ADHD and Narcolepsy Drug Therapy

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy Prior Authorization (PA) program is to ensure appropriate therapy selection according to the Food and Drug Administration (FDA)-approved product labeling and/or clinical guidelines and/or clinical trials and to direct use to more cost-effective generic agents as appropriate.

POLICY

Criteria for Initial Approval

I. The long-acting stimulant agents, Adderall XR, Concerta, Dexedrine ER, Focalin XR, Metadate CD, Metadate ER, Ritalin LA, and generic equivalents, may be considered **medically necessary** for the treatment of narcolepsy or hypersomnia when confirmed by a sleep study.

Approval will be for **24 months.**

II. The long-acting stimulant agents, Adderall XR, Aptensio XR, Astarys, Concerta, Dexedrine ER, Focalin XR, Metadate CD, Metadate ER, Mydayis, Ritalin LA, and generic equivalents, may be considered **medically necessary** for the treatment of ADHD when the following criteria are met:

- Patient must have tried and failed at least **TWO** immediate acting formulary alternatives unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs). Treatment failure cannot be caused by a lack of compliance to therapy or the unwillingness to take an immediate acting formulary alternative; **OR**
- The patient is 19 years of age or younger and attending school which limits the ability to administer the requested medication more than once a day

Approval will be for **24 months.**

III. Daytrana and Xelstrym may be considered **medically necessary** for the treatment of ADHD when the following criteria is met:
- Patient must have a medical condition that prevents them from taking oral medications; **OR**
- Patient must have tried and failed a therapeutic trial of at least **TWO** appropriately dosed and administered long acting stimulants with one being a long acting oral formulation of the requested drug (i.e., methylphenidate when requested drug is Daytrana; dextroamphetamine when requested drug is Xelstrym) unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs)

Approval will be for **12 months.**

IV. Qelbree may be considered **medically necessary** for the treatment of ADHD when the following criteria is met:
- The patient is 6 years of age or older
- The patient meets ONE of the following criteria:
  - The patient must have tried and failed at least **TWO** stimulant medications with different active ingredients
  - The patient has a history of substance abuse/dependence
  - The patient has an FDA-labeled contraindication to **ALL** ADHD stimulant medications
- The patient must have tried and failed atomoxetine OR has an allergy, contraindication, or intolerance to atomoxetine

Approval will be for **12 months.**

V. Quillivant XR, QuilliChew ER, and Cotempla XR may be considered **medically necessary** for the treatment of ADHD when ALL of the following criteria are met:
- Patient must be unable to swallow an intact capsule or tablet; **AND**
- Patient must have tried and failed or have a medical reason to explain why they are unable to swallow contents of immediate acting alternatives when contents are crushed and sprinkled on soft food or liquid unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) **OR** the patient is 19 years of age or younger and attending school which limits the ability to administer the requested medication more than once a day; **AND**
- Patient must have tried and failed or have a medical reason to explain why they are unable to swallow contents of at least one long acting capsules (e.g. Adderall XR, Focalin XR, Metadate CD) when the capsules are opened and the contents are sprinkled on soft food or liquid without crushing or chewing the capsules or the granules unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).

Approval will be for **12 months.**

VI. Adzenys XR-ODT and Dyanavel XR (oral suspension and chewable tablets) may be considered **medically necessary** for the treatment of ADHD when ALL of the following criteria is met:
- The patient is 6 years of age or older
- Patient must be unable to swallow an intact capsule or tablet

- Patient must have tried and failed or have a medical reason to explain why they are unable to swallow contents of immediate acting alternatives (e.g. immediate release mixed Amphetamine salt, immediate release Dextroamphetamine, and immediate release Methylphenidate) when contents are crushed and sprinkled on soft food or liquid unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) OR the patient is 19 years of age or younger and attending school which limits the ability to administer the requested medication more than once a day
- Patient must have tried and failed or have a medical reason to explain why they are unable to swallow contents of at least one long acting capsules (e.g. Adderall XR, Focalin XR, Metadate CD) when the capsules are opened and the contents are sprinkled on soft food or liquid without crushing or chewing the capsules or the granules unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).

