BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

ADZENYS ER™ (amphetamine) extended release oral suspension
ADZENYS XR-ODT® (amphetamine) extended release orally disintegrating tablet
Amphetamine Sulfate oral tablet
DYANAVEL® XR (amphetamine) extended release oral chewable tablet
DYANAVEL® XR (amphetamine) extended release oral suspension
EVEKEO™ (amphetamine sulfate) oral tablet
EVEKEO™ ODT (amphetamine sulfate) orally disintegrating tablet

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require precertification is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

ADZENYS ER™ (amphetamine) extended-release oral suspension
ADZENYS XR-ODT® (amphetamine) extended-release orally disintegrating tablet
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EVEKEO™ ODT (amphetamine sulfate) orally disintegrating tablet

- **Criteria for initial therapy:** Adzenys ER, Adzenys XR-ODT, or Dyanavel XR are considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Psychiatrist
  2. Individual is 6 years of age or older
  3. A confirmed diagnosis of **Attention Deficit Hyperactivity Disorder (ADHD)**
  4. Individual has failure, contraindication per FDA label, or intolerance to a trial of **ONE** drug from **BOTH** of the following:
     a. A generic extended release methylphenidate **OR** a generic extended release dexmethylphenidate (such as generic Concerta, generic Metadate CD and generic Ritalin LA, dexmethylphenidate ER)
     b. Generic dextroamphetamine with amphetamine extended release **OR** a generic extended release dextroamphetamine **OR** Vyvanse (lisdexamfetamine)
  5. There are **NO** FDA-label contraindications, such as:
     a. Known hypersensitivity to amphetamine products
     b. Use of monoamine oxidase inhibitor (MAOI) or within 14 days of the last MAOI dose
  6. There is no history of risky, harmful, non-medical or inappropriate use of these and other substances that might be unhealthy, hazardous or a problem (i.e., multiple providers, multiple pharmacies or multiple controlled substances)
  7. There are no known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmia, coronary artery disease, or other serious heart problems
  8. There is no history of uncontrolled pre-existing psychiatric mood disorder such as depression, history of suicide, bipolar disorder, or psychotic disorder
  9. There are no significant drug interactions

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Adzenys ER, Adzenys XR-ODT, or Dyanavel XR is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met (**samples are not considered for continuation of therapy**):

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Psychiatrist

2. Individual's condition responded while on therapy with response defined as **TWO** of the following:
    a. Achieved and maintains at least a 50% reduction from baseline in core symptoms of hyperactivity, impulsivity, and attention
    b. Achieved and maintains at least a 50% improvement from baseline in SKAMP rating scale
    c. Improved attention and social skills
    d. No aggressive behaviors

3. Individual has been adherent with the medication

4. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use
    a. Contraindications as listed in the criteria for initial therapy section
    b. Significant adverse effect such as:
        i. Aggressive behavior or hostility
        ii. Any cardiovascular event
        iii. Delusional thinking
        iv. Hypertension
        v. Mania
        vi. Peripheral vasculopathy including digital ulceration, Raynaud phenomenon
        vii. Priapism
        viii. Psychotic symptoms
        ix. Seizures
        x. Serotonin Syndrome
        xi. Tourette syndrome or tics
        xii. Visual disturbance

5. There is no history of risky, harmful, non-medical or inappropriate use of these and other substances that might be unhealthy, hazardous or a problem (i.e., multiple providers, multiple pharmacies or multiple controlled substances)

6. There is no history of uncontrolled pre-existing psychiatric mood disorder such as depression, history of suicide, bipolar disorder, or psychotic disorder

7. There are no significant interacting drugs

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

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EVEKEO™ (amphetamine sulfate) oral tablet
EVEKEO™ ODT (amphetamine sulfate) orally disintegrating tablet

1. **Off-Label Use of Non-Cancer Medications**
2. **Off-Label Use of Cancer Medications**

EVEKEO ODT (amphetamine sulfate, orally disintegrating tablet)

