BOSTON MEDICAL CENTER HEALTHNet PLAN

bmchp.org | 888-566-0008

WELL SENSE HEALTH PLAN

wellsense.org | 877-957-1300

Pharmacy Medical Necessity Policy

Cerebral Stimulants and ADHD Medications –Unified Formulary

Policy Number: 9.508
Version Number: 2.1
Version Effective Date: 1/1/2022

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth - MCO ☒ MassHealth - ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit

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

Prior Authorization Policy

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

Reference Table:

Drugs that require PA	No PA (within quantity limits)
Long-acting Amphetamine Cerebral Stimulants (oral, non-solution and transdermal)‖	
Adzenys XR-ODT® (amphetamine extended-release	Adderall XR® (amphetamine salts extended-

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Drugs that require PA	No PA (within quantity limits)
orally disintegrating tablet)	release)[PD] §
Mydayis® (amphetamine salts extended-release)	Vyvanse® (lisdexamfetamine)[PD]
Long-acting Methylphenidate Cerebral Stimulants (oral, non-solution and transdermal)[‖]	
Adhansia XR® (methylphenidate extended-release)	Concerta® (methylphenidate extended-release) §
Aptensio XR® (methylphenidate extended-release)[**]	Daytrana® (methylphenidate transdermal)
Azstarys® (serdexmethylphenidate/dexmethylphenidate)	Focalin XR® (dexmethylphenidate extended-release)[PD] §
Cotempla XR-ODT® (methylphenidate extended-release orally disintegrating tablet)	
Jornay PM® (methylphenidate extended-release)	
methylphenidate extended-release, CD	
methylphenidate extended-release 72 mg tablet‡	
QuilliChew ER® (methylphenidate extended-release chewable tablet)	
Ritalin LA® (methylphenidate)*	
Cerebral Stimulant Liquids[‖]	
Adzenys ER® (amphetamine extended-release 1.25 mg/mL oral suspension)†† **	
Dyanavel XR® (amphetamine extended-release 2.5 mg/mL oral suspension)††	
Quillivant XR® (methylphenidate extended-release oral suspension)††	

† A-rated generic available. Both brand and A-rated generic require PA at these quantities, if applicable.
§ Brand Preferred over generic equivalents. In general, a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent is required.
* A-rated generic available. Both brand and A-rated generic require PA.
** Authorized generic available. Both brand and authorized generic require PA.
‡ A branded generic(s) is available in this formulation. Please review using the appropriate generic NDC within this GSN.
†† Quantity limits do not apply to this agent, singly or in combination with other cerebral stimulants.
[PD] Preferred Drug. In general, a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class is required.
‖ Use of cerebral stimulants, alpha agonists, atomoxetine, and Qelbree in members less than 18 years of age is discussed in the **Pediatric Behavioral Health Medication Initiative**

Procedure:

The **Pediatric Behavioral Health Medication Initiative** may apply to members <18 years of age due to polypharmacy, age, and/or drug restrictions. As indicated within this guideline, please refer to the **Pediatric Behavioral Health Initiative** guideline to assess appropriateness of therapy.

Approval Criteria:

Adzenys ER® (amphetamine extended-release 1.25 mg/mL oral suspension)** **Adzenys XR-ODT®** (amphetamine extended-release orally disintegrating tablet) **Dyanavel XR®** (amphetamine extended-release 2.5 mg/mL oral suspension)	1. The member has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD); **AND** 2. The provider submits clinical rationale for use of the requested agent instead of Adderall XR® (amphetamine salts extended-release); **AND** 3. The provider submits clinical rationale for use of the requested agent instead of Vyvanse® (lisdexamfetamine); **AND** 4. **For brand name Adzenys ER® suspension requests:** The provider submits medical records documenting an inadequate response or adverse reaction to the therapeutically equivalent generic *Notes:* • *Please refer to the **Pediatric Behavioral Health Medication Initiative** guideline regarding the review of requests for members <18 years of age.*
Mydayis® (amphetamine salts extended-release)	1. The member has a diagnosis of ONE of the following: a. Attention Deficit Hyperactivity Disorder (ADHD); **OR** b. Narcolepsy **AND** 2. Member is 13 years of age or older; **AND** 3. The provider submits clinical rationale for use of the requested agent instead of Adderall XR® (amphetamine salts extended-release); **AND** 4. The provider submits clinical rationale for use of the requested agent instead of Vyvanse® (lisdexamfetamine); *Notes:* • *Please refer to the **Pediatric Behavioral Health Medication Initiative** guideline regarding the review of requests for members <18 years of age.*
Adhansia XR® (methylphenidate extended-release) **Aptensio XR®** (methylphenidate extended-release)** **Azstarys®**	1. Member has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD); **AND** 2. The provider submits **ONE** of the following: a. Clinical rationale for use of the requested agent instead of Concerta® (methylphenidate extended-release); **OR** b. Clinical rationale for requested formulation instead of solid oral formulations (e.g., swallowing disorder, dysphagia) **AND** 3. The provider submits clinical rationale for use of the requested agent instead of Focalin XR® (dexmethylphenidate extended-