Approval will be for **12 months.**

VII. Brand and generic Evekeo and Evekeo ODT may be considered **medically necessary** for the treatment of ADHD when ALL of the following criteria is met:
- The patient is 3 years of age or older
- The patient must have tried and failed ALL of the following unless the patient is currently receiving a positive therapeutic outcome on Evekeo through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs):
  - Immediate release mixed Amphetamine salt (Adderall)
  - Immediate release Dextroamphetamine (Dexedrine)
  - Immediate release Methylphenidate (Ritalin) if individual is 6 years of age or older

Approval will be for **12 months.**

VIII. Brand and generic Evekeo and Evekeo ODT may be considered **medically necessary** for the treatment of Narcolepsy when ALL of the following criteria is met:
- The patient is 6 years of age or older
- The patient must have tried and failed ALL of the following unless the patient is currently receiving a positive therapeutic outcome on Evekeo through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs):
  - Immediate release mixed Amphetamine salt (Adderall)
  - Immediate release Dextroamphetamine (Dexedrine)
  - Immediate release Methylphenidate (Ritalin)

Approval will be for **12 months.**

IX. Nuvigil (armodafinil) and Provigil (modafinil) may be considered **medically necessary** for patients 16 years of age and older for the treatment of the following:
- Excessive daytime sleepiness (EDS) and/or fatigue associated with Multiple Sclerosis
- Excessive daytime sleepiness (EDS) and/or fatigue associated with Parkinson's Disease

Approval will be for **12 months.**

X. Nuvigil (armodafinil) and Provigil (modafinil) may be considered **medically necessary** for the treatment of excessive sleepiness due to Shift Work Disorder (SWD) when the following criteria is met:
- Diagnosis is confirmed by <u>one</u> of the following:

- A sleep study that demonstrates loss of a normal sleep-wake pattern
- Patient has had chronic excessive sleepiness or insomnia that is temporally associated with a work period (usually night work) that occurs during the habitual sleep phase

- Patient does not have any unmanaged conditions that are contributing to excessive sleepiness
- Excessive sleepiness has caused significant distress and/or significant impairment at work for at least 3 months

Approval will be for **12 months.**

XI. Nuvigil (armodafinil) and Provigil (modafinil) may be considered **medically necessary** for patients 16 years of age and older for the treatment of excessive daytime sleepiness associated with Obstructive Sleep Apnea (OSA),also referred to as Obstructive Sleep Apnea/Hypopnea Syndrome or OSAHS, when the following criteria is met:

- Diagnosis has been confirmed by a sleep study
- The patient is using AND adherent with continuous positive airway pressure (CPAP) therapy
- Excessive sleepiness has caused significant impairment in activities of daily living

Approval will be for **12 months.**

XII. Nuvigil (armodafinil) and Provigil (modafinil) may be considered **medically necessary** for patients 16 years of age and older for the treatment excessive daytime sleepiness (EDS) with narcolepsy when the following criteria is met:

- Diagnosis has been confirmed by a sleep study

Approval will be for **12 months.**

XIII. Nuvigil (armodafinil) and Provigil (modafinil) may be considered **medically necessary** for patients 16 years of age and older for the treatment of idiopathic hypersomnolence (IH) when **ALL** of the following criteria are met:

- The prescribing physician is a board certified sleep medicine specialist or neurologist
- The diagnosis is confirmed by nocturnal polysomnography and multiple sleep latency test (MSLT)
- Patient does not have any unmanaged conditions that are contributing to excessive sleepiness
- Patient is not taking any medications that cause excessive daytime sleepiness
- The patient must have tried and failed at least one stimulant medication; OR have an allergy, contraindication, or intolerance to standard stimulant therapy unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs)

Approval will be for **12 months.**

XIV. Sunosi (solriamfetol) may be considered **medically necessary** for patients with narcolepsy when **ALL** the following criteria are met:

- The prescribing physician is a board certified sleep medicine specialist or neurologist
- The patient has narcolepsy and the diagnosis is confirmed by a sleep study (documentation required)
- The patient experienced an inadequate treatment response or intolerance, or have a contraindication to at least one CNS stimulant drug (e.g., amphetamine, dextroamphetamine, or methylphenidate) AND one CNS promoting wakefulness drug (e.g., modafinil,, armodafinil) unless the patient is currently receiving a positive therapeutic outcome on the requested

medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs)
- Patient is NOT being treated with any sedative hypnotic agents (e.g., benzodiazepines, barbiturates, zolpidem)

Approval will be for **12 months.**

XV. Sunosi (solriamfetol) may be considered **medically necessary** for patients with obstructive sleep apnea (OSA) when **ALL** the following criteria are met:
- The patient has obstructive sleep apnea (OSA) confirmed by polysomnography (documentation required)
- The patient experienced an inadequate treatment response or intolerance, or have a contraindication to at least one CNS promoting wakefulness drug (e.g., modafinil,, armodafinil) unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs)
- Patient is NOT being treated with any sedative hypnotic agents (e.g., benzodiazepines, barbiturates, zolpidem)
- The patient is using AND adherent with continuous positive airway pressure (CPAP) therapy
- Excessive sleepiness has caused significant impairment in activities of daily living

