ADHD and Narcolepsy Drug Therapy

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

Prior Authorization Criteria

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

Approval will be for lifetime.

II. The long-acting stimulant agents, Adderall XR, Aptensio XR, Concerta, Focalin XR, Metadate CD, Metadate ER, 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 a therapeutic trial of at least TWO appropriately dosed and administered immediate acting formulary alternatives. 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 lifetime.

III. Vyvanse (capsules and chewables) may be considered medically necessary for the treatment of ADHD when one of the following criteria is met:
   • The patient must have tried and failed at least TWO generically available immediate acting stimulant medications with different active ingredients. 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 lifetime.

IV. Vyvanse (capsules and chewables) may be considered medically necessary for the treatment of severe binge eating disorder when the following criteria is met:

For initial requests
- The patient must have a diagnosis of moderate to severe binge eating disorder as defined by DSM-5 criteria AND tried and failed or have a contraindication to one prerequisite agent (e.g. citalopram, escitalopram, sertraline, topiramate, zonisamide); OR

For continuation of therapy requests
- There must be documentation of a positive clinical response (e.g., meaningful reduction in the number of binge eating episodes or binge days per week from baseline, improvement in the signs and symptoms of binge eating disorder) to therapy with Vyvanse

Approval will be for 12 months.

V. Daytrana 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 methylphenidate

Approval will be for 12 months.

VI. Quillivant XR and QuilliChew ER 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 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 (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.

Approval will be for 12 months.

VII. Adzenys XR-ODT and Dyanavel XR 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, immediate release mixed Amphetamine salt, immediate release Dextroamphetamine, and immediate release Methylphenidate, when contents are crushed and sprinkled on soft food or liquid 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 (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.

Approval will be for **12 months.**

VIII. Evekeo 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:
  - Immediate release mixed Amphetamine salt (Adderall)
  - Immediate release Dextroamphetamine (Dexedrine)
  - Immediate release Methylphenidate (Ritalin) if individual is aged 6 and above

Approval will be for **lifetime.**

IX. Evekeo may be considered **medically necessary** for the treatment of Narcolepsy when ALL of the following criteria is met:

- The patient is 12 years of age or older
- The patient must have tried and failed ALL of the following:
  - Immediate release mixed Amphetamine salt (Adderall)
  - Immediate release Dextroamphetamine (Dexedrine)
  - Immediate release Methylphenidate (Ritalin)

Approval will be for **lifetime.**

X. Nuvigil (armodafinil) and Provigil (modafinil) may be considered **medically necessary** for patients 16 years of age and older for the treatment of the following:

- Fatigue associated with Multiple Sclerosis
- EDS associated with Parkinson’s Disease

Approval will be for **lifetime.**

XI. 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 one 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.**

XII. Nuvigil (armodafinil) and Provigil (modafinil) may be considered **medically necessary** for patients 16 years of age and older for the treatment residual 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**.

XIII. 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 (EDS) with narcolepsy when the following criteria is met:

- The patient must have tried and failed at least one stimulant medication (i.e. methylphenidate, dextroamphetamine, or amphetamine/dextroamphetamine); OR have an allergy, contraindication, or intolerance to standard stimulant therapy

**Approval** will be for **12 months**.

XIV. Nuvigil (armodafinil) and Provigil (modafinil) may be considered **medically necessary** for patients 16 years of age and older for the treatment of idiopathic hypersomnia (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

**Approval** will be for **12 months**.

XV. Xyrem (sodium oxybate) may be considered **medically necessary** for patients 18 years of age and older for the treatment of 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 Success Program
- The patient must have cataplexy or excessive daytime sleepiness
- The patient must have tried and failed at least one stimulant medication (i.e. methylphenidate, dextroamphetamine, or amphetamine/dextroamphetamine); OR have an allergy, contraindication, or intolerance to standard stimulant therapy
- The patient must have tried and failed Provigil or Nuvigil; OR have an allergy, contraindication, or intolerance to Provigil and Nuvigil

**Approval** will be for **12 months**.

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

**Quantity limits apply:**
<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>FDA Recommended Maximum Dose/24 hours</th>
<th>Quantity Limit</th>
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<tbody>
<tr>
<td>Adzensys XR-ODT</td>
<td>amphetamine</td>
<td>18.8 mg for patients 6 to 12 yrs</td>
<td>1 tablet per day</td>
</tr>
<tr>
<td>9.4mg, 12.5mg, 15.7mg, 18.8mg</td>
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<td>12.5 mg for patients 13 to 17 yrs</td>
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<td>Adzensys XR-ODT</td>
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<td>2 tablets per day</td>
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<tr>
<td>3.1mg, 6.3mg</td>
<td></td>
<td>12.5 mg for patients 13 to 17 yrs</td>
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<td>Daytrana Patch</td>
<td>Methylphenidate</td>
<td>30 mg/9hr</td>
<td>1 patch per day</td>
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<tr>
<td>Dyanavel XR</td>
<td>Amphetamine extended release suspension</td>
<td>20mg</td>
<td>20mg (8mL) per day</td>
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<tr>
<td>Evekeo 5mg</td>
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<td>7mg</td>
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<td>Guanfacine</td>
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<td>Nuvigil</td>
<td>Armodafanil</td>
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<td>Provigil</td>
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</tr>
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<td>QuilliChew ER 30mg</td>
<td>Methylphenidate chewable tablet</td>
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</tr>
<tr>
<td>Quillivant XR oral</td>
<td>Methylphenidate extended release suspension</td>
<td>60mg</td>
<td>60mg (12mL) per day</td>
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<tr>
<td>Strattera 10mg, 18mg, 25mg, 40mg, 60mg</td>
<td>atomoxetine</td>
<td>100mg</td>
<td>2 tablets per day</td>
</tr>
<tr>
<td>Strattera 80mg, 100mg</td>
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<td>1 tablet per day</td>
</tr>
<tr>
<td>Xyrem</td>
<td>Sodium oxybate</td>
<td>9gm</td>
<td>9gm (18mL) per day</td>
</tr>
</tbody>
</table>

