Pemoline (Cylert®) is a central nervous system (CNS) stimulant. CNS stimulants increase concentrations of neurotransmitters (excitatory brain chemicals) such as epinephrine, norepinephrine, and dopamine. Pemoline (Cylert®) has been FDA approved for the use in children age 6 and older.

By enhancing the release of excitatory neurotransmitters, pemoline (Cylert®) can be useful for the following:

- **Treatment of Attention Deficit Hyperactivity Disorder (ADHD)**
  ADHD is the most common neurobehavioral disorder of childhood, affecting between 8-10% of school-aged children. Studies also indicate that of those children diagnosed with ADHD, 60-80% of them continue to exhibit symptoms into adolescence. One study also estimates the prevalence of ADHD in adults at 4.7%. Common symptoms include inattention, excessive motor hyperactivity or restlessness, and poor impulse control. The Diagnostic and Statistical Manual of Mental Disorders (DSM) provides a list of specific diagnostic criteria that a physician or psychiatrist may use in order to rule out other mental or behavioral disorders and determine if a patient requires treatment for ADHD.

Behavior therapy is an additional treatment option that is best used in conjunction with a medication regimen due to its minimal efficacy when used alone.

- **Promoting wakefulness in patients with narcolepsy.**
  Narcolepsy is a disorder that causes excessive sleepiness, along with periods of cataplexy and REM (rapid eye movement) sleep phenomena such as sleep paralysis and hallucinations. Sleep attacks occur very suddenly and intrusively, usually lasting 15-20 minutes, after which time the person awakes feeling refreshed, only to experience another episode just a few hours later. Cataplexy is characterized by a sudden loss of muscle tone. There may be a mild sensation of weakness affecting just a few parts of the body, or complete collapse due to a virtual state of full-body paralysis. There is no loss of consciousness or memory, and breathing is not impaired during this episode which may last just a few short minutes or as long as an hour. Narcolepsy is estimated to occur in less than 1% of the population, with peak incidence occurring around 14 years of age. Narcolepsy responds best when multiple naps are taken throughout the day, along with stimulant medication.

- **Promoting wakefulness in patients with idiopathic hypersomnolence**
  Idiopathic hypersomnolence is a central nervous system disorder in which the major sleep episode is normal or prolonged, but constant and recurrent excessive daytime sleepiness is still the chief complaint. In this case, cataplexy is not present and the sleep attacks are less sudden, often preceded by a long period of drowsiness, and lasting an hour or more. This syndrome is estimated to account for 5-10% of patients who bring a complaint of sleepiness to a sleep clinic.

- **Offsetting fatigue in patients with multiple sclerosis (MS).**
  Multiple Sclerosis is a progressive, degenerative disease of the central nervous system, which causes muscular weakness and loss of motor control. Fatigue is the most common symptom in MS and has the potential to affect the quality of life. Overall, 75 to 90% of patients with MS report having fatigue, and over half of them report that it is the worst symptom of the disease. Management strategies involve education, energy conservation efforts and the use of various pharmacologic agents, including pemoline (Cylert®).

Pemoline (Cylert®) use should only be considered in patients who have failed treatment with other CNS stimulants or if the patient is unable to use other CNS stimulants. Pemoline (Cylert®) use has resulted in a substantial number of adverse drug events (ADEs) due to liver toxicity. Cases have included mild and transient jaundice, but have also included multiple cases of hepatotoxic death. The U.S. Food and Drug Administration (FDA) has responded by requiring that pemoline (Cylert®) have a black box warning which states that reported liver related ADEs for this product range from 4 to 17 times greater than that expected in the general population. Treatment with pemoline (Cylert®) is only to be initiated in patients without liver impairment, following baseline liver function tests. Further liver testing is recommended at 2 week intervals.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dosing</th>
<th>AWP</th>
<th>Cost per month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cylert® (brand)</td>
<td>37.5mg – 200mg per day in the AM</td>
<td>$1.28 / 18.75mg tab</td>
<td>$60-267</td>
</tr>
<tr>
<td>Tablets: 18.75mg, 37.5mg, 75mg</td>
<td></td>
<td>$2.01 / 37.5mg tab</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>$3.48 / 75mg tab</td>
<td></td>
</tr>
<tr>
<td>Pemoline (generic)</td>
<td>37.5mg – 200mg per day</td>
<td>$0.92 / 18.75mg tab</td>
<td>$42-208</td>
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<tr>
<td>Tablets: 18.75mg, 37.5mg, 75mg</td>
<td></td>
<td>$1.42 / 37.5mg tab</td>
<td></td>
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</tbody>
</table>
Rationale for Prior Authorization

To reduce exposure to cost associated with uncovered uses such as for use in the promotion of weight loss or to offset the effects of voluntary sleep deprivation.

Benefit Design

Coverage for Cylert® is determined through a prior authorization process for every claim.

Coverage Authorization Criteria

1. Coverage is provided in situations where the use of methylphenidate, amphetamines, and dexmethylphenidate have failed to treat the patient’s condition or in situations where the patient is unable to receive treatment with methylphenidate, amphetamines, or dexmethylphenidate.

2. Coverage is not provided in situations where
   - the patient is ≤ 4 years of age or
   - the patient has liver impairment

3. Coverage is provided for the treatment of the following conditions:
   - Attention deficit hyperactivity disorder (ADHD)
   - Narcolepsy or idiopathic hypersomnolence
   - Fatigue associated with multiple sclerosis

4. The prescriber must counsel the patient about the potential risks and toxicity associated with the use of Cylert®.

5. The prescriber will be informed of the following:
   - Because of its association with life threatening hepatic failure, pemoline (Cylert®) should not be considered first line therapy. Liver function tests should be performed at baseline and every 2 weeks while pemoline (Cylert®) is being administered. If no clinical benefit is seen after 3 weeks following dose titration, discontinue pemoline (Cylert®) therapy. The prescriber should obtain written informed consent from the patient prior to the initiation of pemoline (Cylert®) therapy.

Coverage duration: 3 months

References


