BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Policy

Antipsychotics – Unified Formulary

Policy Number: 9.507
Version Number: 2.2
Version Effective Date: 9/1/2021

Product Applicability

☐ **All Plan+ Products**

Well Sense Health Plan

☐ New Hampshire Medicaid

Boston Medical Center HealthNet Plan

☒ MassHealth ACO

☒ MassHealth MCO

☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct

☐ Senior Care Options

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

Policy

Reference Table:‡

Drugs That Require PA	No PA
Abilify® Maintena® (aripiprazole extended-release injection) and QL >1 injection/month	
Aristada® (aripiprazole lauroxil 441 mg, 662 mg and 882 mg) PD >1 injection/month	Aristada® (aripiprazole lauroxil 441 mg, 662 mg and 882 mg) PD ≤1 injection/month
Aristada® (aripiprazole lauroxil 1,064 mg) PD >1 injection/2 months	Aristada® (aripiprazole lauroxil 1,064 mg) PD ≤1 injection/2 months
Aristada Initio® (aripiprazole lauroxil 675 mg) PD >1 injection/month	Aristada Initio® (aripiprazole lauroxil 675 mg) PD ≤1 injection/month
Invega Sustenna® (paliperidone extended-release 1-month injection) PD >2 injections month 1, >1 injection/month thereafter	Invega Sustenna® (paliperidone extended-release 1-month injection) PD ≤2 injections month 1, ≤1 injection/month thereafter
Invega Trinza® (paliperidone extended-release 3-month injection) PD >1 injection/3 months	Invega Trinza® (paliperidone extended-release 3-month injection) PD ≤1 injection/3 months
Perseris® (risperidone extended-release subcutaneous injection) ‖	

Drugs That Require PA	No PA
Risperdal® Consta® (risperidone extended-release intramuscular injection) ‖	
Zyprexa® Relprevv® (olanzapine extended-release injection) ‖	

[PD] Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Please note, for Invega Trinza®, a trial with a preferred agent is not required prior to approval of a non-preferred agent.
‖ This is a non-preferred product included in the table for reference. At this time, this product is not subject to the Unified Pharmacy Product List protocols.

NOTE: MassHealth will allow for a lower strength of the same tablet to be filled for "breakthrough psychosis" as necessary. See the Appendix for more information.

Procedure:[1-89]

The **MassHealth Pediatric Behavioral Health Medication Initiative** may apply to MassHealth 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 Diagnosis:	**Please refer to Table 1 above for FDA-approved indications.** *Notes:* • *Other indications will be reviewed on a case by case basis. See appendix for details.*
Approval Criteria: **Exceeding Quantity Limits**	**<u>All Members:</u>** Prescriber provides documentation of **ONE** of the following: 1. Clinical rationale why the dose cannot be consolidated 2. Clinical rationale why the member requires dosing at intervals exceeding what is recommended by the FDA (for example twice daily when FDA approved dosing is only once daily) *Notes:* • *Please refer to the **MassHealth Pediatric Behavioral Health Medication Initiative** guideline regarding the review of requests for members <18 years of age.* • *Please see the appendix for examples of approvable requests.*
Approval Criteria: **Abilify® Maintena® (aripiprazole extended-release injection)**	**<u>All Members:</u>** Prescriber provides documentation of **ALL** of the following: 1. Clinical rationale for use of the requested agent instead of Aristada® (aripiprazole lauroxil) 2. Requested quantity does not exceed established quantity limits of 1 injection/month *Notes:* • *A diagnosis of bipolar I disorder is not a sufficient rationale to bypass a trial with Aristada® (aripiprazole lauroxil)* • *For requests where a prescriber documents patient refusal of Aristada® (aripiprazole lauroxil) for reasons such as, but not limited to, site of administration (e.g., gluteal), please forward to Clinical Review prior to denial.*