(serdexmethylphenidate/ dexmethylphenidate) **Cotempla XR-ODT®** (methylphenidate extended-release orally disintegrating tablet) **Jornay PM®** (methylphenidate extended-release) **QuilliChew ER®** (methylphenidate extended-release chewable tablet) **Quillivant XR®** (methylphenidate extended-release oral suspension)	release); **AND** 4. The provider submits clinical rationale for use of the requested agent instead of Daytrana® (methylphenidate transdermal); **AND** 5. **If the request is for brand name Aptensio XR®** prescriber must also provide medical records documenting an inadequate response or adverse reaction to the therapeutically equivalent generic *Notes:* • *Please refer to the **Behavioral Health Medication Initiative** guideline regarding the review of requests for members <18 years of age*
methylphenidate extended-release, CD **Ritalin LA®** (methylphenidate)*	1. The member has a diagnosis of ONE of the following: a. Attention Deficit Hyperactivity Disorder (ADHD); **OR** b. Narcolepsy **AND** 2. The provider submits **ONE** of the following: a. Clinical rationale for use of the requested agent instead of Concerta® (methylphenidate extended-release); **OR** b. Clinical rationale for requested formulation instead of solid oral formulations (e.g., swallowing disorder, dysphagia) **AND** 3. The provider submits clinical rationale for use of the requested agent instead of Focalin XR® (dexmethylphenidate extended-release); **AND** 4. The provider submits clinical rationale for use of the requested agent instead of Daytrana® (methylphenidate transdermal); **AND** 5. **If the request is for brand name Ritalin LA®** prescriber must also provide medical records documenting an inadequate response or adverse reaction to the generic equivalent being requested *Notes:* • *Please refer to the **Pediatric Behavioral Health Medication Initiative** guideline regarding the review of requests for members <18 years of age*
methylphenidate	1. Member has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD); **AND**

extended-release 72 mg tablet‡	2. The provider submits clinical rationale for use of the requested agent instead of two Concerta® (methylphenidate extended-release) 36 mg tablets; **AND** 3. The provider submits clinical rationale for use of the requested agent instead of Focalin XR® (dexmethylphenidate extended-release); **AND** 4. The provider submits clinical rationale for use of the requested agent instead of Daytrana® (methylphenidate transdermal) *Notes:* • *Please refer to the **Pediatric Behavioral Health Medication Initiative** guideline regarding the review of requests for members <18 years of age*
Duration/Quantity of Authorization:	• Prior authorizations may be issued for up to **1 year.** • If the member is <18 years of age, review using the criteria and approval duration in the **Pediatric Behavioral Health Medication Initiative** guideline, if applicable.

Request Over Quantity Limit Authorization Policy

The Plan may authorize coverage of the below products in excess of the quantity limits listed for members meeting the criteria below:

Reference Table:

Quantity Limits	
Adderall XR® (amphetamine salts extended-release)† PD §	2 units/day
Vyvanse® (lisdexamfetamine)PD	2 units/day
Concerta® (methylphenidate extended-release)† §	2 units/day
Daytrana® (methylphenidate transdermal)	1 unit/day
Focalin XR® (dexmethylphenidate extended-release)† PD §	2 units/day
Adzenys XR-ODT® (amphetamine extended-release orally disintegrating tablet)	1 unit/day
Mydayis® (amphetamine salts extended-release)	1 unit/day
Adhansia XR® (methylphenidate extended-release)	1 unit/day
Aptensio XR® (methylphenidate extended-release) **	1 unit/day
Azstarys® (serdexmethylphenidate/dexmethylphenidate)	1 unit/day
Cotempla XR-ODT® (methylphenidate extended-release orally disintegrating tablet)	1 unit/day
Jornay PM® (methylphenidate extended-release)	1 unit/day
methylphenidate extended-release, CD	2 units/day

methylphenidate extended-release 72 mg tablet‡	1 unit/day
QuilliChew ER® (methylphenidate extended-release chewable tablet)	2 units/day
Ritalin LA® (methylphenidate)*	2 units/day

† A-rated generic available. Both brand and A-rated generic require PA at these quantities, if applicable.
§ Brand Preferred over generic equivalents. In general, a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent is required
* A-rated generic available. Both brand and A-rated generic require PA.
** Authorized generic available. Both brand and authorized generic require PA.
‡ A branded generic(s) is available in this formulation. Please review using the appropriate generic NDC within this GSN.
PD Preferred Drug. In general, a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class is required.