Approval will be for **12 months.**

XVI. Wakix (pitolisant) may be considered **medically necessary** for adult patients with excessive daytime sleepiness (EDS) associated with narcolepsy when **ALL** of the following criteria are met:
- The prescribing physician is a board certified sleep medicine specialist or neurologist
- The diagnosis of narcolepsy is confirmed by clinical documentation (e.g., chart notes, lab values, sleep study results) of all of the following:
  - The patient has recurrent episodes of irrepressible need to sleep, lapsing into sleep, or napping occurring within the same day with the episodes occurring at least 3 times per week for at least 3 months
  - A mean sleep latency of ≤ 8 minutes and two or more sleep onset REM periods (SOREMPs) are found on a MSLT performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT
- The patient experienced an inadequate treatment response or intolerance, or have a contraindication to at least one CNS stimulant drug (e.g., amphetamine, dextroamphetamine, or methylphenidate **AND** one CNS promoting wakefulness drug (e.g., modafinil or armodafinil) unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs)
- Patient is NOT being treated with any sedative hypnotic agents (e.g., benzodiazepines, barbiturates, zolpidem)
- Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders).
- Patient does NOT have severe hepatic impairment
- In patients who are being treated with a strong CYP2D6 inhibitor (e.g., paroxetine, bupropion, fluoxetine) dosage will be initiated at 8.9 mg once daily and increased after 7 days to a maximum of 17.8 mg once daily

Approval will be for **12 months.**

XVII. Wakix (pitolisant) may be considered **medically necessary** for adult patients for the treatment of cataplexy associated with narcolepsy when **ALL** of the following criteria are met:

- The prescribing physician is a board certified sleep medicine specialist or neurologist
- The diagnosis of narcolepsy type I (with cataplexy) is confirmed by clinical documentation (e.g., chart notes, lab values, sleep study results) of all of the following:
  - The patient has recurrent episodes of irrepressible need to sleep, lapsing into sleep, or napping occurring within the same day with the episodes occurring at least 3 times per week for at least 3 months; AND
  - The patient has ONE or BOTH of the following:
    - Cerebrospinal fluid (CSF) hypocretin-1 deficiency (i.e., CSF hypocretin-1 concentration < 110 pg/mL or less than one-third of the normative values with the same standardized assay);
    - A mean sleep latency of ≤ 8 minutes and two or more sleep onset REM periods (SOREMPs) are found on a MSLT performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT; AND
  - The patient has experienced cataplexy at least a few times per month (> 1 episode of generally brief [< 2 minutes], usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness)
- Patient is NOT being treated with any sedative hypnotic agents (e.g., benzodiazepines, barbiturates, zolpidem)
- Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders).
- Patient does NOT have severe hepatic impairment
- In patients who are being treated with a strong CYP2D6 inhibitor (e.g., paroxetine, bupropion, fluoxetine) dosage will be initiated at 8.9 mg once daily and increased after 7 days to a maximum of 17.8 mg once daily

Approval will be for **12 months.**

XVIII. Xyrem (sodium oxybate) may be considered **medically necessary** for patients 7 years of age and older for the treatment of cataplexy associated with narcolepsy when **ALL** of the following criteria are met:

- The prescribing physician is a board certified sleep medicine specialist or neurologist
- The patient and physician must be enrolled in the Xyrem REMS Program
- The diagnosis of narcolepsy type I (with cataplexy) is confirmed by clinical documentation (e.g., chart notes, lab values, sleep study results) of all of the following:
  - The patient has recurrent episodes of irrepressible need to sleep, lapsing into sleep, or napping occurring within the same day with the episodes occurring at least 3 times per week for at least 3 months; AND
  - The patient has ONE or BOTH of the following:
    - Cerebrospinal fluid (CSF) hypocretin-1 deficiency (i.e., CSF hypocretin-1 concentration < 110 pg/mL or less than one-third of the normative values with the same standardized assay);
    - A mean sleep latency of ≤ 8 minutes and two or more sleep onset REM periods (SOREMPs) are found on a MSLT performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT; AND

- The patient has experienced cataplexy at least a few times per month (> 1 episode of generally brief [< 2 minutes], usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness)
- Patient is NOT being treated with any sedative hypnotic agents (e.g., benzodiazepines, barbiturates, zolpidem)
- Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders).
- The dose does not exceed 9gm/day