Denial Criteria:	Cases that do not meet the approval criteria will be denied. If a request is denied and the prescriber has additional clinical documentation, a **new** prior authorization request must be submitted.
Duration/Quantity of Authorization:	**All agents:** • Prior authorization may be issued for **1 month** to **1 year (please see appendix for details)** • If the member is <18 years of age, review using the criteria and approval duration in the **MassHealth Pediatric Behavioral Health Medication Initiative** guideline, if applicable. • Provisional prior authorization may be issued for 1 month for members who do not meet the **Pediatric Behavioral Health Medication Initiative** guideline approval criteria to avoid risk of destabilization only if the member was stabilized on the medication [e.g., medication was covered by a previous insurer or third party liability (TPL) claims]. Provisional approvals do not apply to new starts for medications that require prior authorization (e.g., drug, quantity limits, brand name). Prescriber outreach via telephone will be attempted on all provisional approvals.
Recertification Criteria:	**All agents**: • Prescriber provides documentation of the following: • Continued stability on the specifically requested regimen (evidence of regularly paid claims or notification on the PA form is sufficient documentation) • Recertification may be issued for **1 year**

Appendix:

Stability/Court Orders

Requests for Abilify® Maintena® (aripiprazole extended-release injection)

A point of sale rule for Abilify® Maintena® (aripiprazole extended-release injection) will allow a claim to pay without a submitted prior authorization if the member has 90 days of therapy out of the last 120 days. If there are no claims in history, documentation of stability on Abilify® Maintena® will be accepted if the member has been stable for at least three months and the provider documents the start date of therapy. Members with breaks in therapy will be required to transition to Aristada® (aripiprazole lauroxil) unless there is documentation of a hospitalization or other compelling situation. In addition, any submitted court order (Roger's Order) that cites a specific drug, dose, dosage form and regimen should be approved.

For members <18 years of age, all requests will be reviewed using the **MassHealth Pediatric Behavioral Health Medication Initiative** guideline, regardless of stability.

Grandfathering

Information is not applicable.

MassHealth Pediatric Behavioral Health Medication Initiative

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The Pediatric Behavioral Health Medication Initiative requires prior authorization for members <18 years of age for behavioral health medication classes and/or specific medication combinations (i.e., polypharmacy) that have limited evidence for safety and efficacy in the pediatric population. The aspects of the **MassHealth Pediatric Behavioral Health Medication Initiative** that may apply to the Second-generation (Atypical) Antipsychotic guideline include the following:

1. Behavioral health medication polypharmacy (pharmacy claims for 4 or more behavioral health medications [i.e., alpha$_2$ agonists, antidepressants, antipsychotics, atomoxetine, benzodiazepines, buspirone, cerebral stimulants, donepezil , hypnotic agents, memantine, modafinil/armodafinil, mood stabilizers, naltrexone, and viloxazine] filled within a 45 day period)
2. Antipsychotic polypharmacy (overlapping pharmacy claims for 2 or more antipsychotics for ≥60 days within a 90 day period)
3. Antipsychotic pharmacy claim for pediatric members less than 6 years old

Please refer to the **MassHealth Pediatric Behavioral Health Medication Initiative** guideline to assess appropriateness of therapy when reviewing prior authorization requests for pediatric members <18 years of age.

Duration of Approval

Please note: For members <18 years of age, all requests for antipsychotics will also be reviewed using additional criteria in the **MassHealth Pediatric Behavioral Health Medication Initiative** guideline.

Drug – use for Abilify Maintena® (aripiprazole extended-release injection) monotherapy

- **Drug – Standard Approval** (1 year)
    - The request is for monotherapy not above quantity limits and the appropriate approval criteria are met for Abilify Maintena® monotherapy

Renal and Hepatic Dosing[2-18, 85-89,101-102]

Many second-generation (atypical) antipsychotics do not require dose adjustment for renal or hepatic impairment. The prescribing information suggests avoiding the use of Caplyta® (in moderate or severe hepatic impairment), Fanapt® (not recommended in any level of hepatic impairment), paliperidone (in severe renal impairment), and Saphris® (in severe hepatic impairment). Please take all information (including other therapies that could be used) into consideration if request addresses renal or hepatic impairment. Requests for paliperidone that state "hepatic impairment" should generally not be approved as risperidone can be dose adjusted in all cases and many other second-generation (atypical) antipsychotics that do not require PA also do not require adjustment for hepatic impairment.

