### 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) and 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.

<table>
<thead>
<tr>
<th>No PA</th>
<th>PA Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aristada® (aripiprazole lauroxil 441 mg, 662 mg and 882 mg) PD ≤ 1 injection/month</td>
<td>Aristada® (aripiprazole lauroxil 441 mg, 662 mg and 882 mg) PD &gt; 1 injection/month</td>
</tr>
<tr>
<td>Aristada® (aripiprazole lauroxil 1,064 mg) PD ≤ 1 injection/2 months</td>
<td>Aristada® (aripiprazole lauroxil 1,064 mg) PD &gt; 1 injection/2 months</td>
</tr>
<tr>
<td>Aristada Initio® (aripiprazole lauroxil 675 mg) PD ≤ 1 injection/month</td>
<td>Aristada Initio® (aripiprazole lauroxil 675 mg) PD &gt; 1 injection/month</td>
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<tr>
<td>Invega Sustenna® (paliperidone extended-release 1-month injection) ≤ 2 injections month 1, ≤ 1 injection/month thereafter</td>
<td>Invega Sustenna® (paliperidone extended-release 1-month injection) &gt; 2 injections month 1, &gt; 1 injection/month thereafter</td>
</tr>
</tbody>
</table>
No PA | PA Required
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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, Invega Sustenna)
2. Schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers or antidepressants. (Invenga Trinza, Invega Sustenna)

**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

<table>
<thead>
<tr>
<th>Drug</th>
<th>Quantity Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Invega Trinza</td>
<td>1 injection every 3 months</td>
</tr>
<tr>
<td>Invega Sustenna</td>
<td>1 injection every 1 month</td>
</tr>
<tr>
<td>Aristada Initio</td>
<td>1 injection</td>
</tr>
<tr>
<td>Aristada</td>
<td>1 injection every 1 month</td>
</tr>
</tbody>
</table>

**References**
1. Aristada Initio (aripiprazole lauroxil) [prescribing information]. Waltham, MA: Alkermes, Inc; August 2019.

**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.