for Concerta) methylphenidate CD capsules (generic for Metadate CD) methylphenidate LA capsules (generic for Ritalin LA) methylphenidate ER capsules (generic for Aptensio XR)
Concerta (methylphenidate extended-release 18 mg, 27 mg, 36 mg and 54 mg tablets)	BOTH of the following: <ul style="list-style-type: none"> methylphenidate extended-release (generic Concerta)[±] ALL of the following: <ul style="list-style-type: none"> dexmethylphenidate ER (generic for Focalin XR) dextroamphetamine/amphetamine ER (generic for Adderall XR) OR Mydayis (mixed amphetamine salts) Vyvanse (lisdexamphetamine) 	BOTH of the following: <ul style="list-style-type: none"> methylphenidate extended-release (generic Concerta)[±] BOTH of the following: <ul style="list-style-type: none"> dexmethylphenidate ER (generic for Focalin XR) dextroamphetamine/amphetamine ER (generic for Adderall XR)
Cotempla XR ODT (methylphenidate extended-release 8.6 mg, 17.3 mg and 25.9 mg orally disintegrating tablets)	ALL of the following: <ul style="list-style-type: none"> dexmethylphenidate ER (generic for Focalin XR) dextroamphetamine/amphetamine ER (generic for Adderall XR) OR Mydayis (mixed amphetamine salts) methylphenidate ER capsules (generic for Ritalin LA OR generic for Aptensio XR) Vyvanse (lisdexamphetamine) <p>Note: The preferred product criteria does not apply to the Legacy Drug List Plan</p>	ALL of the following: <ul style="list-style-type: none"> dexmethylphenidate ER (generic for Focalin XR) dextroamphetamine/amphetamine ER (generic for Adderall XR) methylphenidate ER capsules (generic for Ritalin LA OR generic for Aptensio XR)
Desoxyn (methamphetamine 5 mg tablets)	BOTH of the following: <ul style="list-style-type: none"> methamphetamine (generic Desoxyn)[±] ALL of the following: <ul style="list-style-type: none"> dexmethylphenidate (generic for Focalin) dextroamphetamine/amphetamine (generic for Adderall) 	

Non-Covered Product	Standard/Performance/Legacy	Value/Advantage/Cigna Total Savings
	<ul style="list-style-type: none"> ○ dextroamphetamine tablet (generic for Zenzedi) OR Procentra (dextroamphetamine solution) ○ methylphenidate chewable tablet OR methylphenidate tablet (generic for Ritalin) OR methylphenidate oral solution (generic for Methylin) 	
Dexedrine (dextroamphetamine 5 mg, 10 mg, 15 mg sustained release capsules)	BOTH of the following: <ul style="list-style-type: none"> ● dextroamphetamine (generic Dexedrine)[‡] ● ALL of the following: <ul style="list-style-type: none"> ○ dextroamphetamine/amphetamine ER (generic for Adderall XR) OR Mydayis (mixed amphetamine salts) ○ dexmethylphenidate ER (generic for Focalin XR) ○ methylphenidate ER capsules (generic for Ritalin LA OR generic for Aptensio XR) OR methylphenidate ER tablets (generic for Concerta) ○ Vyvanse (lisdexamphetamine) 	BOTH of the following: <ul style="list-style-type: none"> ● dextroamphetamine (generic Dexedrine)[‡] ● ALL of the following: <ul style="list-style-type: none"> ○ dextroamphetamine/amphetamine ER (generic for Adderall XR) ○ dexmethylphenidate ER (generic for Focalin XR) ○ methylphenidate ER capsules (generic for Ritalin LA OR generic for Aptensio XR) OR methylphenidate ER tablets (generic for Concerta)
Dyanavel XR (amphetamine extended-release 2.5mg/mL oral suspension)	Covered as a Non-Preferred Brand	ALL of the following: <ul style="list-style-type: none"> ● dexmethylphenidate ER (generic for Focalin XR) ● dextroamphetamine/amphetamine ER (generic for Adderall XR) ● methylphenidate ER capsules (generic for Ritalin LA OR generic for Aptensio XR)
Evekeo (amphetamine immediate-release 5 mg and 10 mg tablets)	BOTH of the following: <ul style="list-style-type: none"> ● amphetamine immediate-release (generic Evekeo)[‡] ● THREE of the following: <ul style="list-style-type: none"> ○ 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 methylphenidate oral solution (generic for Methylin) ○ Vyvanse (lisdexamphetamine) 	BOTH of the following: <ul style="list-style-type: none"> ● amphetamine immediate-release (generic Evekeo)[‡] ● THREE of the following: <ul style="list-style-type: none"> ○ 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 methylphenidate oral solution (generic for Methylin)
Evekeo ODT (amphetamine immediate-release 5 mg, 10 mg, 15 mg and 20 mg orally disintegrating tablets)	Covered as a Non-Preferred Brand	FOUR of the following: <ul style="list-style-type: none"> ● amphetamine immediate-release tablets (generic for Evekeo) ● dexmethylphenidate (generic for Focalin) ● dextroamphetamine sulfate (generic for Zenzedi) OR Procentra (dextroamphetamine solution) ● methamphetamine (generic for Desoxyn)