- **Criteria for initial therapy**: Evekeo ODT is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Psychiatrist
2. Individual is 3 to 17 years of age
3. A confirmed diagnosis of **Attention Deficit Disorder with Hyperactivity**
4. Individual has failure, contraindication per FDA label, or intolerance to a trial of **ALL** of the following:
    a. Methylphenidate **or** a dexmethylphenidate
    b. Generic dextroamphetamine with amphetamine extended release **or** a dextroamphetamine product **or** Vyvanse (lisdexamfetamine)
5. There is no history of risky, harmful, non-medical or inappropriate use of these and other substances that might be unhealthy, hazardous or a problem (i.e., multiple providers, multiple pharmacies, or multiple controlled substances)
6. There are no known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmia, coronary artery disease, or other serious heart problems
7. There is no history of uncontrolled pre-existing psychiatric mood disorder such as depression, history of suicide, bipolar disorder, or psychotic disorder
8. There are **NO** FDA-label contraindications, such as:
    a. During or within 14 days following the administration of monoamine oxidase inhibitors
    b. Known hypersensitivity to amphetamine products
9. There are no significant drug interactions

Initial approval duration: 6 months

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DYANAVEL® XR (amphetamine) extended release oral suspension
EVEKEO™ (amphetamine sulfate) oral tablet
EVEKEO™ ODT (amphetamine sulfate) orally disintegrating tablet

- **Continuation of coverage (renewal request):** Evekeo ODT is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met (**samples are not considered for continuation of therapy**):

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Psychiatrist

2. Individual's condition has responded while on therapy with response defined as **TWO** of the following:
    a. Achieved and maintains at least a 50% reduction from baseline in core symptoms of hyperactivity, impulsivity, and attention
    b. Achieved and maintains at least a 50% improvement from baseline in SKAMP rating scale
    c. Improve attention and social skills
    d. No aggressive behaviors

3. Individual has been adherent with the medication

4. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use
    a. Contraindications as listed in the criteria for initial therapy section
    b. Significant adverse effect such as:
        i. Aggressive behavior or hostility
        ii. Any cardiovascular event
        iii. Delusional thinking
        iv. Hypertension
        v. Mania
        vi. Peripheral vasculopathy including digital ulceration, Raynaud phenomenon
        vii. Priapism
        viii. Psychotic symptoms
        ix. Seizures
        x. Serotonin Syndrome
        xi. Tourette syndrome or tics
        xii. Visual disturbance

5. There is no history of risky, harmful, non-medical or inappropriate use of these and other substances that might be unhealthy, hazardous or a problem (i.e., multiple providers, multiple pharmacies, or multiple controlled substances)

6. There is no history of uncontrolled pre-existing psychiatric mood disorder such as depression, history of suicide, bipolar disorder, or psychotic disorder

7. There are no significant interacting drugs

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**
2. **Off-Label Use of Cancer Medications**

EVEKEO (amphetamine sulfate) tablet
Amphetamine Sulfate tablet

- **Criteria for initial therapy**: Evekeo or generic amphetamine sulfate is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Psychiatrist, Pulmonologist, or Bariatric Physician depending upon requested use
2. A confirmed diagnosis of **ONE** of the following:
   a. **Attention Deficit Disorder with Hyperactivity,** in an individual **3 years of age or older** who has failure, contraindication per FDA-label, or intolerance to a trial of **ALL** of the following:
      i. Immediate release mixed amphetamine/dextroamphetamine salt
      ii. Immediate release dextroamphetamine

   b. **Narcolepsy with excessive daytime sleepiness,** confirmed by presence of clinical symptoms and polysomnography followed by a multiple sleep latency test (MSLT) indicating sleep onset of less than 8 minutes and ≥ 2 sleep onset REM periods **AND** has an Epworth Sleep Scale (ESS) score of 10 or more in an individual **6 years of age or older** who has failure, contraindication per FDA label, or intolerance to a trial of **ALL** of the following:
      i. Immediate release mixed amphetamine/dextroamphetamine salt
      ii. Immediate release dextroamphetamine
      iii. Methylphenidate
      iv. Modafinil or armodafinil

   c. **Exogenous Obesity** in an individual **12 years of age or older** and **ALL** of the following:
      i. Benefit plan design must include weight loss as a covered benefit
      ii. Has failed alternative therapy, e.g., repeated diets, group programs and other drugs

iii. Has failure, contraindication per FDA label, or intolerance, to immediate release methamphetamine
iv. To be used as adjunct short-term treatment (a few weeks) in a regimen of weight reduction based on caloric restriction

3. There is no history of risky, harmful, non-medical or inappropriate use of these and other substances that might be unhealthy, hazardous or a problem (i.e., multiple providers, multiple pharmacies, or multiple controlled substances)

4. There are no known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmia, coronary artery disease, or other serious heart problems