Approval will be for **12 months.**

XIX. Xyrem (sodium oxybate) and Xywav (calcium, magnesium, potassium, and sodium oxybate) may be considered **medically necessary** for patients 7 years of age and older for the treatment of excessive daytime sleepiness associated with narcolepsy when **ALL** of the following criteria are met:

- The prescribing physician is a board certified sleep medicine specialist or neurologist
- The patient and physician must be enrolled in the Xyrem/Xywav REMS Program
- The diagnosis of narcolepsy type II (absence of cataplexy) is confirmed by clinical documentation (e.g., chart notes, lab values, sleep study results) of all of the following:
  - The patient has recurrent episodes of irrepressible need to sleep, lapsing into sleep, or napping occurring within the same day with the episodes occurring at least 3 times per week for at least 3 months
  - A mean sleep latency of ≤ 8 minutes and two or more sleep onset REM periods (SOREMPs) are found on a MSLT performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT
  - The patient has not experienced cataplexy (> 1 episode of generally brief [< 2 minutes], usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness)
  - The patient's cerebrospinal fluid (CSF) hypocretin-1 concentration is > 110 pg/mL or greater than one-third of the normative values with the same standardized assay OR the CSF hypocretin-1 concentration has not been measured
- The patient experienced an inadequate treatment response or intolerance, or have a contraindication to at least one CNS stimulant drug (e.g., amphetamine, dextroamphetamine, or methylphenidate) **AND** one CNS promoting wakefulness drug (e.g., modafinil,, armodafinil) unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs)
- Patient is NOT being treated with any sedative hypnotic agents (e.g., benzodiazepines, barbiturates, zolpidem)
- Xywav only: patient has a clinical reason to restrict sodium intake, such as renal impairment, heart failure, or hypertension AND has failed therapy with Xyrem despite limiting dietary intake of sodium (documentation required). Failure is defined as worsening of renal function, cardiac output, or blood pressure and is attributed to the high sodium content of Xyrem and not to other causes.
- Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders).
- The dose does not exceed 9gm/day

Approval will be for **12 months.**

XX. Xywav (calcium, magnesium, potassium, and sodium oxybate) may be considered **medically necessary** for patients 7 years of age and older for the treatment of cataplexy associated with narcolepsy when **ALL** of the following criteria are met:

- The prescribing physician is a board certified sleep medicine specialist or neurologist
- The patient and physician must be enrolled in the Xywav REMS Program
- The diagnosis of narcolepsy type I (with cataplexy) is confirmed by clinical documentation (e.g., chart notes, lab values, sleep study results) of all of the following:
  - The patient has recurrent episodes of irrepressible need to sleep, lapsing into sleep, or napping occurring within the same day with the episodes occurring at least 3 times per week for at least 3 months; AND
  - The patient has ONE or BOTH of the following:
    - Cerebrospinal fluid (CSF) hypocretin-1 deficiency (i.e., CSF hypocretin-1 concentration < 110 pg/mL or less than one-third of the normative values with the same standardized assay);
    - A mean sleep latency of ≤ 8 minutes and two or more sleep onset REM periods (SOREMPs) are found on a MSLT performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT; AND
  - The patient experiences at least 14 episodes of cataplexy in a typical 2-week period (episodes are generally brief [< 2 minutes], usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness)
- Patient is NOT being treated with any sedative hypnotic agents (e.g., benzodiazepines, barbiturates, zolpidem)
- Patient has a clinical reason to restrict sodium intake, such as renal impairment, heart failure, or hypertension AND has failed therapy with Xyrem despite limiting dietary intake of sodium (documentation required). Failure is defined as worsening of renal function, cardiac output, or blood pressure and is attributed to the high sodium content of Xyrem and not to other causes.
- Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders).
- The dose does not exceed 9gm/day

Approval will be for **12 months.**

XXI. Xyrem (sodium oxybate) and Xywav (calcium, magnesium, potassium, and sodium oxybate) may be considered **medically necessary** for adult patients for the treatment of idiopathic hypersomnia when **ALL** of the following criteria are met:

- The prescribing physician is a board certified sleep medicine specialist or neurologist
- The patient and physician must be enrolled in the Xyrem/Xywav REMS Program
- The diagnosis of idiopathic hypersomnia is supported by clinical documentation (e.g., chart notes, lab values, sleep study results) of all of the following:
  - The patient has recurrent episodes of irrepressible need to sleep, lapsing into sleep, or napping occurring within the same day with the episodes occurring at least 3 times per week for at least 3 months; AND
  - A mean sleep latency of ≤ 8 minutes on MSLT; AND
  - Less than two sleep onset REM periods (SOREMPs) are found on a MSLT or no SOREMPs if the REM sleep latency preceding polysomnogram is 15 minutes or less; AND
  - Documentation of at least 660 minutes of average daily sleep time; AND
  - Patient has not experienced cataplexy and does not have known hypocretin deficiency

- Patient is NOT being treated with any sedative hypnotic agents (e.g., benzodiazepines, barbiturates, zolpidem)
- The patient experienced an inadequate treatment response or intolerance, or have a contraindication to at least one CNS stimulant drug (e.g., amphetamine, dextroamphetamine, or methylphenidate) **AND** one CNS promoting wakefulness drug (e.g., modafinil,, armodafinil) unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs)
- Xywav only: patient has a clinical reason to restrict sodium intake, such as renal impairment, heart failure, or hypertension AND has failed therapy with Xyrem despite limiting dietary intake of sodium (documentation required). Failure is defined as worsening of renal function, cardiac output, or blood pressure and is attributed to the high sodium content of Xyrem and not to other causes.
- Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders).
- The dose does not exceed 9gm/day

Approval will be for **12 months.**

XXII. The agents in this policy are considered **not medically necessary** for patients who do not meet the criteria set forth above.

Continuation of Therapy

I. The request for continuation of Wakix (pitolisant) may be considered medically necessary when ALL initial authorization criteria is met AND clinical documentation is provided showing the patient has experienced a positive response to therapy (e.g., improvement in excessive daytime sleepiness/reduction in symptoms of excessive daytime sleepiness compared to baseline or a decrease in cataplexy episodes compared to baseline).

Approval will be for **12 months.**

II. The request for continuation of Xyrem (sodium oxybate) and Xywav (calcium, magnesium, potassium, and sodium oxybate) may be considered medically necessary when ALL initial authorization criteria is met AND clinical documentation is provided showing the patient has experienced a positive response of therapy (e.g., improvement in excessive daytime sleepiness/reduction in symptoms of excessive daytime sleepiness compared to baseline or a decrease in cataplexy episodes compared to baseline).

Approval will be for **12 months.**

III. All patients (including new patients) requesting authorization for continuation of therapy of other agents in this policy not mentioned above must meet ALL initial authorization criteria.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Quantity Limits			
Brand Name	**Generic Name**	**FDA Recommended Maximum Dose/24 hours**	**Quantity Limit**
Adzensys XR-ODT 9.4mg, 12.5mg, 15.7mg, 18.8mg	Amphetamine	18.8 mg for patients 6 to 12 yrs 12.5 mg for patients 13 to 17 yrs	1 tablet per day
Adzensys XR-ODT 3.1mg, 6.3mg	Amphetamine	18.8 mg for patients 6 to 12 yrs 12.5 mg for patients 13 to 17 yrs	2 tablets per day
Azstarys 26.1mg/5.2mg, 39.2mg/7.8mg, 52.3mg/10.4mg	Serdexmethylphenidate and dexmethylphenidate	52.3mg/10.4mg	1 capsule per day
Daytrana Patch	Methylphenidate	30 mg/9hr	1 patch per day
Dyanavel XR oral suspension	Amphetamine extended release suspension	20mg	20mg (8mL) per day
Dynavel XR chewable tablet	Amphetamine extended release chewable tablet	20 mg	1 tablet per day
Evekeo ODT 2.5mg, Evekeo 5mg Evekeo ODT 5mg	Amphetamine	60mg	3 tablets per day
Evekeo 10mg Evekeo ODT 10mg, 15mg	Amphetamine	60mg	4 tablets per day
Evekeo ODT 20mg	Amphetamine	60mg	3 tablets per day
Qelbree ER 100mg	Viloxazine	600mg	1 tablet per day
Qelbree ER 150mg, 200mg	Viloxazine	600MG	3 tablets per day
Intuniv 1mg, 2mg, 4mg	Guanfacine	7mg	1 tabet per day
Intuniv 3mg	Guanfacine	7mg	2 tablets per day
Mydayis	Dextroamphetamine and Amphetamine	12.5mg, 25mg, 37.5mg, 50mg	1 capsule per day
Nuvigil	Armodafanil	250mg	1 tablet per day
Provigil	Modafanil	400mg	2 tablets per day
QuilliChew ER 20mg, 40mg	Methylphenidate chewable tablet	60mg	1 tablet per day
QuilliChew ER 30mg	Methylphenidate chewable tablet	60mg	2 tablets per day
Quillivant XR oral suspension	Methylphenidate extended release suspension	60mg	60mg (12mL) per day