Non-Covered Product	Standard/Performance/Legacy	Value/Advantage/Cigna Total Savings
		<ul style="list-style-type: none"> • methylphenidate chewable tablet OR methylphenidate tablet (generic for Ritalin) OR methylphenidate oral solution (generic for Methylin)
Focalin (dexamethylphenidate immediate-release 2.5 mg, 5 mg and 10 mg tablets)	BOTH of the following: <ul style="list-style-type: none"> • dexamethylphenidate immediate-release (generic Focalin)[‡] • THREE of the following: <ul style="list-style-type: none"> ○ amphetamine (generic for Evekeo) OR dextroamphetamine/amphetamine (generic for Adderall) ○ dextroamphetamine sulfate (generic for Zenzedi) OR Procentra (dextroamphetamine solution) ○ methamphetamine (generic for Desoxyn) ○ methylphenidate chewable tablet OR methylphenidate tablet (generic for Ritalin) OR methylphenidate oral solution (generic for Methylin) ○ Vyvanse (lisdexamphetamine) 	BOTH of the following: <ul style="list-style-type: none"> • dexamethylphenidate immediate-release (generic Focalin)[‡] • THREE of the following: <ul style="list-style-type: none"> ○ amphetamine (generic for Evekeo) OR dextroamphetamine/amphetamine (generic for Adderall) ○ dextroamphetamine sulfate (generic for Zenzedi) OR Procentra (dextroamphetamine solution) ○ methamphetamine (generic for Desoxyn) ○ methylphenidate chewable tablet OR methylphenidate tablet (generic for Ritalin) OR methylphenidate oral solution (generic for Methylin)
Focalin XR (dexamethylphenidate extended-release 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 35 mg and 40 mg capsules)	BOTH of the following: <ul style="list-style-type: none"> • dexamethylphenidate extended-release (generic Focalin XR)[‡] • ALL of the following: <ul style="list-style-type: none"> ○ dextroamphetamine/amphetamine ER (generic for Adderall XR) OR Mydayis (mixed amphetamine salts) ○ methylphenidate ER capsules (generic for Ritalin LA or generic for Aptensio XR) OR methylphenidate ER tablet (generic for Concerta) ○ Vyvanse 	BOTH of the following: <ul style="list-style-type: none"> • dexamethylphenidate extended-release (generic Focalin XR)[‡] • BOTH of the following: <ul style="list-style-type: none"> ○ dextroamphetamine/amphetamine ER (generic for Adderall XR) ○ methylphenidate ER capsules (generic for Ritalin LA or generic for Aptensio XR) OR methylphenidate ER tablet (generic for Concerta)
Jornay PM (methylphenidate extended-release 20 mg, 40 mg, 60 mg, 80 mg and 100 mg capsules)	ALL of the following: <ul style="list-style-type: none"> • dexamethylphenidate ER (generic for Focalin XR) • dextroamphetamine/amphetamine ER (generic for Adderall XR) OR Mydayis (mixed amphetamine salts) • methylphenidate ER capsules (generic for Ritalin LA OR generic for Aptensio XR) OR methylphenidate ER tablet (generic for Concerta) • Vyvanse 	ALL of the following: <ul style="list-style-type: none"> • dexamethylphenidate ER (generic for Focalin XR) • dextroamphetamine/amphetamine ER (generic for Adderall XR) • methylphenidate ER capsules (generic for Ritalin LA OR generic for Aptensio XR) OR methylphenidate ER tablet (generic for Concerta)
Methylin (methylphenidate immediate-release 5 mg/5 mL and 10 mg/ 5 mL oral solution)	BOTH of the following: <ul style="list-style-type: none"> • methylphenidate immediate-release (generic Methylin)[‡] • THREE of the following: 	BOTH of the following: <ul style="list-style-type: none"> • methylphenidate immediate-release (generic Methylin)[‡] • THREE of the following: <ul style="list-style-type: none"> ○ amphetamine (generic for Evekeo) OR dextroamphetamine/amphetamine (generic for Adderall)