5. There is no history of uncontrolled pre-existing psychiatric mood disorder such as depression, history of suicide, bipolar disorder, or psychotic disorder

6. There are **NO** FDA-label contraindications, such as:
   a. During or within 14 days following the administration of monoamine oxidase inhibitors
   b. Known hypersensitivity to amphetamine products

Initial approval duration:
ADHD & Narcolepsy: 6 months
Exogenous Obesity: 1 month

- **Continuation of coverage (renewal request):** Evekeo (amphetamine sulfate) or amphetamine sulfate is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met (**samples are not considered for continuation of therapy**):

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Psychiatrist, Pulmonologist, or Bariatric Physician depending upon requested use

2. Individual's condition has responded while on therapy with response defined as:
   a. For ADHD **TWO** of the following:
      i. Achieved and maintains at least a 50% reduction from baseline in core symptoms of hyperactivity, impulsivity, and attention
      ii. Achieved and maintains at least a 50% improvement from baseline in SKAMP rating scale
      iii. Improved attention and social skills
      iv. No aggressive behaviors
   b. For Narcolepsy, **either**:
      i. Achieved and maintains an improvement in daytime sleepiness and alertness over baseline and reduced number of cataplexy episode (if it was present)

ii. Achieved and maintains an improvement in the Epworth Sleepiness Scale (ESS) score of 7or less

c. For Exogenous Obesity:
   i. Achieved and maintains at least a 10% reduction in weight

3. Individual has been adherent with the medication

4. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use
   a. Contraindications as listed in the criteria for initial therapy section
   b. Significant adverse effect such as:
      i. Aggressive behavior or hostility
      ii. Any cardiovascular event
      iii. Delusional thinking
      iv. Hypertension
      v. Mania
      vi. Peripheral vasculopathy including digital ulceration, Raynaud phenomenon
      vii. Priapism
      viii. Psychotic symptoms
      ix. Seizures
      x. Serotonin Syndrome
      xi. Tourette syndrome or tics
      xii. Visual disturbance

5. There is no history of risky, harmful, non-medical or inappropriate use of these and other substances that might be unhealthy, hazardous or a problem (i.e., multiple providers, multiple pharmacies, or multiple controlled substances)

6. There is no history of uncontrolled pre-existing psychiatric mood disorder such as depression, history of suicide, bipolar disorder, or psychotic disorder

7. There are no significant interacting drugs

Renewal duration:
ADHD & Narcolepsy: 12 months
Exogenous Obesity: 6 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

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DYANAVEL® XR (amphetamine) extended release oral suspension
EVEKEO™ (amphetamine sulfate) oral tablet
EVEKEO™ ODT (amphetamine sulfate) orally disintegrating tablet

1. **Off-Label Use of Non-Cancer Medications**
2. **Off-Label Use of Cancer Medications**

Description:

Adzenys ER (amphetamine, extended release suspension), Adzenys XR-ODT (amphetamine, extended release oral disintegrating tablet), and Dyanavel XR (amphetamine, extended release suspension) are central nervous system stimulants indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in individuals 6 years of age or older. Amphetamines are non-catecholamine sympathomimetic amines with stimulant activity. The mode of therapeutic action in ADHD is not known. Amphetamines are thought to block the reuptake of norepinephrine and dopamine into the presynaptic neuron and increase the release of these monoamines into the extraneuronal space.

Evekeo (amphetamine sulfate) and amphetamine sulfate are indicated for the treatment of individuals 3 years of age or older with ADHD; for the treatment of individuals 12 years or age or older with narcolepsy; and for the short term treatment (a few weeks) of individuals 12 years of age or older with exogenous obesity as an adjunct in a regimen of weight reduction based on caloric restriction for patients refractory to alternative therapy such as repeated diets, group programs, and other drugs.

Evekeo ODT (amphetamine sulfate, orally disintegrating tablet) is indicated for the treatment of individuals 6 to 17 years of age with ADHD.

ADHD is one of the most commonly diagnosed neurobehavioral disorders of childhood. It is more frequently diagnosed in males than in females. ADHD is characterized by inattention, hyperactivity that exceeds the usual developmental pattern, and impulsivity that impair activities of daily living. Comorbidities are also common and may include mood disorder, anxiety disorder, substance abuse, tics, learning difficulties, and disruptive behaviors such as oppositional defiance or conduct disorder. Symptoms can persist into adolescence and into adulthood.

