Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/1/2018**
Policy Number: PA.CP.PHAR.290	**Effective Date: 10/17/2018** **Revision Date: 10/17/2018**
Policy Name: Aripiprazole Long-Acting Injections (Abilify Maintena, Aristada)	**HC Approval Date:**

Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

New Policy created.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: Aripiprazole Long-Acting Injections (Abilify Maintena, Aristada)

Reference Number: PA.CP.PHAR.290
Effective Date: 10.17.18
Last Review Date: 10.17.18

Coding Implications
Revision Log

Description
Aripiprazole monohydrate (Abilify Maintena®) and aripiprazole lauroxil (Aristada®) are atypical antipsychotics.

FDA Approved Indication(s)
Abilify Maintena is indicated:

- For the treatment of schizophrenia in adults
- For maintenance monotherapy treatment of bipolar I disorder in adults

Aristada is indicated for the treatment of schizophrenia.

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

It is the policy of health plans affiliated with PA Health & Wellness® that Abilify Maintena and Aristada are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Schizophrenia (must meet all)**:**

1. Diagnosis of schizophrenia;
2. Prescribed by or in consultation with a psychiatrist;
3. History of non-adherence to oral antipsychotic therapy (*see Appendix D for examples*);
4. Established tolerability with oral aripiprazole;
5. Dose does not exceed the following (a or b):
   a. Abilify Maintena: 400 mg/month;
   b. Aristada: 882 mg/month.

Approval duration: 6 months

B. Bipolar Disorder (must meet all)**:**

1. Diagnosis of bipolar disorder;
2. Request is for Abilify Maintena;
3. Prescribed by or in consultation with a psychiatrist;
4. History of non-adherence to oral antipsychotic therapy (*see Appendix D for examples*);
5. Established tolerability with oral aripiprazole;
6. Dose does not exceed 400 mg/month.

Approval duration: 6 months

C. Other diagnoses/indications
1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed the following (a or b):
   a. Abilify Maintena: 400 mg/month;
   b. Aristada: 882 mg/month.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53;

B. Dementia-related psychosis.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
aripiprazole (Abilify®)	Bipolar Disorder and Schizophrenia Adults: 10-15 mg PO QD	30 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications
Not applicable

Appendix D: Examples of Oral Antipsychotics – Generic (Brand)

Typical/First Generation Antipsychotics†	Atypical/Second Generation Antipsychotics
• Chlorpromazine (Thorazine®) • Fluphenazine (Prolixin®) • Haloperidol (Haldol®) • Loxapine (Loxitane®) • Perphenazine (Trilafon®) • Pimozide (Orap®) • Thioridazine (Mellaril®) • Thiothixene (Navane®) • Trifluoperazine (Stelazine®)	• 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®)

†Most typical/first generation antipsychotics are available only as generics in the U.S.
**Long-acting injectable formulation available*

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Aripiprazole monohydrate (Abilify Maintena)	Schizophrenia Bipolar I disorder	The recommended starting and maintenance dose is 400 mg IM monthly (no sooner than 26 days after the previous injection). Dose can be reduced to 300 mg in patients with adverse reactions. Known CYP2D6 poor metabolizers: Recommended starting and maintenance dose is 300 mg IM monthly as a single injection.	400 mg/month
Aripiprazole lauroxil (Aristada)	Schizophrenia	Depending on individual patient's needs, treatment can be initiated at a dose of 441 mg, 662 mg or 882 mg IM administered monthly, 882 mg administered every 6 weeks or 1064 mg administered every 2 months.	882 mg/month

Drug Name	Indication	Dosing Regimen	Maximum Dose
		Dose adjustments are required for 1) known CYP2D6 poor metabolizers and 2) for patients taking CYP3A4 inhibitors, CYP2D6 inhibitors, or CYP3A4 inducers for more than 2 weeks.	

VI. Product Availability

Drug Name	Availability
Aripiprazole monohydrate (Abilify Maintena)	Extended-release injectable suspension (single-dose pre-filled dual chamber syringe and single-dose vial): 300 mg and 400 mg
Aripiprazole lauroxil (Aristada)	Extended-release injectable suspension (single-use pre-filled syringe): 441 mg, 662 mg, 882 mg or 1064 mg

VII. References

1. Abilify Maintena Prescribing Information. Rockville, MD: Otsuka America Pharmaceutical, Inc.; March 2018. Available at https://www.abilifymaintena.com/. Accessed April 30, 2018.
2. Aristada Prescribing Information. Waltham, MA: Alkermes, Inc.; January 2018. Available at https://www.aristada.com. Accessed April 30, 2018.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
C9470	Injection, aripiprazole lauroxil, 1 mg
J0401	Injection, aripiprazole, extended release, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy Created	10/18	