

Clinical Policy Title:	Long Acting Injectable Antipsychotics
Policy Number:	RxA.655
Drug(s) Applied:	Abilify Maintena® (aripiprazole extended release), Aristada® (aripiprazole lauroxil), Aristada Initio® (aripiprazole lauroxil), Zyprexa Relprevv™ (olanzapine pamoate), Invega Sustenna® (paliperidone palmitate), Invega Trinza® (paliperidone palmitate), Risperdal Consta® (risperidone microspheres), Perseris™ (risperidone subcutaneous)
Original Policy Date:	9/4/2020
Last Review Date:	9/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Long-acting injectable (LAI) antipsychotics are a pharmacologic strategy for treating patients with schizophrenia and bipolar I disorder who relapse due to nonadherence to antipsychotic medication. Rather than the daily pill-taking required with oral antipsychotics, LAI antipsychotics are administered by injection at two to four-week intervals.

As with oral antipsychotics, dosing of the LAI antipsychotics is optimized when clinical effectiveness is achieved while minimizing size effects.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
aripiprazole extended release (Abilify Maintena®)	<ul style="list-style-type: none"> Treatment of schizophrenia in adults Maintenance monotherapy treatment of bipolar I disorder in adults 	200 to 400 mg every 4 weeks	400 mg every 4 weeks
aripiprazole lauroxil (Aristada®, Aristada Initio®)	<ul style="list-style-type: none"> Aristada®: <ul style="list-style-type: none"> Treatment of schizophrenia in adults Aristada Initio®: <ul style="list-style-type: none"> In combination with oral aripiprazole, is indicated for the initiation of Aristada® when used for the treatment of schizophrenia in adults 	<p>Aristada®: Every 4 weeks (441, 662, 882 mg)</p> <p>Every 6 weeks (882 mg only)</p> <p>Every 8 weeks (1064 mg only)</p> <p>Aristada Initio®: One time dose of 675 mg injection and one 30 mg dose of oral aripiprazole in conjunction with the</p>	882 mg every 4 weeks

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

		first Aristada injection	
olanzapine pamoate (Zyprexa Relprevv™)	<ul style="list-style-type: none"> Treatment of schizophrenia 	150 to 405 mg every 2 to 4 weeks	300 mg every 2 weeks
paliperidone palmitate (Invega Sustenna®, Invega Trinza®)	<ul style="list-style-type: none"> Invega Trinza®: <ul style="list-style-type: none"> Treatment of schizophrenia in patients after they have been adequately treated with Invega Sustenna® Invega Sustenna®: <ul style="list-style-type: none"> Treatment of schizophrenia in adults. Treatment of schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants. 	<p>Invega Sustenna®: 39 to 234 mg every 4 weeks</p> <p>Invega Trinza®: 273 to 819 mg every 12 weeks</p>	<p>Invega Sustenna®: 234 mg every 4 weeks</p> <p>Invega Trinza®: 819 mg every 12 weeks</p>
risperidone microspheres (Risperdal Consta®)	<ul style="list-style-type: none"> Treatment of schizophrenia Monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of Bipolar I Disorder 	12.5 to 50 mg every 2 weeks	50 mg every 2 weeks
risperidone subcutaneous (Perseris™)	<ul style="list-style-type: none"> Treatment of schizophrenia in adults 	90 to 120 mg every 4 weeks	120 mg every 4 weeks

Dosage Forms

- Abilify Maintena®: 300 mg, and 400 mg; single-dose pre-filled dual chamber syringe, single-dose vial
- Aristada®: 441 mg, 662 mg, 882 mg or 1064 mg; single-dose pre-filled syringe
- Aristada Initio®: 675 mg; single-dose pre-filled syringe
- Zyprexa Relprevv™: 210 mg/vial, 300 mg/vial, and 405 mg/vial
- Invega Sustenna®: 39 mg, 78 mg, 117 mg, 156 mg, or 234 mg; injectable suspension
- Invega Trinza®: 273 mg, 410 mg, 546 mg, or 819 mg; injectable suspension
- Risperdal Consta®: 12.5 mg, 25 mg, 37.5 mg, and 50 mg; vial kits
- Perseris™: 90 mg and 120 mg; injectable suspension