The published literature suggests that central nervous system (CNS) stimulant medications are considered first line therapy in uncomplicated ADHD. Methylphenidate or mixed Amphetamine salts, or Dextroamphetamine are often recommended as first line therapy. Evidence for the use of Methylphenidate is derived from well-designed efficacy and safety trials. Due to limited number of trial information the strength of evidence for the other stimulants is ranked as fair.

When one stimulant fails to manage the condition due to an inadequate response or intolerable adverse effects occur, it is suggested to change to another one of the first line stimulants within a different class. Approximately 50% of individuals not responding to one stimulant may respond to the other. It is further suggested that if two first line stimulants are ineffective, non-stimulant medications may be added or used as monotherapy. Use of non-stimulant medications may also be beneficial in situations such as concerns about substance abuse or diversion,

tic disorder, impulsivity, sleep problems, anxiety, psychosis, aggression, or cardiac abnormalities associated with use of stimulants. Non-stimulant medications may include Atomoxetine, Clonidine, or Guanfacine.

There are many agents available with brand and generic options for the treatment of ADHD. Several agents are available as both immediate acting and long acting formulations. Comparative trials of stimulant medications are lacking, but it is apparent that all stimulant medications have similar effects and adverse effects and given the extensive evidence of efficacy and safety, they still remain agent first choice. There are clinically meaningful differences in dosing, time to onset, route, duration of action, and cost among the various compounds. Sustained-release formulations of stimulants may show benefit over immediate release forms at specific times of day depending on the pharmacokinetics of the specific formulation used, but overall differences on safety and efficacy are not found.

For individuals with swallowing difficulties, many capsule forms of extended release stimulants can be opened and sprinkled onto food. Liquid formulations are also available, and some products have a chewable dosage form that can be used.

Narcolepsy is a chronic neurologic disorder of the central nervous system characterized by the brain's inability to control sleep-wake cycles, resulting in excessive daytime sleepiness (EDS) and intermittent bouts of rapid eye movement (REM) sleep during wakefulness. At various times throughout the day, individuals with narcolepsy experience irresistible and sudden bouts of sleep, which can last from a few seconds to several minutes. In addition to EDS, other major symptoms of narcolepsy include cataplexy (a sudden loss of voluntary muscle tone), hypnagogic hallucinations (vivid dream-like images or hallucinations during sleep onset or upon waking), and sleep paralysis (brief episodes of total paralysis, also during sleep onset or upon waking). Most individuals experience poor sleep quality that can involve frequent awakenings during nighttime sleep, and other sleep disorders. Sleep may be disrupted by insomnia, vivid dreaming, sleep talking, acting out while dreaming, and periodic leg movements.

The diagnosis of narcolepsy is confirmed with a polysomnogram that rules out other sleep disorders and a multiple sleep latency test (MSLT) that demonstrates an average sleep latency less than eight minutes and/or at least two sleep onset rapid eye movement periods (SOREMPs). True cataplexy is highly suggestive of narcolepsy. Other conditions that cause chronic daytime sleepiness include insufficient sleep, untreated sleep apnea, periodic limb movements of sleep, and idiopathic hypersomnia (chronic sleepiness but without SOREMPs or other evidence of abnormal REM sleep). The effects of sedating medications should be excluded. The goal of therapy is to improve alertness to the point where performance and safety are adequate for important activities like school or work. Once therapy has been optimized, the severity of residual sleepiness should be assessed with the Epworth Sleepiness Scale (ESS) or the Maintenance of Wakefulness Test (MWT).

Amphetamine, immediate release forms of mixed salts of amphetamine/dextroamphetamine, dextroamphetamine, methamphetamine, many methylphenidate products, Provigil (modafinil), Nuvigil (armodafinil), and Sunosi (solriamfetol) are effective for treatment of daytime sleepiness due to narcolepsy and are FDA-approved for use for this disorder. Many of these agents are available as a generic formulation.

