Antipsychotics
Abilify Maintena ® (aripiprazole extended release injection)
Aristada Initio® (aripiprazole lauroxil extended-release injection)
Aristada ® (aripiprazole lauroxil extended-release injection)
Invega Hafyera® (paliperidone extended-release injection)
Invega Trinza ® (paliperidone extended-release injection)
Invega Sustenna ® (paliperidone extended-release injection)
Perseris ® (risperidone extended release subcutaneous injection)
Risperdal Consta ® (risperidone extended release intramuscular injection
Zyprexa Relprevv ® (olanzepine extended release injection)
Effective 11/01/2022

Plan	☒ MassHealth (UPPL) ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Aristada and Aristada Initio® (aripiprazole lauroxil extended release injection) is a prodrug of aripiprazole. Aristada Initio is used prior to the initiation of Aristada®, in combination with oral aripiprazole, when used for the treatment of schizophrenia in adults. Aristada is used as a long-term treatment of aripiprazole. Invega Sustenna® (paliperidone extended release injection) is a major, active metabolite of risperidone and is used for the treatment of schizophrenia and schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers or antidepressants. Invega Trinza® (paliperidone extended release injection) and Invega Hafyera® (paliperidone extended-release injection) are indicated for the treatment of schizophrenia.

No PA	PA Required
	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

No PA	PA Required
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 Hafyera® (paliperidone extended-release 6-month injection) [PD] ≤ 1 injection/6 months	Invega Hafyera® (paliperidone extended-release 6-month injection) [PD] > 1 injection/6 months
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
	Lybalvi® (olanzapine/samidorphan)
	Perseris® (risperidone extended-release subcutaneous injection) and QL > 1 injection/month
Risperdal® Consta® (risperidone extended-release intramuscular injection) ≤2 injections/month	Risperdal® Consta® (risperidone extended-release intramuscular injection) > 2 injections/month
Zyprexa® Relprevv® (olanzapine 210 mg, 300 mg extended-release injection) QL ≤2 vials/month	Zyprexa® Relprevv® (olanzapine 210 mg, 300 mg extended-release injection) > 2 vials/month
Zyprexa® Relprevv® (olanzapine 405 mg extended-release injection) QL ≤1 vial/month	Zyprexa® Relprevv® (olanzapine 405 mg 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. Please note, for Invega Trinza®, a trial with a preferred agent is not required prior to approval of a non-preferred agent. Please note, for non-preferred agents, a trial with Invega Sustenna® , Invega Trinza® or Invega Hafyera® is not required prior to approval of a non-preferred agent.
‡ Use of antipsychotics in members <18 years of age is discussed in the **MassHealth Pediatric Behavioral Health Medication Initiative** guideline.

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.

FDA Approved Indications:

Drug	FDA Approved Indication(s)
Abilify Maintena® (aripiprazole), Aristada® (aripiprazole lauroxil)	• Schizophrenia (adults ages 18 years and older) • Maintenance treatment of bipolar I disorder – monotherapy (adults) • Acute treatment of agitation associated with schizophrenia or bipolar I disorder (adults)
Aristada Initio® (aripiprazole lauroxil)	• Initiation of Aristada (aripiprazole lauroxil) when used for the treatment of schizophrenia in adults in combination with oral aripiprazole
Invega Sustenna® (paliperidone)	• Schizophrenia (adults) • Schizoaffective disorder – monotherapy or as an adjunct to mood stabilizers and/or antidepressants (adults)
Invega Trinza®, Invega Hafyera® (paliperidone)	• Schizophrenia (adults)
Lybalvi® (olanzapine/samidorphan)	• Schizophrenia (adults)

Drug	FDA Approved Indication(s)
	• Bipolar I disorder – acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate, maintenance monotherapy (adults)
Perseris® (risperidone extended-release)	• Schizophrenia (adults)
Risperdal Consta®, (risperidone)	• Schizophrenia (adults) • Maintenance treatment of bipolar I disorder – alone or as adjunctive therapy to lithium or valproate (adults)
Zyprexa® Relprevv® (olanzapine)	• Schizophrenia (adults)

Coverage Guidelines

Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

Exceeding Quantity Limits

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)

Note: Additional criteria may apply for members < the age of 18. Please refer to the MassHealth Pediatric Behavioral Health Medication Initiative guideline for criteria.

