Azstarys (serdexmethylphenidate and dexmethylphenidate)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Attention Deficit Hyperactivity Disorder (ADHD) is a chronic condition that is often characterized by difficulty with paying attention, hyperactivity, impulsivity, and poor self-control. It is a neurological condition that affects an individual's development and functioning, often impacting their academic performance and social relationships. The cause of ADHD is still unknown, however it is believed to be genetically linked and has been associated with a range of environmental and lifestyle factors.

Symptoms of ADHD can vary from person to person, and can be further divided into three primary categories: inattention, hyperactivity, and impulsivity. Inattention symptoms may include a lack of focus, not listening when spoken to, difficulty following instructions, disorganization, and easily distracted. Hyperactivity symptoms may include fidgeting, talking excessively, and a need for constant activity or motion. Impulsivity symptoms can include difficulty waiting for their turn, blurting out answers, and interrupting others.

Treatment for ADHD is often a combination of counseling and medication, depending on the individual and the severity of their symptoms. Cognitive Behavioral Therapy (CBT) is often used to help those with ADHD better manage their thoughts and behaviors, while medications such as stimulants, nonstimulants, and antidepressants can help regulate dopamine levels, which often play an important role in the disorder.

Azstarys is a combination medication consisting of two drugs, serdexmethylphenidate (a prodrug of dexmethylphenidate) and dexmethylphenidate, and is used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). This medication is indicated for those 6 years of age and older (Azstarys was not studied in those > 65 years of age). Azstarys (serdexmethylphenidate, dexmethylphenidate) is a stimulant, and works by increasing levels of neurotransmitters in the brain that are associated with concentration, focus, and impulse control. It works quickly, with effects typically felt within an hour after taking the medication. Azstarys (serdexmethylphenidate, dexmethylphenidate) is explicitly not recommended in those less than 6 years of age, as it has been found that these individuals experience a higher plasma exposure and higher incidence of adverse reactions (such as weight loss) than those 6 years of age and older.

Definitions

"Attention Deficit Hyperactivity Disorder (ADHD)" is a mental health disorder characterized by difficulty paying attention, impulsivity, and hyperactivity.

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"Hyperactivity" refers to excessive activity or restlessness, often expressed as difficulty sitting still, fidgeting, or talking excessively.

"Impulsivity" refers to difficulty controlling impulses, often expressed as interrupting others, blurting out answers, or making decisions without thinking.

"Inattention" refers to difficulty with paying attention, difficulty sustaining attention, or difficulty concentrating on tasks.

"[s]" indicates state mandates may apply.

"Stimulant" medications refer to the class of medications used primarily for ADHD that increase the neurotransmitters dopamine and norepinephrine (chemicals in the brain). Stimulants typically fall under the class of amphetamines or methylphenidates, and predominantly work by increasing alertness, focus, and attention.

Clinical Indications

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Attention deficit hyperactivity disorder

The Plan considers Azstarys (serdexmethylphenidate and dexmethylphenidate) medically necessary when ALL of the following criteria are met:

1. The member is 6 years of age or older; *AND*
2. The member has a diagnosis of attention-deficit/hyperactivity disorder (ADHD) per the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria; *AND*
3. The member is unable to use or has adequately tried and failed TWO (2) preferred (long-acting) once-daily stimulant preparation alternatives (e.g., generic Adderall XR, Concerta, Focalin XR, Metadate CD, Ritalin LA);[s] *AND*
4. Clinical chart documentation is provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, the requested medication will be approved for 12 months.[s]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Attention deficit hyperactivity disorder

The Plan considers Azstarys (serdexmethylphenidate and dexmethylphenidate) medically necessary when recent chart documentation (within the last 6 months) shows that the member has experienced clinical benefit(s) to the requested medication as evidenced by ONE (1) of the following:

1. Achievement of target functional goals established at the onset of therapy (e.g., improved academic performance, relationships (e.g., peer, sibling), safety in the community); *OR*
2. Improvements in core symptoms of inattention and hyperactivity/impulsivity.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.[5]

Experimental or Investigational / Not Medically Necessary[5]

Azstarys (serdexmethylphenidate and dexmethylphenidate) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, unproven, or not medically necessary.

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