Non-Covered Product	Standard/Performance/Legacy	Value/Advantage/Cigna Total Savings
	<ul style="list-style-type: none"> ○ amphetamine (generic for Evekeo) OR dextroamphetamine/amphetamine (generic for Adderall) ○ dexmethylphenidate (generic for Focalin) ○ dextroamphetamine sulfate (generic for Zenzedi) OR Procentra (dextroamphetamine solution) ○ methamphetamine (generic for Desoxyn) ○ Vyvanse (lisdexamphetamine) 	<ul style="list-style-type: none"> ○ dexmethylphenidate (generic for Focalin) ○ dextroamphetamine sulfate (generic for Zenzedi) OR Procentra (dextroamphetamine solution) ○ methamphetamine (generic for Desoxyn)
Mydayis (mixed salts of a single-entity amphetamine product extended-release 12.5 mg, 25 mg, 37.5 mg, 50 capsules)	Covered as a Preferred Brand	ALL of the following: <ul style="list-style-type: none"> ● dexmethylphenidate ER (generic for Focalin XR) ● dextroamphetamine/amphetamine ER (generic for Adderall XR) ● methylphenidate ER capsules (generic for Ritalin LA OR generic for Aptensio XR) OR methylphenidate ER tablet (generic for Concerta)
Quillichew ER (methylphenidate extended-release 20 mg, 30 mg and 40 mg chewable tablets)	Covered as a Non-Preferred Brand	ALL of the following: <ul style="list-style-type: none"> ● dexmethylphenidate ER (generic for Focalin XR) ● dextroamphetamine/amphetamine ER (generic for Adderall XR) ● methylphenidate ER capsules (generic for Ritalin LA OR generic for Aptensio XR)
Relexxi (methylphenidate ER 72 mg tablets)	<ul style="list-style-type: none"> ● methylphenidate ER tablet (generic for Concerta) 	
Methylphenidate ER 72 mg tablets	<ul style="list-style-type: none"> ● methylphenidate ER tablet (generic for Concerta) 	
Ritalin (methylphenidate immediate release 5 mg, 10 mg and 20 mg tablets)	BOTH of the following: <ul style="list-style-type: none"> ● methylphenidate immediate-release (generic Ritalin)[‡] ● THREE of the following: <ul style="list-style-type: none"> ○ amphetamine (generic for Evekeo) OR dextroamphetamine/amphetamine (generic for Adderall) ○ dexmethylphenidate (generic for Focalin) ○ dextroamphetamine sulfate (generic for Zenzedi) OR Procentra (dextroamphetamine solution) ○ methamphetamine (generic for Desoxyn) ○ Vyvanse (lisdexamphetamine) 	BOTH of the following: <ul style="list-style-type: none"> ● methylphenidate immediate-release (generic Ritalin)[‡] ● THREE of the following: <ul style="list-style-type: none"> ○ amphetamine (generic for Evekeo) OR dextroamphetamine/amphetamine (generic for Adderall) ○ dexmethylphenidate (generic for Focalin) ○ dextroamphetamine sulfate (generic for Zenzedi) OR Procentra (dextroamphetamine solution) ○ methamphetamine (generic for Desoxyn)
Ritalin LA (methylphenidate extended-release 10	BOTH of the following: <ul style="list-style-type: none"> ● methylphenidate extended-release (generic Ritalin LA)[‡] ● ALL of the following: <ul style="list-style-type: none"> ○ dexmethylphenidate ER (generic for Focalin XR) 	BOTH of the following: <ul style="list-style-type: none"> ● methylphenidate extended-release (generic Ritalin LA)[‡] ● BOTH of the following: <ul style="list-style-type: none"> ○ dexmethylphenidate ER (generic for Focalin XR)