**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, 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.

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.

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.

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 recommend 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.

### Binge Eating Disorder

According to the American Psychiatric Association guidelines, there is substantial evidence that suggests that treatment with antidepressant medications, particularly the SSRIs citalopram, escitalopram, and sertraline (Grade A), are associated with at least a short-term reduction in binge eating behavior. Topiramate and zonisamide are also stated to be effective for binge reduction but can also cause side effects.

In 2015, the FDA approved Vyvanse for the treatment of moderate to severe binge-eating disorder (BED). The efficacy of Vyvanse in the treatment of B.E.D. was demonstrated in two 12-week randomized, double-blind, multi-center, parallel-group, placebo-controlled, dose-optimization studies in adults aged 18 to 55 years (Study 1: N=374, Study 2: N=350) with protocol-defined moderate to severe B.E.D. (severity was defined as having at least 3 binge days per week for 2 weeks prior to the baseline visit and a Clinical Global Impression Severity score of ≥4 at baseline). The primary efficacy outcome for the two studies was defined as the change from baseline at week 12 in the number of binge days per week. Baseline is defined as the weekly average of the number of binge days per week for the 14 days prior to the baseline visit. Subjects from both studies on Vyvanse had a statistically significant greater reduction from baseline in mean number of binge days per week at Week 12. In study 1, Vyvanse reduced the mean number of binge days per week from 4.79 at baseline to 0.78 at study endpoint compared with 4.60 to 2.22 for placebo. Similar results were seen in study 2.

The essential feature of binge-eating disorder is recurrent episodes of binge eating that must occur, on average, at least once a week for 3 months. The level of severity is based on the frequency of episodes of binge eating, moderate is defined as 4-7 episodes per week and severe as 8-13 episodes per week. Binge-eating disorder appears to be relatively persistent, and the course is comparable to that of bulimia nervosa in terms of severity and duration; it may be chronic or intermittent, with periods of remission alternating with recurrences of binge eating. A patient is considered to be in partial remission if after full criteria for binge-eating disorder were previously met, binge eating occurs at an average frequency of less than one episode per week for a sustained period of time; and in full remission if after full criteria for binge-eating disorder were previously met, none of the criteria have been met for a sustained period of time. Over longer-term follow-up, the symptoms of many individuals appear to diminish with or without treatment, although treatment clearly impacts outcome. Vyvanse should be discontinued if binge eating does not improve.

### Appendix A: Medication that can cause excessive daytime sleepiness*

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<thead>
<tr>
<th>Drug Class</th>
<th>Generic/Chemical Name</th>
<th>Brand Name</th>
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<td>Sedative Hypnotics</td>
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<td>Eszopiclone</td>
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<td>Barbiturates</td>
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<td>Tapentadol</td>
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*This is not intended to be an all inclusive list*

### Appendix B: Contraindications

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<thead>
<tr>
<th>Drug</th>
<th>FDA Labeled Contraindications</th>
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</thead>
</table>
| Adderall, Adderall XR (amphetamine/dextroamphetamine); Desoxyn (methamphetamine); Dexedrine, Procentra, Zenzedi (dextroamphetamine) | Advanced arteriosclerosis  
Symptomatic cardiovascular disease  
Moderate to severe hypertension  
Hyperthyroidism  
Glaucama  
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 (dextroamphetamine) | Marked anxiety, tension, or agitation  
Glaucama  
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 |
Vyvanse (lisdexamfetamine) Use with monoamine oxidase (MAO) inhibitor, or within 2 weeks of the last MAO inhibitor dose Known hypersensitivity to amphetamine products or other ingredients in Vyvanse

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.

- Code(s), if applicable

REFERENCES

• Focalin XR product information. Novartis Pharmaceuticals Corporation, January 2012.
• Evekeo product information. Atlanta, GA. Arbor Pharmaceuticals, Inc. February 2015.
• Kollins SH. Abuse liability of medications used to treat attention-deficit/hyperactivity disorder (ADHD). Am J Addict. 2007;16(suppl 1):35–42.
• Nuvigil (armodafinil) [package insert], Frazer, PA; Cephalon, Inc., June 2013.

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