Clinical Policy: Aripiprazole (Abilify) for Oral Use

Reference Number: OH.PHAR.PPA.16
Effective Date: 03.05.18
Last Review Date: 01.19 Revision Log
Line of Business: Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Aripiprazole (Abilify®) is an atypical antipsychotic.

FDA Approved Indication(s)
The oral formulations of Abilify are indicated for the:
- Treatment of schizophrenia
- Acute treatment of manic and mixed episodes associated with bipolar I disorder
- Adjunctive treatment of major depressive disorder
- Treatment of irritability associated with autistic disorder
- Treatment of Tourette's disorder

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that oral formulations of Abilify are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Schizophrenia (must meet all):
1. Diagnosis of schizophrenia;
2. Member meets one of the following (a or b):
   a. Failure of two of the following atypical antipsychotics: risperidone, quetiapine, olanzapine, or ziprasidone at up to maximally indicated doses, each trialed for ≥ 4 weeks, unless all are contraindicated or clinically significant adverse effects are experienced;
   b. Member has diabetes mellitus or body mass index (BMI) > 30;
3. If request is for the Discmelt formulation, documentation supports necessity of this formulation over the oral tablet formulation;
4. Dose does not exceed 30 mg/day.

Approval duration: 12 months

B. Bipolar Disorder (must meet all):
1. Diagnosis of bipolar disorder;
2. Failure of lithium or valproic acid, unless both are contraindicated or clinically significant adverse effects are experienced;
3. Member meets one of the following (a or b):

   a. Failure of a ≥ 4 week trial of one of the following atypical antipsychotics: risperidone, quetiapine, olanzapine, or ziprasidone at up to maximally indicated doses, unless all are contraindicated or clinically significant adverse effects are experienced;
   b. Member has diabetes mellitus or BMI > 30;
4. If request is for the Discmelt formulation, documentation supports necessity of this formulation over the oral tablet formulation;
5. Dose does not exceed 30 mg/day.

Approval duration: 12 months

C. Major Depressive Disorder (must meet all)**:**

1. Diagnosis of major depressive disorder;
2. Failure of **THREE antidepressants** (e.g., selective serotonin reuptake inhibitor, serotonin/norepinephrine reuptake inhibitor, tricyclic antidepressant, bupropion, mirtazapine, etc.) from at least **TWO different classes** at maximum indicated doses, each trialed for ≥ 4 weeks, unless member is unable to satisfy this requirement due to contraindications or clinically significant adverse effects to multiple antidepressants;
3. Aripiprazole will be used concurrently with an antidepressant;
4. If request is for the Discmelt formulation, documentation supports necessity of this formulation over the oral tablet formulation;
5. Dose does not exceed 15 mg/day.

Approval duration: 12 months

D. Tourette's Syndrome (must meet all):

1. Diagnosis of Tourette's syndrome;
2. Age ≥ 6 and ≤ 18 years;
3. Failure of haloperidol or risperidone, unless both are contraindicated or clinically significant adverse effects are experienced;
4. If request is for the Discmelt formulation, documentation supports necessity of this formulation over the oral tablet formulation;
5. Dose does not exceed (a or b):
   a. If weight < 50 kg: 10 mg/day;
   b. If weight ≥ 50 kg: 20 mg/day.

Approval duration: 12 months

E. Autistic Disorder (must meet all):

1. Diagnosis of autistic disorder;
2. Age ≥ 6 and ≤ 17 years;
3. Member meets one of the following (a or b):
   a. Failure of a ≥ 4 week trial of risperidone at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   b. Member has diabetes mellitus or BMI > 30;
4. If request is for the Discmelt formulation, documentation supports necessity of this formulation over the oral tablet formulation;
5. Dose does not exceed 15 mg/day.

