

Pharmacy Medical Necessity Policy

Clonidine ER

Policy Number: 9.505

Version Number: 2

Version Effective Date: 1/1/2022

<p>Product Applicability <input type="checkbox"/> All Plan+ Products</p>	
<p>Well Sense Health Plan</p> <p><input type="checkbox"/> New Hampshire Medicaid</p>	<p>Boston Medical Center HealthNet Plan</p> <p><input checked="" type="checkbox"/> MassHealth - MCO</p> <p><input checked="" type="checkbox"/> MassHealth - ACO</p> <p><input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct</p> <p><input type="checkbox"/> Senior Care Options</p>
<p>Benefit</p>	<p><input checked="" type="checkbox"/> Pharmacy Benefit</p> <p><input type="checkbox"/> Medical Benefit</p>

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **clonidine ER**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Required Medical Information	<p>clonidine extended- release tablet</p> <ol style="list-style-type: none"> 1. Member has diagnosis of Attention Deficit Hyperactivity Disorder(ADHD); AND 2. Member has a history of, or potential for substance abuse; AND ; 3. Member has a history of a trial of generic immediate-release formulation of clonidine; AND 4. Member has had an inadequate response, intolerance, or contraindication to 2 of the following: <ul style="list-style-type: none"> • Adderall XR
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	<ul style="list-style-type: none"> • Focalin XR • Concerta • Vyvanse
Coverage Duration	12 months

Clinical Background Information and References

1. Krull KR. Attention Deficit Hyperactivity Disorder in Children and Adolescents: Treatment with Medications. UpToDate®. Accessed Aug 2013.
2. McVoy M, Findling R. Child and Adolescent Psychopharmacology Update. Psychiatr Clin N Am 32 (2009):111-133.
3. Pliszka S, AACAP Work Group. Practice Parameter for the Assessment and Treatment of Children and Adolescents with Attention-Deficit/Hyperactivity Disorder. J Am Acad Child Adolesc Psychiatry 2007;46(7):894-921.
4. Searight HR, Burke JM. Adult attention deficit hyperactivity disorder. UpToDate®. Updated Feb 2011. Accessed Aug 2012.
5. Wigal SB, Chae S, Patel A. Advances in the Treatment of Attention-Deficit/Hyperactivity Disorder: A Guide for Pediatric Neurologists. Semin Pediatr Neurol 2010;17:230-236.
6. Prescribing Information. Kapvay™ (clonidine hydrochloride extended-release). ShionogiPharma, Inc., Atlanta, GA 30328. Sept 2010.
7. Brent D. Pharmacotherapy for Adult ADHD. UpToDate®. Accessed Aug 2013.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
9/10/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
9/10/2020	P&T Annual Review: 9.160 ADHD policy (MH) retired, new policy created; updated QL table; Added branded generic Aptensio XR to policy; updated criteria for methylphenidate 72 mg ER; slightly updated criteria for clonidine ER; updated	1/1/2021	P&T Committee

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Policy Revisions History			
	initial approval duration from 24 months to 12 months		
12/1/2020	Moved generic- Adderall XR, Concerta, Focalin XR, Metadata CD and Ritalin LA to Non preferred; Moved methylphenidate 72 mg ER, Aptensio, Quillichew and Quillivant and Mydayis to non-preferred	1/1/2021	P&T Committee
2/11/2021	Quillichew ER and Quillivant XR added to coverage and policy	6/1/2021	P&T Committee
10/1/2021	Updated to remove Adzenys ER, Adzenys XR ODT, Dyanavel XR, QuilliChew ER, Quillivant XR, Cotempla XR-ODT, and Daytrana as these drugs are now in the MassHealth UPPL policy	1/1/2022	P&T Committee

Next Review Date

2/2022

Other Applicable Policies

9.500 Pediatric Behavioral Health Medication Initiative

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with

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applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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