Abilify® Maintena® (aripiprazole extended-release injection)

Prescriber provides documentation of **ALL** of the following:

1. Physician attestation of inadequate response, adverse reaction, or contraindication to Aristada® (aripiprazole lauroxil)
2. Requested quantity does not exceed established quantity limits of 1 injection/month

Perseris® (risperidone extended-release subcutaneous injection)

Prescriber provides documentation of **ALL** of the following:

1. **ONE** of the following:
    a. Pharmacy claim or provider attestation of inadequate response or adverse reaction to **ONE** of the following:
        i. Risperdal Consta® (risperidone ER injection)
        ii. Invega Sustenna® (paliperidone ER injection)
        iii. Invega Trinza® (paliperidone ER injection)
        iv. Invega Hafyera® (paliperidone ER injection
    b. Physician documentation of contraindication to Risperdal Consta® (risperidone extended-release intramuscular injection) **AND** Invega Sustenna® (paliperidone extended-release injection)
2. Requested quantity does not exceed established quantity limits of 1 syringe/month

Lybalvi® (olanzapine/samidorphan)

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Member is ≥ 18 years of age

3. Paid claims or physician attestation of inadequate response or adverse reaction to **TWO** second-generation (atypical) antipsychotics (generic or brand) or a contraindication to **ALL** second-generation (atypical) antipsychotics
4. **BOTH** of the following:
    a. Claims history showing that member is not being treated with an opioid within the last 7 days (short-acting) or 14 days (long-acting)
    b. Member is not being treated for acute opioid withdrawal
5. Requested quantity does not exceed 1 unit/day

Note: Additional criteria may apply for members < the age of 18. Please refer to the MassHealth Pediatric Behavioral Health Medication Initiative guideline for criteria.

Continuation of Therapy

Reauthorization requires physician documentation of continued stability on the requested medication (evidence of regularly paid claims OR provider documentation that member is compliant).

Limitations

1. Initial approvals will be for:
    a. All agents: 1 month to 12 months
    b. Abilify Maintena or Perseris monotherapy: 12 months
    c. Use of all second generation (atypical) antipsychotics above quantity limit will be approved for 1 year in ANY of the following cases:
        i. The request states (or claims show history) that the requested drug was ineffective at maximum FDA recommended dosing
        ii. The member is currently suicidal
2. Reauthorizations will be approved for 12 months
3. The following quantity limits apply

Invega Hafyera	1 injection every 6 months
Invega Trinza	1 injection every 3 months
Invega Sustenna	1 injection every 1 month
Abilify Maintena	1 injection every 1 month
Aristada Initio	1 injection
Aristada	1 injection every 1 month
Perseris	1 syringe every 1 month
Lybalvi	30 tablets per 30 days

References

1. Aristada Initio (aripiprazole lauroxil) [prescribing information]. Waltham, MA: Alkermes, Inc; August 2019.
2. Aristada (aripiprazole lauroxil) [prescribing information]. Waltham, MA: Alkermes, Inc; August 2019.
3. Invega Trinza (paliperidone) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals; July 2018.
4. Invega Sustenna (paliperidone) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals; July 2018.
5. Invega Hafyera (paliperidone) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals Inc; August 2021.

6. Lybalvi (olanzapine and samidorphan) [prescribing information]. Waltham, MA: Alkermes Inc; May 2021.

Review History

02/20/2019 – Reviewed in P&T Meeting
11/05/2020 – Updated and reviewed Nov P&T Mtg; renamed criteria 'Antipsychotics' and added Invega Trinza and Aristada to criteria; updated references; Effective 1/1/21 Updated to be in compliance with the Masshealth partial unified formulary requirements
03/17/2021 – Updated and reviewed; added Invega Sustenna to criteria. Updated references. Effective 06/01/2021.
11/1/2021 – Updated and reviewed: added Perseris, Risperdal Consta, and Zyprexa Relprevv; matched criteria with MH UPPL. Effective 01/01/2022
03/16/2022 – Updated and reviewed for March P&T; Guideline updated to reflect updated criteria for Abilify Maintena and Perseris to remove "clinical rationale" and include specific verbiage. Perseris criteria also updated to include additional drug trials that may be accepted
05/18/2022 – Updated and reviewed for May P&T; Matched MH UPPL. Guideline updated to include Invega Hafyera to UPPL without PA with QL of 1 injection/6 months. Updated approval criteria for Perseris to clarify required trials. Updated references. Effective 7/1/22.
09/21/2022 – Updated and reviewed for September P&T; Matched MH UPPL. Guideline updated to include Lybalvi (olanzapine/samidorphan). Updated references. Effective 11/01/2022

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