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Adult individuals with a body mass index (BMI) of 25-29.9 kg/m^2 are considered overweight and those with a BMI of ≥ 30 kg/m^2 are considered obese. Diet and exercise are the preferred methods for losing weight and there are several drugs that are FDA-approved as adjuncts to diet and exercise for weight loss. Amphetamines are non-catecholamine, sympathomimetic amines with CNS stimulant activity. Drugs in this class when used in the treatment of obesity are commonly referred to as "anorectics" or "anorexigenics." The mechanism of action of such drugs in treating obesity has not been established, however they act primarily to cause appetite suppression. Other CNS actions or metabolic effects may be involved. Methamphetamine is also FDA-approved for short-term treatment of obesity. Coverage of Evekeo for exogenous obesity is dependent upon benefit plan design that includes weight loss as a covered benefit

Definitions:

Attention Deficit Hyperactivity Disorder (ADHD)

- ADHD types:
  - Inattentive Type, *at least 6* of the following symptoms must have persisted for *at least 6 months*
    - Lack of attention to details/careless mistakes
    - Lack of sustained attention
    - Poor listener
    - Failure to follow through on tasks
    - Poor organization
    - Avoids tasks requiring sustained mental effort
    - Loses things
    - Easily distracted
    - Forgetful
  - Hyperactive-Impulsive Type, *at least 6* of the following symptoms must have persisted for *at least 6 months*
    - Fidgeting/squirming
    - Leaving seat
    - Inappropriate running/climbing
    - Difficulty with quiet activities
    - "On the go"
    - Excessive talking
    - Blurting answers
    - Can't wait turn
    - Intrusive
  - Combined Type requires both inattentive and hyperactive-impulsive criteria to be met

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ADHD medications – stimulants: [Note may not be a complete list]

Methylphenidate-type products:		
Methylphenidate		
Aptensio XR	ER Cap 24 h	10, 15, 20, 30, 40, 50, 60 mg
Concerta	ER Tab	18, 27, 36, 54 mg
Daytrana	Transdermal	10 mg/9 hr, 15 mg/9 hr, 20 mg/9 hr, 30 mg/ 9 hr
Metadate CD	ER Cap	10, 20, 30, 40, 50, 60 mg
Metadate ER	ER Tab	20 mg
Methylin	Tab chewable	2.5, 5, 10 mg
	Solution	5 mg / 5 mL, 10 mg / 5 mL
Methylphenidate	Tab	5, 10, 20 mg
	Tab chewable	2.5, 5, 10 mg
	Solution	5 mg /5 mL, 10 mg / 5 mL
Methylphenidate ER	ER Tab	10, 18, 20, 27, 36, 54 mg
Methylphenidate ER	ER Tab 24 h	18, 27, 36, 54 mg
Methylphenidate ER (CD)	ER Cap	10, 20, 30, 40, 50, 60 mg
Methylphenidate ER (LA)	ER Cap 24 h	20, 30, 40 mg
Quillivant XR	ER Suspension	25 mg / 5 mL
Ritalin	Tab	5, 10, 20 mg
Ritalin LA	ER Cap 24 h	10, 20, 30, 40, 60 mg
Ritalin SR	ER Tab	20 mg
Dexmethylphenidate		
Dexmethylphenidate	Tab	2.5, 5, 10 mg
Dexmethylphenidate ER	ER Cap 24 h	5, 10, 15, 30, 40 mg
Focalin	Tab	2.5, 5, 10 mg
Focalin XR	ER Cap 24 h	5, 10, 15, 20, 25, 30, 35, 40 mg
Listing does not imply formulary status or need for precertification or need step-therapy		

Amphetamine-type products:		
Amphetamine		
Adzenys XR-ODT	Tab ODT 24h	3.1, 6.3, 9.4, 12.5, 15.7, 18.8 mg
Dyanavel XR	Suspension	2.5 mg/mL
Evekeo	Tab	5, 10 mg
Mixed salts: Amphetamine (25%) / Dextroamphetamine (75%)		
Adderall	Tab	5, 7.5, 10,12.5, 15, 20, 30 mg
Adderall XR	ER Cap 24 h	5, 10, 15, 20, 25, 30 mg
Amphetamine / Dextroamphetamine	Tab	5, 7.5, 10,12.5, 15, 20, 30 mg
	ER Cap 24 h	5, 10, 15, 20, 25, 30 mg
Dextroamphetamine		
Dexedrine	ER Cap 24 h	5, 10, 15 mg
Dextroamphetamine	Tab	5, 10 mg

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	Solution	5 mg / 5 mL
Dextroamphetamine ER	ER Cap 24 h	5, 10, 15 mg
ProCentra	Solution	5 mg / 5 mL
Zenzedi	Tab	2.5, 5, 7.5, 10, 15, 20, 30 mg
Lisdexamfetamine		
Vyvanse	Cap	10, 20, 30, 40, 50, 60, 70 mg
Methamphetamine		
Desoxyn	Tab	5 mg
Methamphetamine	Tab	5 mg
Listing does not imply formulary status or need for precertification or need step-therapy		