Drug	Renal Dosing	Hepatic Dosing
Abilify®, Abilify® Maintena®, Abilify Mycite® (aripiprazole)	No change	No change
Aristada®, Aristada Initio® (aripiprazole lauroxil)	No change	No change
Invega®, Invega®	Mild impairment (CrCL ≥50	Mild-moderate impairment (Class

Drug	Renal Dosing	Hepatic Dosing
Sustenna®, Invega® Trinza® (paliperidone)	mL/min to <80 mL/min): 3 to 6 mg daily; for Invega® Sustenna®: 156 mg on treatment day 1 and 117 mg one week later followed by monthly injections of 78 mg Moderate/severe impairment (CrCL ≥10 mL/min to <50 mL/min): 1.5 to 3 mg daily; Invega® Sustenna® is not recommended for use in patients with CrCL <50 mL/min CrCL <10 mL/min: not recommended for use	A/B): no dose adjustment Severe impairment: not studied

Prescriber Specialty and Acceptable Psychiatry Consults

Mid-level practitioners (e.g., nurse practitioners, physician assistants with a psychiatry focus) will need to provide documentation of their collaborating specialist physician. Please see below for details on how to review these requests.

- If the request is from a mid-level practitioner and does NOT document the collaborating specialist physician and is not listed in the internal DUR mid-level practitioner log, please outreach to the prescriber's office to verify the collaborating physician for the mid-level practitioner.
- If the office is unable to provide the collaborating physician's name, then a provisional approval may be considered if appropriate and a resubmission with this information is required.
- If the office is unable to provide the collaborating physician's specialty, then please check the MA Board of Registration in Medicine website at http://profiles.ehs.state.ma.us/Profiles/Pages/FindAPhysician.aspx to verify the specialty and refer to steps below.
    a. If the collaborating physician is a specialist (e.g., psychiatrist, neurologist) that is considered appropriate, criteria will be fulfilled, and a full duration of approval may be granted if ALL other criteria is met.
    b. If the collaborating physician is not a specialist (e.g., internal medicine), then a specialist consult will be required as outlined in the criteria and a provisional approval may be granted. Please consult a supervisor if there are any questions.

Psychiatry consults dated within the last year are acceptable. Medical records or notes from the consult are not required. Documentation of the consult on the PA form with an appropriate prescriber and date (within the last year) is acceptable. Provisional approvals may be considered if the consult date is not provided or is more than 1 year ago. Tailoring of the outgoing message and/or outreach to the prescriber should be considered.

Point of Sale Criteria

Second-Generation (atypical) Long-acting IM injectables

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Abilify® Maintena® (070669, 070670, 073298, 073299)

Criteria:

1. Claims for Abilify Maintena® at a quantity ≤ 1 syringe/vial within the last 30 days will usually process and pay at the pharmacy without prior authorization if the member has a history of paid claims for the reference agent for at least 90 out of 120 days.

Responsibility and Accountability

Policy History

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**
12/1/2020	Created policy for MH Partial Unified Formulary	1/1/2021	P&T Committee
1/19/2021	Updated policy to reflect PUF changes as of 11/20/20	1/19/2021	P&T Committee
2/11/2021	Annual policy review, no changes	6/1/2021	P&T Committee
6/16/2021	Updated policy to reflect changes from MassHealth 6/11/21. Invega Sustenna noted as PD (preferred product) and minor verbiage changes to appendices	9/1/2021	P&T Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
7/23/2021	Updated policy to reflect changes from MassHealth 6/24/21 dated changes: Updated reference table to include Perseris® (risperidone extended-release subcutaneous injection), Risperdal® Consta® (risperidone extended-release intramuscular injection), and Zyprexa® Relprevv® (olanzapine extended-release injection) as non-UPPL, non-preferred products. These products are included as a reference. Reference table, appendices, and criteria were also updated to include Abilify® Maintena® (aripiprazole extended-release injection).	9/1/2021	P&T Committee

Next Review Date

2/2022

Other Applicable Policies

References

Reference to Applicable Laws and Regulations, if Any

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.