

## Azstarys (serdexmethylphenidate and dexamethylphenidate)

### 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 disorder 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 and dexamethylphenidate, and is used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). This medication is indicated for children aged 6-17 years, as well as adults aged 18-65 years. Azstarys 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.

### Definitions

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

**“Inattention”** refers to difficulty with paying attention, difficulty sustaining attention, or difficulty concentrating on tasks.

**“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.

### Medical Necessity Criteria for Initial Authorization

The Plan considers **Azstarys (serdexmethylphenidate and dexamethylphenidate)** 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** preferred (long-acting) once-daily preparations alternatives (e.g., generic Adderall XR, Concerta, Focalin XR, Metadate CD, Ritalin LA); **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.**

### **Medical Necessity Criteria for Reauthorization**

Reauthorization for 12 months will be granted if 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.

### **Experimental or Investigational / Not Medically Necessary**

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

### **References**

1. Attention-deficit/hyperactivity disorder. In: diagnostic and statistical manual of mental disorders. 5th ed. DSM-5 Washington, DC: American Psychiatric Association. 2013:59-66.
2. Austerman J. ADHD and behavioral disorders: Assessment, management, and an update from DSM-5. Cleve Clin J Med. 2015; 82:S2-7.
3. Azstarys (serdexmethylphenidate and dexamethylphenidate) [prescribing information]. Grand Rapids, MI: Corium Inc; June 2021.
4. Cortese S. Pharmacologic Treatment of Attention Deficit-Hyperactivity Disorder. N Engl J Med. 2020; 383:1050-1056.
5. Faraone SV, Banaschewski T, Coghill D et al. The World Federation of ADHD International Consensus Statement: 208 Evidence-based conclusions about the disorder. Neurosci Biobehav Rev. 2021; 128:789-818.
6. Kooij JJS, Bijlenga D, Salerno L et al. Updated European Consensus Statement on diagnosis and treatment of adult ADHD. Eur Psychiatry. 2019; 56:14-34.
7. Posner J, Polanczyk GV, Sonuga-Barke E. Attention-deficit hyperactivity disorder. Lancet. 2020; 395:450-462.
8. Steingard R, Taskiran S, Connor DF et al. New Formulations of Stimulants: An Update for Clinicians. J Child Adolesc Psychopharmacol. 2019; 29:324-339.

9. Volkow ND, Swanson JM. Clinical practice: Adult attention deficit-hyperactivity disorder. N Engl J Med. 2013; 369:1935-44.
10. Wigal S, Chappell P, Palumbo D et al. Diagnosis and Treatment Options for Preschoolers with Attention-Deficit/Hyperactivity Disorder. J Child Adolesc Psychopharmacol. 2020; 30:104-118.
11. Wolraich ML, Hagan JF Jr, Allan C et al. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. Pediatrics. 2019; 144

### Clinical Guideline Revision / History Information

Original Date: 3/23/2023

Reviewed/Revised: 3/21/2024