Non-Covered Product	Standard/Performance/Legacy	Value/Advantage/Cigna Total Savings
mg, 20 mg, 30 mg and 40 mg capsules)	<ul style="list-style-type: none"> ○ dextroamphetamine/amphetamine ER (generic for Adderall XR) OR Mydayis (mixed amphetamine salts) ○ Vyvanse 	<ul style="list-style-type: none"> ○ dextroamphetamine/amphetamine ER (generic for Adderall XR)
Vyvanse (lisdexamphetamine 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg and 70 mg capsules)	Covered as a Preferred Brand	<p>ALL of the following:</p> <ul style="list-style-type: none"> ● dexamethylphenidate ER (generic for Focalin XR) ● dextroamphetamine/amphetamine ER (generic for Adderall XR) ● methylphenidate ER capsules (generic for Ritalin LA OR generic for Aptensio XR) OR methylphenidate ER tablets (generic for Concerta) <p>Note: The preferred product criteria does not apply to a diagnosis of binge-eating disorder.</p>
Vyvanse (lisdexamphetamine 10 mg, 20 mg, 30 mg, 40 mg, 50 mg and 60 mg chewable tablets)	Covered as a Preferred Brand	<p>ALL of the following:</p> <ul style="list-style-type: none"> ● dexamethylphenidate ER (generic for Focalin XR) ● dextroamphetamine/amphetamine ER (generic for Adderall XR) ● methylphenidate ER capsules (generic for Ritalin LA OR generic for Aptensio XR) <p>Note: The preferred product criteria does not apply to a diagnosis of binge-eating disorder.</p>
Zenzedi (dextroamphetamine immediate-release 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg and 30 mg tablets)	<p>BOTH of the following:</p> <ul style="list-style-type: none"> ● dextroamphetamine immediate-release (generic Zenzedi) ● THREE of the following: <ul style="list-style-type: none"> ○ amphetamine (generic for Evekeo) OR dextroamphetamine/amphetamine (generic for Adderall) ○ dexamethylphenidate (generic for Focalin) ○ methamphetamine (generic for Desoxyn) ○ methylphenidate chewable tablet OR methylphenidate tablet (generic for Ritalin) OR methylphenidate oral solution (generic for Methylin) ○ Vyvanse (lisdexamphetamine) 	<p>BOTH of the following:</p> <ul style="list-style-type: none"> ● dextroamphetamine immediate-release (generic Zenzedi) ● THREE of the following: <ul style="list-style-type: none"> ○ amphetamine (generic for Evekeo) OR dextroamphetamine/amphetamine (generic for Adderall) ○ dexamethylphenidate (generic for Focalin) ○ methamphetamine (generic for Desoxyn) ○ methylphenidate chewable tablet OR methylphenidate tablet (generic for Ritalin) OR methylphenidate oral solution (generic for Methylin)

^aWhere applicable, documentation that individual has tried the bioequivalent generic product AND cannot take due to a formulation difference in the inactive ingredient(s) [for example, difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction.