Quantity Limits			
Brand Name	**Generic Name**	**FDA Recommended Maximum Dose/24 hours**	**Quantity Limit**
Strattera 10mg, 18mg, 25mg, 40mg, 60mg	Atomoxetine	100mg	2 tablets per day
Strattera 80mg, 100mg	Atomoxetine	100mg	1 tablet per day
Sunosi 75mg, 150mg	Solriamfetol	150mg	1 tablet per day
Wakix 4.45mg, 17.8mg	Pitolisant	35.6mg	2 tablets per day
Xelstrym Patch	Dextroamphetamine	4.5 mg/hr, 9 mg/hr, 13.5 mg/hr, 18 mg/hr	1 patch per day
Xyrem	Sodium oxybate	9gm	9gm (18mL) per day
Xywav	Calcium, magnesium, potassium, and sodium oxybate	9gm	9gm (18mL) per day

CLINICAL RATIONALE

ADHD

The American Academy of Pediatrics (AAP) Clinical Practice Guidelines for the treatment of children and adolescents with ADHD considers stimulants as first-line agents in the treatment of ADHD. Evidence suggests that the two stimulant types, methylphenidate or amphetamine, are equally efficacious in the treatment of ADHD and either would be appropriate choices when initiating therapy. Non-stimulant ADHD medications, Intuniv, Kapvay, Qelbree, and Strattera, have demonstrated some efficacy in reducing ADHD symptoms but the evidence supporting their use and effects on reducing symptoms is smaller than that for stimulants. Subsequently, non-stimulant medications are generally recommended as second-line therapies for treating ADHD, after one or more stimulant medications have failed.

The decision regarding the initial pharmacologic treatment of ADHD is based on several factors including the different adverse effects of each agent, compliance issues, potential drug diversion and/or misuse, and the presence of comorbid conditions. A non-stimulant medication may be considered as a first line agent for individuals with an active substance abuse problem.

Extended-release formulations are available for many ADHD medications, decreasing some of the difficulties associated with multiple daily dosing such as compliance and the social stigma and inconvenience of taking medications while in school. If a long acting agent is desired and the patient has difficulties swallowing capsules and tablets, there are alternative agents available that allow you to open the capsule and sprinkle contents on food or liquid as long as granules are not chewed (Adderall XR, Focalin XR, Metadate CD).

Daytrana (methylphenidate transdermal system) has been shown to be effective for improving ADHD symptoms in children and adolescents but has not demonstrated clinical superiority over already available oral medications for ADHD**.** After methylphenidate is absorbed through the skin by the topical patch, there is no difference in the action of the medication than had it been taken orally. The primary cause of stimulant-induced anorexia is due to the medication's effect on the central nervous system (CNS) and is not related

to gastrointestinal absorption or irritation of the gastrointestinal tract. Daytrana and all oral stimulant medications affect the CNS regardless of the route of administration.

Adult ADHD

Attention Deficit/Hyperactivity Disorder (ADHD) was once recognized as a disorder affecting only children. Over time, experts discovered that ADHD should be recognized and treated as a chronic illness that can last through adolescence and into adulthood. As many as 30% to 70% of children with ADHD may continue to experience symptoms as an adult. According to the National Health Institute, ADHD is present in approximately 4.1% of the U.S. adult population, or 8 million adults, with 41.3% of diagnosed adults classified as having severe symptoms. This is equal to approximately 1.7% of the total U.S. adult population.

The medications used in the treatment of children and adolescents with ADHD are the same for adults. The standard of care for adults has evolved largely from studies in children. There are currently no established clinical guidelines in the United States that address the treatment of ADHD in adults. The American Academy of Pediatrics (AAP) Clinical Practice Guidelines for the treatment of children and adolescents with ADHD consider stimulants as first-line agents in the treatment of ADHD. The U.K. National Institute for Health and Clinical Excellence (NICE) have specific clinical guidelines for adults with ADHD that recommend methylphenidate be used first-line.

Immediate-release formulations of stimulants last 3-6 hours and require multiple daily doses (2-3 daily doses) to manage symptoms. The decreased dosing frequency of the longer-acting agents add convenience and more continuous coverage for patients that are noncompliant. Long-acting, once daily formulations are considered a dosing form of convenience for the adult population due to a lower risk of social stigma compared to that of school-aged children unless they are medically necessary for reasons other than the comfort and convenience of the patient.