ADHD medications – non-stimulants: [Note may not be a complete list]

Norepinephrine re-uptake inhibitor		
Atomoxatine (Strattera)	Cap	10, 18, 25, 40, 60, 80, 100 mg
Clonidine – central alpha-2 agonist		
Catapres	Tab	0.1, 0.2, 0.3 mg
Clonidine	Tab	0.1, 0.2, 0.3 mg
Clonidine ER	ER Tab 12 h	0.1 mg
Kapvay (clonidine ER)	ER Tab 12 h	0.1, 0.2 mg
Guanfacine – central alpha-2a agonist		
Guanfacine	Tab	1, 2 mg
Guanfacine ER	ER Tab 24 h	1, 2, 3, 4 mg
Intuniv (guanfacine ER)	ER Tab 24 h	1, 2, 3, 4 mg
Tenex	Tab	1, 2 mg
Listing does not imply formulary status or need for precertification or need step-therapy		

Swanson, Kotkin, Agler, M-Flynn, and Pelham (SKAMP) rating scale:

- A validated 13-item teacher-rated scale that assesses manifestations of ADHD in a classroom setting
- The rating scale consists of 13 items rated on a 7-point impairment scale (0 = normal to 6 = maximal impairment)
- The combined scores for the SKAMP are obtained by summing the values of all 13 items
- Subscale scores for attention (items 1-4), behavior (items 5-8), quality of work (items 9-11) and compliance (items 12-13) are obtained by summing the values of their corresponding items

	Impairment Scale 0-7
1. Getting started on assignments for classroom periods	1__2__3__4__5__6__7
2. Sticking with tasks or activities for the allotted time	1__2__3__4__5__6__7
3. Attending to an activity or a discussion of the class	1__2__3__4__5__6__7
4. Stopping and making transition to the next period	1__2__3__4__5__6__7

5. Interacting with other children	1__2__3__4__5__6__7
6. Interacting with the teacher or aide	1__2__3__4__5__6__7
7. Remaining quiet according to classroom rules	1__2__3__4__5__6__7
8. Staying seated according to classroom rules	1__2__3__4__5__6__7
9. Completing assigned work	1__2__3__4__5__6__7
10. Performing work accurately	1__2__3__4__5__6__7
11. Being careful and neat while writing or drawing	1__2__3__4__5__6__7
12. Complying with the teacher's usual requests or directions	1__2__3__4__5__6__7
13. Following the rules established for the classroom	1__2__3__4__5__6__7

Diagnostic criteria for narcolepsy type 1:

Criteria A and B must be met:
A. The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months.*
B. The presence of one or both of the following:
1. Cataplexy and a mean sleep latency of ≤ 8 minutes and two or more SOREMPs on an MSLT performed according to standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal PSG may replace one of the SOREMPs on the MSLT.¶ 2. CSF hypocretin-1 concentration, measured by immunoreactivity, is either ≤110 pg/mL or <1/3 of mean values obtained in normal subjects with the same standardized assay.
CSF: cerebrospinal fluid; MSLT: multiple sleep latency test; PSG: polysomnography; SOREMPs: sleep-onset rapid eye movement periods. * In young children, narcolepsy may sometimes present as excessively long night sleep or as resumption of previously discontinued daytime napping. ¶ If narcolepsy type 1 is strongly suspected clinically but the MSLT criteria of B1 are not met, a possible strategy is to repeat the MSLT.

Diagnostic criteria for narcolepsy type 2:

Criteria A through E must be met:
A. The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months.
B. A mean sleep latency of ≤ 8 minutes and two or more SOREMPs are found on an MSLT performed according to standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal PSG may replace one of the SOREMPs on the MSLT.
C. Cataplexy is absent.*

D. Either CSF hypocretin concentration has not been measured or CSF hypocretin concentration measured by immunoreactivity is either >110 pg/mL or >1/3 of mean values obtained in normal subjects with the same standardized assay.¶
E. The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal.
CSF: cerebrospinal fluid; MSLT: multiple sleep latency test; PSG: polysomnography; SOREMPs: sleep-onset rapid eye movement periods. * If cataplexy develops later, then the disorder should be reclassified as narcolepsy type 1. ¶ If the CSF hypocretin-1 concentration is tested at a later stage and found to be either ≤110 pg/mL or <1/3 of mean values obtained in normal subjects with the same assay, then the disorder should be reclassified as narcolepsy type 1.