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.

Note: 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 is up to 12 months.

Reauthorization approval duration is up to 12 months.

Conditions Not Covered

Attention Deficit Hyperactivity Disorder (ADHD) stimulants are considered experimental, investigational or unproven for ANY other use 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®, 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: ^{1-24,45,46,50-54}

- **Attention deficit hyperactivity disorder (ADHD)**, treatment. All of the stimulant medications in this policy are indicated for the treatment of ADHD.
- **Binge eating disorder (BED)**, treatment. Vyvanse is the only stimulant medication indicated for the treatment of BED.
- **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. Adderall XR (generics), Adzenys ER, Adzenys XR-ODT, Mydayis, Vyvanse, Concerta (generics), and several methylphenidate products are indicated for use in adults with ADHD. Jornay PM is the only stimulant taken in the evening.

Disease Overview

Idiopathic hypersomnia, a condition similar to narcolepsy, 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.³¹⁻³⁴

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).^{43,44} 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.²⁷ 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 (EDS), 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.²⁸ There are no clear guidelines regarding the length of time stimulants should be coadministered. 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 well-being, as well as a higher rate of remission, compared with either drug alone.⁴⁷

Cancer-related fatigue: The National Comprehensive Cancer Network (NCCN) guidelines on cancer-related fatigue (version 2.2020 – May 4, 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.²⁹ The NCCN guidelines on adult cancer pain (version 1.2020 – April 8, 2020) state that sedation may hinder the achievement of dose titration of opioids to levels that provide adequate analgesia.³⁰ 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, or modafinil, 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.⁴⁸ A review of methylphenidate for cancer-related fatigue found a small but significant improvement in fatigue over placebo (P = 0.005).⁴⁹

Appendix 1

Immediate-release Attention Deficit Hyperactivity Disorder (ADHD) Stimulant medications include the following:

amphetamine sulfate (Evekeo, Evekeo ODT)
dexmethylphenidate HCl (Focalin)
dextroamphetamine sulfate (ProCentra, Zenzedi)
methamphetamine HCl (Desoxyn)
methylphenidate HCl (Methylin, Ritalin)
mixed amphetamine salts (Adderall)

Appendix 2

Extended-release Attention Deficit Hyperactivity Disorder (ADHD) Stimulant medications include the following:

amphetamine ER (Adzenys XR, Adzenys XR-ODT, Dyanavel XR)
dexmethylphenidate ER (Focalin XR)
dextroamphetamine SR (Dexedrine Spansule)
lisdexamphetamine ER (Vyvanse)
methylphenidate ER (Adhansia XR, Aptensio XR, Concerta, Cotempla XR-ODT, Daytrana, Jornay PM, Metadate CD, QuilliChew ER, Quillivant XR, Relexxii, Ritalin LA)
mixed amphetamine salts ER (Adderall XR, Mydayis)

Attention-Deficit/Hyperactivity Disorder (ADHD) product information:

MEDICATION	DOSING CONSIDERATIONS	DURATION OF ACTION	DOSAGE FORM
<i>Long-Acting Stimulants (amphetamine)</i>			
Adzenys ER (amphetamine)	May be taken with or without food.	10 to 12 hours	oral suspension
Adzenys XR-ODT (amphetamine)	May be taken with or without food	10 to 12 hours	orally disintegrating tablet
Dyanavel XR (amphetamine)	May be taken with or without food	Up to 13 hours	oral suspension