Narcolepsy and Hypersomnia

Many of the stimulant agents used for the treatment of ADHD also have FDA-approved labeling for the treatment of narcolepsy. A consensus statement by the American Academy of Sleep Medicine recommends modafinil, sodium oxybate, amphetamine, methamphetamine, dextroamphetamine, methylphenidate, and selegiline for the treatment of sleepiness associated with narcolepsy.

Idiopathic hypersomnia (IH) is a diagnosis of exclusion, applied to patients who are excessively sleepy, have difficulty arousing from sleep, and wake without feeling refreshed. The etiology of IH is largely unknown; diagnosis is made through a thorough history and exclusion of other sleep disorders by nocturnal polysomnography and multiple sleep latency test (MSLT). The AASM practice parameters considered modafinil an ***option*** for the treatment of IH. The authors, however, define option as "a patient-care strategy that reflects uncertain clinical use". The term option implies either inconclusive or conflicting evidence or conflicting expert opinion. AASM lists the following other treatment options for IH: amphetamine, methamphetamine, dextroamphetamine and methylphenidate, all considerably more cost-effective than armodafinil and modafinil. A retrospective study found that methylphenidate is chosen more often than modafinil as the final monotherapy in treatment of IH, despite the fact it is less commonly used initially. The same study demonstrated a higher percentage of complete and partial responses for patients who received methylphenidate compared to modafinil, although statistical significance was not reached.

Continuous positive airway pressure (CPAP) is the gold standard treatment for patients with OSA, and thus, a maximal effort to treat with CPAP for an adequate period of time should be made prior to initiating modafinil or armodafinil. Both agents should be used adjunctively with CPAP, and not as monotherapy. Ongoing education and emphasis relating to the importance of CPAP therapy along with periodic assessment of CPAP adherence is essential for the effective treatment of OSA.

Given their wakefulness promoting properties, modafinil and armodafinil have been proposed for and used off-label for the treatment of several indications. While the majority of off-label data involves the use of modafinil, armodafinil as the R-enantiomer of modafinil, is generally anticipated to confer similar results.

AASM practice parameters are supportive of modafinil for the treatment of fatigue associated with multiple sclerosis (MS) providing it with a guideline level recommendation. Limited options, other than amantadine, are available for this patient population. The American Academy of Neurology (AAN), in its 2010 practice parameters for treatment of nonmotor symptoms of Parkinson disease, provided a Level A recommendation for modafinil to improve patients perception of EDS.

Modafinil is not indicated for children under the age of 16 years old, while armodafinil is not indicated for children under the age of 17. Serious rash, including Stevens-Johnson Syndrome, requiring hospitalization and discontinuation of treatment has been reported in children with the use of modafinil (and both modafinil and armodafinil in adults). Several cases of the rashes were associated with fever, vomiting and other abnormalities, such as leukopenia. Labeling for both products make clear that neither are approved for pediatric patients for any indication, including ADHD.

The recommended dose of modafinil is 200mg given once a day. For patients with narcolepsy and OSA, modafinil should be taken as a single dose in the morning. For patients with shift work sleep disorder (SWSD), Modafinil should be taken approximately 1 hour prior to the start of their shift. Doses up to 400mg/day, given as a single dose have been well tolerated, but there is no consistent evidence that this dose confers additional benefit beyond that of the 200mg dose.

The recommended dose of armodafinil is 150 mg or 250 mg given as a single daily dose in the morning. In patients with OSA, doses up to 250 mg/day, given as a single dose, have been well tolerated, but there is no consistent evidence that this dose confers additional benefit beyond that of the 150 mg/day dose.

The recommended dose of Xyrem (sodium oxybate) is 9gm per night divided into two equal doses. The efficacy and safety of Xyrem at doses higher than 9gm per day have not been evaluated.

The recommended dose of Wakix (pitolisant) is 17.8 mg to 35.6 mg once daily. Dosage should be titrated, starting with 8.9 mg once daily and increasing to 17.8 mg after one week of therapy. After one week of therapy at 17.8 mg once daily, dosage may be increased to the maximum recommended dosage of 35.6 mg once daily. Patients with moderate hepatic or moderate to severe renal impairment should initiate Wakix at 8.9 mg once daily and increase to a maximum of 17.8 mg once daily after 14 and 7 days, respectively.