Epworth Sleepiness Scale (ESS):
The ESS subjectively measures sleepiness as it occurs in ordinary life situations. It can be used to screen for excessive sleepiness or to follow an individual's subjective response to an intervention. A score > 10 is consistent with excessive sleepiness.

Sitting and standing	No chance of dozing	0 points
	Slight chance of dozing	1 point
	Moderate chance of dozing	2 points
	High chance of dozing	3 points
Watching television	No chance of dozing	0 points
	Slight chance of dozing	1 point
	Moderate chance of dozing	2 points
	High chance of dozing	3 points
Sitting inactive in a public place	No chance of dozing	0 points
	Slight chance of dozing	1 point
	Moderate chance of dozing	2 points
	High chance of dozing	3 points
Sitting for an hour as a passenger in a car	No chance of dozing	0 points
	Slight chance of dozing	1 point
	Moderate chance of dozing	2 points
	High chance of dozing	3 points
Lying down in the afternoon to rest	No chance of dozing	0 points
	Slight chance of dozing	1 point
	Moderate chance of dozing	2 points
	High chance of dozing	3 points
Sitting and talking to another person	No chance of dozing	0 points
	Slight chance of dozing	1 point
	Moderate chance of dozing	2 points

	High chance of dozing	3 points
Sitting quietly after lunch (no alcohol at lunch)	No chance of dozing	0 points
	Slight chance of dozing	1 point
	Moderate chance of dozing	2 points
	High chance of dozing	3 points
Sitting in a car, stopped for a few minutes due to traffic	No chance of dozing	0 points
	Slight chance of dozing	1 point
	Moderate chance of dozing	2 points
	High chance of dozing	3 points
Total points:		
Score assessment: 1-6 points: Normal sleep 7-8 points: Average sleepiness 9-24 points: Abnormal (possibly pathologic) sleepiness		

Maintenance of Wakefulness Test (MWT):

- MWT measures the ability to stay awake
- It objectively measures the ability of an individual to remain awake for a defined period of time
- It is based on the premise that individuals with a greater degree of sleepiness are less likely to remain awake than individuals with less sleepiness
- MWT may be used to assess an individual's response to therapy
- It is the direction of change, not the degree of change, that is meaningful
- During the MWT:
    - Sit in a recumbent position
    - Instructed to sit still and try to remain awake for as long as possible
    - Look directly ahead and do not look directly at the light
    - Avoid extraordinary measures to stay awake (e.g., slapping the face, singing)
    - A session is ended after unequivocal sleep, or after 40 minutes if sleep does not occur
    - Sleep is considered unequivocal after three consecutive periods of stage 1 sleep or one period of any other stage of sleep
    - For each session, the sleep latency is recorded
    - It is documented as being 40 minutes if the patient does not fall asleep
    - This is repeated every two hours, until the patient has completed four sessions
- The primary measure from the MWT is the mean sleep latency
- Healthy individuals who complete four 40-minute protocol sessions, the mean sleep latency is approximately 30 minutes, with > 97% of individuals having a mean sleep latency of ≥ 8 minutes
    - A mean sleep latency of < 8 minutes is generally considered abnormal
    - Staying awake for at least 40 minutes during all four sessions is strong objective evidence that an individual can stay awake

- A mean sleep latency between 8 and 40 minutes has uncertain significance

Multiple sleep latency test (MSLT):

- MSLT measures the tendency to fall asleep
- It tests for excessive daytime sleepiness (EDS) by measuring how quickly one falls asleep in a quiet environment during the day
  - EDS occurs when you are sleepy when you should be awake and alert
- MSLT is the standard tool used to diagnose narcolepsy and idiopathic hypersomnia
- MSLT is a full-day test that consists of five scheduled naps separated by two-hour breaks
- During the MSLT
  - Lying flat in bed for the MSLT
  - Instructed to lie quietly, assume a comfortable position, keep eyes closed, and try to fall asleep
  - The test will measure how long it takes for to fall asleep
  - You will be awakened after sleeping 15 minutes
  - If you do not fall asleep within 20 minutes, the nap trial will end

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Resources:

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