MEDICATION	DOSING CONSIDERATIONS	DURATION OF ACTION	DOSAGE FORM
Adderall XR (mixed amphetamine salts)	May be taken whole, or the capsule may be opened and sprinkled on applesauce.	10 to 12 hours	capsule
Mydayis (mixed amphetamine salts)	May be taken whole, or the capsule may be opened and sprinkled on applesauce.	16 hours	capsule
Long-Acting Stimulants (dexamethylphenidate)			
Focalin XR (dexamethylphenidate)	May be taken whole, or the capsule may be opened and sprinkled on applesauce.	10 to 12 hours	capsule
Long-Acting Stimulants (lisdexamphetamine)			
Vyvanse capsule (lisdexamphetamine)	May be swallowed whole or can be opened, emptied, and mixed with yogurt, water, or orange juice	10 to 12 hours	capsule
Vyvanse tablet (lisdexamphetamine)	Must be chewed thoroughly before swallowing.	10 to 12 hours	chewable tablet
Long-Acting Stimulants (methylphenidate)			
Adhansia XR (methylphenidate)	May be taken whole, or the capsule may be opened and sprinkled on applesauce or yogurt.	16 hours	capsule
Aptensio XR (methylphenidate)	May be taken whole, or the capsule may be opened and sprinkled on applesauce.	12 hours	capsule
Concerta (methylphenidate)	The tablets should not be chewed or crushed.	10 to 12 hours	tablet
Cotempla XR-ODT (methylphenidate)	May be taken with or without food.	12 hours	orally disintegrating tablet
Jornay PM (methylphenidate)	May be taken whole, or the capsule may be opened and sprinkled on applesauce.	Peak concentration occurs 14 hours after dose with gradual decline thereafter	capsule
Metadate CD (methylphenidate)	May be taken whole, or the capsule may be opened and sprinkled on applesauce.	8 to 12 hours	capsule
methylphenidate ER	The tablets should not be chewed or crushed.	10 to 12 hours	tablet
QuilliChew ER (methylphenidate)	May be taken with or without food.	12 hours	chewable tablet
Quillivant XR (methylphenidate)	May be taken with or without food.	12 hours	oral suspension
Ritalin LA (methylphenidate)	May be taken whole, or the capsule may be opened and sprinkled on applesauce.	8 to 12 hours	capsule
Daytrana (methylphenidate)	The patch should be applied to the hip area 2 hours before an effect is needed and removed within 9 hours	10 to 12 hours	transdermal patch
Intermediate-Acting Stimulants			
Dexedrine Spansule (dextroamphetamine)	n/a	6 to 8 hours	capsule
methylphenidate ER	The tablets should not be chewed or crushed.	3 to 8 hours	tablet

MEDICATION	DOSING CONSIDERATIONS	DURATION OF ACTION	DOSAGE FORM
Short-Acting Stimulants			
Adderall (mixed amphetamine salts)	n/a	4 to 6 hours	tablet
Evekeo (amphetamine sulfate)	n/a	4 to 6 hours	tablet
Evekeo ODT (amphetamine)	As soon as the blister pack is opened, the tablet should be placed on the patient's tongue and allowed to disintegrate without chewing or crushing	4 to 6 hours	orally disintegrating tablet
Desoxyn (methamphetamine HCl)	n/a	3 to 5 hours	tablet
Focalin (dexmethylphenidate HCl)	May be administered with or without food	5 to 6 hours	tablet
Methylin Solution (methylphenidate HCl)	n/a	3 to 5 hours	oral solution
Methylin Chewable Tablet (methylphenidate HCl)	Should be taken with at least 8 ounces (a full glass) of water or other liquid	3 to 5 hours	chewable tablet
ProCentra (dextroamphetamine sulfate)	n/a	4 to 6 hours	oral solution
Ritalin (methylphenidate HCl)	n/a	3 to 5 hours	tablet
Zenzedi (dextroamphetamine sulfate)	n/a	4 to 6 hours	tablet
Non-Stimulants			
Intuniv (guanfacine HCl extended-release)	The tablets should not be crushed, chewed, broken prior to swallowing or administered with high fat meals.	8 to 24 hours	tablet
Kapvay (clonidine HCl extended-release)	The tablets should not be crushed, chewed, or broken prior to swallowing.	12 hours	tablet
Strattera (atomoxetine HCl)	The capsules are not intended to be opened and should be taken whole, and may be taken with or without food.	24 hours	capsule

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