Xywav is an oxybate product with a unique composition of cations resulting in 92% less sodium than Xyrem (sodium oxybate) but shares the same indication. The efficacy of Xywav for the treatment of cataplexy and EDS in 201 adult patients with narcolepsy was established in a double-blind, placebo-controlled, randomized-withdrawal study. The main study consisted of a 12-week open-label optimized treatment and titration period, followed by a 2-week stable-dose period (SDP), and finally a 2-week double-blind randomized-withdrawal period (DB RWP). The primary endpoint was the change in frequency of cataplexy attacks from the 2 weeks of the SDP to the 2 weeks of the DB RWP. The key secondary endpoint was the change in the Epworth Sleepiness Scale (ESS) score, as a measure of reduction in EDS from the end of the SDP to the end of the DB RWP. The mean change from baseline (2 weeks of the SDP) to the 2 weeks of the DB RWP in the number of weekly cataplexy attacks was 11.5 and 0.1 for placebo and Xywav, respectively ($p < 0.0001$). The mean change from end of SDP to end of DB RWP in the ESS score was 3.0 and 0.0 for placebo and Xywav, respectively ($p < 0.0001$). The effectiveness of Xywav in pediatric patients is based upon a clinical study in patients treated with Xyrem and additional pharmacokinetic information.

Xywav carries a boxed warning for central nervous system (CNS) depression and abuse and misuse. Because of the risks of CNS depression and abuse and misuse, Xywav is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Xywav and Xyrem REMS.

The recommended dosage of Xywav is 6 grams to 9 grams per night divided into two equal doses. Doses higher than 9 grams per night have not been studied and ordinarily should not be administered.

Appendix A: Medication that can cause excessive daytime sleepiness*

Drug Class	Generic/Chemical Name	Brand Name
Sedative Hypnotics	Chloral Hydrate Eszopiclone Ramelteon Suvorexant Tasimelteon Zaleplon Zolpidem	Somnote Lunesta Rozerem Belsomra Hetlioz Sonata Ambien IR, Ambien ER, Edluar, Intermezzo, Zolpimist
Barbiturates	Butabarbital Phenobarbital Secobarbital	Butisol Seconal
Benzodiazepines	Alprazolam Clonazepam Chlordiazepoxide HCl Clorazepate Lorazepam Diazepam Flurazepam Estazolam Quazepam Temazepam Triazolam	Xanax Klonopin Librium Tranxene-T Ativan Valium Dalmane Prosom Doral Restoril Halcion
Skeletal Muscle Relaxants	Baclofen Carisoprodol Chlorzoxazone Cyclobenzaprine Tizantidine Metaxalone Methocarbamol Orphenadrine	Soma Lorzone, Parafon Forte Flexeril Zanaflex Skelaxin Robaxin Norflex
Opioids	Fentanyl Hydrocodone Bitartrate Hydromorphone HCl Meperidine HCl Methadone HCl Morphine sulfate Oxycodone HCl Oxymorphone HCl Tapentadol	Actiq, Duragesic, Fentora, Lazanda, Subsys Hycet, Lorcet, Lortab, Norco, Vicodin, Zohydro ER Dilaudid, Exalgo Demerol Dolophine Avinza, Kadian, MS Contin Percocet, Oxycontin, Roxicet, Roxicodone, Zartemis XR Opana Nucynta, Nucynta ER

***This is not intended to be an all inclusive list**

Appendix B: Contraindications

Drug	FDA Labeled Contraindications

Adderall, Adderall XR (amphetamine/ dextroamphetamine); Desoxyn (methamphetamine); Dexedrine,Xelstrym Procentra, Zenzedi (dextroamphetamine); Evekeo	Advanced arteriosclerosis Symptomatic cardiovascular disease Moderate to severe hypertension Hyperthyroidism Glaucoma Agitated states History of drug abuse During or within 2 weeks following the administration of monoamine oxidase inhibitors (MAOI) Known hypersensitivity or idiosyncrasy to the sympathomimetic amines
Aptensio XR, Concerta, Daytrana, Metadate CD, Metadate ER, Quillivant XR, Ritalin/ Ritalin LA (methylphenidate); Focalin, Focalin XR (dexmethylphenidate)	Marked anxiety, tension, or agitation Glaucoma Tics or a family history or diagnosis of Tourette's syndrome Patients currently using or within 2 weeks of using an MAO inhibitor Known hypersensitivity to methylphenidate
Evekeo ODT	Use with monoamine oxidase (MAO) inhibitor, or within 2 weeks of the last MAO inhibitor dose

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

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