Antipsychotics Quantity Limit
Aristada Initio® (aripiprazole lauroxil extended-release injection)
Aristada ® (aripiprazole lauroxil extended-release injection)
Invega Trinza ® (paliperidone extended-release injection)
Effective January 1, 2021

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐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 Trinza® (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.

No PA	PA Required
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 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

[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.

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:

1. Schizophrenia (Aristada, Aristada Initio, Invenga Trinza)
2. Schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers or antidepressants. (Invega Trinza)

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.

Continuation criteria:

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. Invega Trinza and Aristada: 3 months
    b. Aristada Initio: 1 injection for 1 month
2. Reauthorizations will be approved for Aristada and Invega Trinza 12 months
3. The following quantity limits apply

Invega Trinza	1 injection every 3 months
Aristada Initio	1 injection
Aristada	1 injection every 1 month

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.

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