Cerebral Stimulant Quantity Limits Approval Criteria:

>1 unit/day for: **Adhansia XR®** (methylphenidate ER) **Adzenys XR-ODT®** (amphetamine ER ODT) **Aptensio XR®** (methylphenidate ER) **Azstarys®** (serdexmethylphenidate/ dexmethylphenidate) **Cotempla XR-ODT®** (methylphenidate ER ODT) **Daytrana®** (methylphenidate transdermal) **Jornay PM®** (methylphenidate ER) **Mydayis®**	1. The provider submits documentation of medical necessity for an increased dosage that results in requiring quantities that exceed 1 unit/day 2. **If request is for a brand name medication with an A-rated generic**, prescriber must also provide medical records documenting an inadequate response or adverse reaction to the generic equivalent being requested *Notes:* • *Please refer to the **MassHealth Pediatric Behavioral Health Medication Initiative** guideline regarding the review of requests for members <18 years of age.*
>2 unit/day for: **methylphenidate extended-release, CD** **QuilliChew ER®** (methylphenidate extended-release chewable tablet) **Ritalin LA®** (methylphenidate)*	1. The provider submits documentation of medical necessity for an increased dosage that results in requiring quantities that exceed 2 unit/day 2. **If request is for a brand name medication with an A-rated generic**, prescriber must also provide medical records documenting an inadequate response or adverse reaction to the generic equivalent being requested *Notes:* • *Please refer to the **MassHealth Pediatric Behavioral Health Medication Initiative** guideline regarding the review of requests for members <18 years of age.*

>2 unit/day for: **Adderall XR®** (amphetamine salts extended-release)† [PD] § **Concerta®** (methylphenidate extended-release)† § **Vyvanse®** (lisdexamfetamine)[PD] **Focalin XR®** (dexmethylphenidate extended-release)† [PD] §	1. The provider submits documentation of medical necessity for an increased dosage that results in requiring quantities that exceed 2 unit/day *Notes:* • *Please refer to the **MassHealth Pediatric Behavioral Health Medication Initiative** guideline regarding the review of requests for members <18 years of age.*
Duration/Quantity of Authorization:	• Prior authorizations may be issued for up to **1 year.** • If the member is <18 years of age, review using the criteria and approval duration in the **Pediatric Behavioral Health Medication Initiative** guideline, if applicable.

Appendix:

Clinical Background Information and References

1. Adhansia XR (methylphenidate extended-release) [prescribing information]. Stamford, CT: Adlon Therapeutics, LP; June 2021.
2. Adzenys ER (amphetamine) oral suspension [prescribing information]. Grand Prairie, TX: Neos Therapeutics; September 2017.
3. Adzenys XR-ODT (amphetamine) [prescribing information]. Grand Prairie, TX: Neos Therapeutics; December 2017.
4. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, 5th edition. Arlington, VA., American Psychiatric Association, 2013.
5. Aptensio XR (methylphenidate) [prescribing information]. Coventry, RI: Rhodes Pharmaceuticals; January 2017.
6. Daytrana (methylphenidate) [prescribing information]. Miami, FL: Noven Therapeutics, LLC; June 2021.
7. Dyanavel XR (amphetamine) [prescribing information]. Monmouth Junction, NJ: Tris Pharma, Inc.; February 2019.
8. Focalin XR (dexmethylphenidate) [prescribing information]. East Hanover, NJ.: Novartis; June 2021.
9. Jornay PM (methyphenidate extended-release) [prescribing information]. Cherry Hill, NJ: Ironshore Pharmaceuticals; June 2021.
10. Mydayis (amphetamine) [prescribing information]. Lexington, MA. Shire; September 2019.

11. QuilliChew ER (methylphenidate) [prescribing information]. Monmouth Junction, NJ. NextWave Pharmaceuticals, Inc.: June 2021.
12. Quillivant XR (methylphenidate oral solution ext-rel). Monmouth Junction, NJ: NextWave Pharmaceuticals Inc.; June 2021.
13. Ritalin LA (methylphenidate) [prescribing information]. East Hanover, NJ: Novartis; January 2017.
14. Vyvanse (lisdexamphetamine) [prescribing information]. Wayne, PA: Shire US, Inc.; January 2018.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	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 initial approval duration from 24 months to 12 months	1/1/2021	P&T Committee
12/1/2020	Aligned policy to meet MassHealth's PDL requirements	1/1/2021	P&T Committee
2/11/2021	Annual policy review. No changes	6/1/2021	P&T Committee
10/1/2021	MassHealth UPPL Update: Fifteen agents added to UPPL to unify all long-acting stimulants. These include the following: Adzenys ER®, Adzenys XR-ODT®, Adhansia XR®, Aptensio XR®, Azstarys®, Cotempla XR-ODT®, Daytrana®, Dyanavel XR®, Jornay PM®, methylphenidate CD, Mydayis®, QuilliChew ER®, Quillivant	1/1/2022	P&T Committee

Policy Revisions History			
	XR®, Relexxii ER, Ritalin LA®.		

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