BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Medical Necessity Policy

Antipsychotics – Unified Formulary

Policy Number: 9.507
Version Number: 2.3
Version Effective Date: 1/1/2022

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
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit

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)	
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-	Invega Trinza® (paliperidone extended-release 3-

Drugs That Require PA	No PA
month injection) [PD] >1 injection/3 months	month injection) [PD] ≤1 injection/3 months
Perseris® (risperidone extended-release subcutaneous injection)	
Risperdal® Consta® (risperidone extended-release intramuscular injection)>2 injections/month	Risperdal® Consta®(risperidone extended-release intramuscular injection) ≤2 injections/month
Zyprexa® Relprevv® (olanzapine 210mg, 300mg extended-release injection) >2 vials/month	Zyprexa® Relprevv® (olanzapine 210mg, 300mg extended-release injection) ≤2 vials/month
Zyprexa® Relprevv® (olanzapine 405mg extended-release injection) >1 vial/month	Zyprexa® Relprevv® (olanzapine 405mg extended-release injection) ≤1 vial/month

[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. Please note, for non-preferred agents, a trial with Invega Sustenna® and Invega Trinza®, is not required prior to approval of a non-preferred agent.

‡Use of antipsychotics in members <18 years of age is discussed in the **Pediatric Behavioral Health Medication Initiative** guideline.

Procedure:[1-89]

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.

Exceeding Quantity Limits Approval Criteria:

Aristada® and Aristada Initio® (aripiprazole lauroxil) **Invega Sustenna® and Invega Trinza®** (paliperidone) **Risperdal Consta®** (risperidone) **Zyprexa® Relprevv®** (olanzapine)	1. Member has an appropriate diagnosis by requested medication as outlined below: a. **Aristada** i. Schizophrenia; **OR** ii. Maintenance treatment of bipolar I disorder – monotherapy; **OR** iii. Acute treatment of agitation associated with schizophrenia or bipolar I disorder b. **Aristada Initio** i. Treatment of schizophrenia in combination with oral aripiprazole c. **Invega Sustenna or Invega Trinza** i. Schizophrenia; **OR** ii. Schizoaffective disorder – monotherapy or as an adjunct to mood stabilizers and/or antidepressants d. **Risperdal Consta** i. Schizophrenia; **OR** ii. Maintenance treatment of bipolar I disorder – alone or as adjunctive therapy to lithium or valproate e. **Zyprexa Relprevv** i. Schizophrenia **AND** 2. Prescriber provides documentation of **ONE** of the following: a. Clinical rationale why the dose cannot be consolidated; **OR** b. 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 **Pediatric Behavioral Health Medication Initiative** guideline regarding the review of requests for members <18 years of age.*
Duration of Authorization:	• Prior authorization may be issued for **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.

Approval Criteria:

Abilify® Maintena® (aripiprazole extended-release injection)	1. Member has a diagnosis of the following: a. Schizophrenia; **OR** b. Maintenance treatment of bipolar I disorder – monotherapy; **OR** c. Acute treatment of agitation associated with schizophrenia or bipolar I disorder **AND** 2. Clinical rationale for use of the requested agent instead of Aristada® (aripiprazole lauroxil); **AND** 3. 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)* • *Please refer to the **Pediatric Behavioral Health Medication Initiative** guideline regarding the review of requests for members <18 years of age.*
Perseris® (risperidone extended-release subcutaneous injection)	1. Member has a diagnosis of schizophrenia; **AND** 2. Member has **ONE** of the following: a. Inadequate response or adverse reaction to Risperdal Consta®; **OR** b. Inadequate response or adverse reaction to Invega Sustenna®; **OR** c. Clinical rational for use of the requested agent instead of Risperdal Consta® or Invega Sustenna® **AND** 3. Requested quantity does not exceed established quantity limits of 1 syringe/month *Notes:* • *Please refer to the **Pediatric Behavioral Health Medication Initiative** guideline regarding the review of requests for members <18 years of*

	age.
Duration of Authorization:	• Prior authorization may be issued for 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.

HCPCS/CPT Codes:

Code	Description
J2798	Injection, risperidone, (Perseris), 0.5 mg
J2426	Injection, paliperidone palmitate extended release, 1 mg (Invega Sustenna)
J0401	Injection, aripiprazole, extended-release 1 mg (Ability Maintena)
J1944	Injection, aripiprazole lauroxil, (aristada), 1 mg
J1943	Injection, aripiprazole lauroxil (aristada initio), 1 mg
J2749	Injection, risperidone (Risperdal consta), 0.5 mg
J2358	Injection, olanzapine, long-acting, 1 mg (Zyprexa Relprevv)
S0166	Injection, olanzapine, 2.5 mg

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
10/1/2021	Updated policy to reflect changes to UPPL effective 1/1/22; Three new agents added, Perseris® (risperidone extended-release subcutaneous injection), Risperdal® Consta® (risperidone extended-release intramuscular injection), and Zyprexa® Relprevv® (olanzapine extended-release injection)] to UPPL.	1/1/2022	

Next Review Date

2/2022

Other Applicable Policies

References

1. Abilify Maintena (aripiprazole) [prescribing information]. Rockville, MD: Otsuka Pharmaceuticals; June 2020.
2. Aristada (aripiprazole lauroxil) [prescribing information]. Waltham, MA: Alkermes, Inc.; March 2021.
3. Aristada Initio (aripiprazole lauroxil extended-release) [prescribing information]. Waltham, MA; Alkermes, Inc.; March 2021.
4. Invega Sustenna (paliperidone) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; February 2021.

5. Invega Trinza (paliperidone) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; February 2021.
6. Perseris (risperidone) [prescribing information]. North Chesterfield, VA: Indivior, Inc.; December 2019.

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.