Approval duration: 12 months

F. Other diagnoses/indications
1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).
Discmelt formulation requires additional rationale supporting use over oral tablet formulation

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit;
   b. Documentations supports that member is currently receiving aripiprazole for schizophrenia or bipolar disorder and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed (a, b, or c):
   a. Schizophrenia, bipolar disorder: 30 mg/day;
   b. Major depressive disorder, autistic disorder: 15 mg/day;
   c. Tourette's syndrome (i or ii):
      i. If weight < 50 kg: 10 mg/day;
      ii. If weight ≥ 50 kg: 20 mg/day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).
   Discmelt formulation requires additional rationale supporting use over oral tablet formulation

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 policy - CP.PMN.53 or evidence of coverage documents;

B. Dementia-related psychosis.

IV. Appendices/General Information

Appendix A: Abbreviation Key
BMI: body mass index
FDA: Food and Drug Administration

V. Dosage and Administration

Indication	Dosing Regimen*	Maximum Dose
Schizophrenia	Adults: 10-15 mg PO QD Adolescents: initial: 2 mg PO QD; target: 10 mg PO QD	30 mg/day
Bipolar mania	Adults, as monotherapy: 15 mg PO QD Adults, as adjunct to lithium or valproate: 10-15 mg PO QD Pediatric, as monotherapy or as an adjunct to lithium or valproate: initial: 2 mg PO QD; target: 10 mg PO QD	30 mg/day
Major depressive disorder	Adults, as adjunct to antidepressants: initial: 2-5 mg PO QD; target: 5-10 mg PO QD	15 mg/day
Irritability associated with autistic disorder	Pediatric: initial: 2 mg PO QD; target: 5-10 mg PO QD	15 mg/day
Tourette's disorder	< 50 kg: initial: 2 mg PO QD; target: 5 mg PO QD ≥ 50 kg: initial: 2 mg PO QD; target: 10 mg PO QD	< 50 kg: 10 mg/day ≥ 50 kg: 20 mg/day

**Known CYP2D6 poor metabolizers: Half of the usual dose*

VI. Product Availability

- Tablets: 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg
- Orally disintegrating tablets: 10 mg and 15 mg
- Oral solution: 1 mg/mL

VII. References

1. Abilify Prescribing Information. Tokyo, Japan: Otsuka Pharmaceutical Co.; February 2017. Available at: http://www.abilify.com/. Accessed July 6, 2017.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/.
3. Gelenberg AJ, Freeman MP, Markowitz JC, et al. Practice guideline for the treatment of patients with major depressive disorder, third edition. Arlington, VA: American Psychiatric Association; May 2010. Available online at http://www.psychiatryonline.org/guidelines. Accessed July 6, 2017.
4. Lehman AF, Lieberman JA, Dixon LB, et al. Practice guideline for the treatment of patients with schizophrenia, second edition. Arlington, VA: American Psychiatric Association; February 2004. Available online at http://www.psychiatryonline.org/guidelines. Accessed July 6, 2017.
5. Dixon L, Perkins D, Calmes C. Guideline watch: practice guideline for the treatment of patients with schizophrenia. Arlington, VA: American Psychiatric Association;

September 2009. Available online at http://www.psychiatryonline.org/guidelines. Accessed July 6, 2017.
6. Hirschfeld RMA. Guideline watch: practice guideline for the treatment of patients with bipolar disorder. Arlington, VA: American Psychiatric Association; November 2005. Available online at http://www.psychiatryonline.org/guidelines. Accessed July 6, 2017.
7. Hirschfeld RMA, Bowden CL, Gitlin MJ, et al. Practice guideline for the treatment of patients with bipolar disorder, second edition. Arlington, VA: American Psychiatric Association; April 2002. Available online at http://www.psychiatryonline.org/guidelines. Accessed July 6, 2017.
8. Murphy TK, Lewin AB, Storch EA, Stock S, and the American Academy of Child and Adolescent Psychiatry (AACAP) Committee on Quality Issues (CQI). Practice parameter for the assessment and treatment of children and adolescents with tic disorders. J Am Acad Child Adolesc Psychiatry. 2013; 52(12): 1341-1359.
9. Volkmar F, Siegel M, Woodbury-Smith M, et al. Practice parameter for the assessment and treatment of children and adolescents with autism spectrum disorder. J Am Acad Child Adolesc Psychiatry. 2014; 53: 237.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New Buckeye Health Plan specific policy	01.18	01.18
Annual Review – No Changes	01.19	01.19

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to

applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.