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

- A. Schizophrenia** (must meet all):
- Diagnosis of schizophrenia;
 - Age ≥ 18 years;

3. Prescribed by or in consultation with a psychiatrist;
4. History of non-adherence to oral antipsychotic therapy;
5. Must meet (a, b, c, or d):
 - a. If request is for Abilify Maintena, Aristada, or Aristada Initio: Established tolerability with oral aripiprazole
 - b. If request is for Risperdal Consta or Perseris: Established tolerability with oral risperidone
 - c. If request is for Zyprexa Relprevv: Established tolerability with oral olanzapine
 - d. If request is for Invega Sustenna or Invega Trinza: Established tolerability with oral paliperidone or risperidone
6. If Invega Trinza is requested, adequate treatment has been established with Invega Sustenna for ≥ 4 months;
7. If Aristada Initio is requested, it is used in conjunction with Aristada and an oral one time 30 mg dose of aripiprazole.

Approval Duration

Commercial: 6 months

Medicaid: 6 months

B. Bipolar I Disorder (must meet all):

8. Diagnosis of bipolar I disorder
9. Request is for one of the following: Abilify Maintena or Risperdal Consta;
10. Age ≥ 18 years;
11. Prescribed by or in consultation with a psychiatrist;
12. History of non-adherence to oral antipsychotic therapy;
13. Must meet (a or b):
 - a. If request is for Abilify Maintena: Established tolerability with oral aripiprazole
 - b. If request is for Risperdal Consta: Established tolerability with oral risperidone

Approval Duration

Commercial: 6 months

Medicaid: 6 months

II. Continued Therapy Approval

A. Schizophrenia (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;

Approval Duration

Commercial: 12 months

Medicaid: 12 months

B. Bipolar I Disorder (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;

Approval Duration

Commercial: 12 months

Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

LAI: Long-acting injectable

APPENDIX B: Therapeutic Alternatives

Not applicable.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
 - Known hypersensitivity to the active ingredient
- Boxed Warning(s):
 - All products: Increased mortality in elderly patients with dementia-related psychosis.
 - Zyprexa Relprevv: Post-injection delirium/sedation syndrome

APPENDIX D: Oral Antipsychotics

Typical/First Generation Antipsychotics	Atypical/Second Generation Antipsychotics
<ul style="list-style-type: none"> • Chlorpromazine (Thorazine) • Fluphenazine (Prolixin) • Haloperidol (Haldol) • Loxapine (Loxitane) • Perphenazine (Trilafon) • Pimozide (Orap) • Thioridazine (Mellaril) • Thiothixene (Navane) • Trifluoperazine (Stelazine) 	<ul style="list-style-type: none"> • Aripiprazole (Abilify) • Asenapine maleate (Saphris) • Brexpiprazole (Rexulti) • Cariprazine (Vraylar) • Clozapine (Clozaril) • Iloperidone (Fanapt) • Lurasidone (Latuda) • Olanzapine (Zyprexa) • Olanzapine/fluoxetine (Symbyax) • Paliperidone (Invega) • Quetiapine (Seroquel) • Risperidone (Risperdal) • Ziprasidone (Geodon)

References

1. Abilify Maintena (aripiprazole) [prescribing information]. Tokyo, Japan: Otsuka Pharmaceutical Co.; June 2020. Accessed on September 4, 2020.
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5. Invega Sustenna (paliperidone palmitate) [prescribing information]. Titusville, NJ: Janssen Pharmaceutical; January 2019. Accessed on September 4, 2020.
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8. Perseris (risperidone) [prescribing information]. North Chesterfield, VA: Indivior Inc.; December 2019. Accessed on September 4, 2020.
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Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	9/4/2020	09/14/2020