# Clinical Policy: aripiprazole (Abilify®) for oral use

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Effective Date: 06/15
Last Review Date: 09/16

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## Description

The intent of the criteria is to ensure that patients follow selection elements established by *Envolve Pharmacy Solutions* for the use of aripiprazole (Abilify®) for oral use.

## Policy/Criteria

It is the policy of health plans affiliated with *Envolve Pharmacy Solutions* ® that aripiprazole (Abilify®) for oral use is **medically necessary** for members meeting the following criteria:

**<u>Initial Approval Criteria</u>**

I. **Schizophrenia or Schizoaffective Disorder** (must meet all):
   - **A.** Diagnosis of schizophrenia/schizoaffective disorder;
   - **B.** Age ≥ 13 years;
   - **C.** Failure to least 2 atypical antipsychotics, unless contraindicated;
   - **D.** Request does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.

**Approval duration: 12 months**

II. **Bipolar Disorder** (must meet all):
   - **A.** Diagnosis of bipolar disorder;
   - **B.** Age ≥ 10 years;
   - **C.** Failure to least 2 atypical antipsychotics, unless contraindicated;
   - **D.** Request does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.

**Approval duration: 12 months**

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

- **A.** Diagnosis of major depressive disorder;
- **B.** Age ≥ 18 years;
- **C.** Current antidepressant use as evidenced by pharmacy claims record;
- **D.** Request does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.

**Approval duration: 12 months**

**IV. Tourette's Syndrome** (must meet all):
- **A.** Diagnosis of Tourette's syndrome;
- **B.** Age 6 - 18 years;
- **C.** Failure of haloperidol or risperidone, unless contraindicated;
- **D.** Request does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.

**Approval duration: 12 months**

**V. Autistic Disorder** (must meet all):
- **A.** Diagnosis of autistic disorder;
- **B.** Age 6 - 17 years;
- **C.** Failure of risperidone, unless contraindicated;
- **D.** Request does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.

**Approval duration: 12 months**

**VI. New Patients Stable on Therapy** (must meet all):
- **A.** Any of the following diagnoses: schizophrenia or schizoaffective disorder, bipolar disorder, Tourette's syndrome, autistic disorder, or major depressive disorder;
- **B.** Stable on aripiprazole therapy for 30 days;
- **C.** Request does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.

**Approval duration: 12 months**

**Continued Approval** (must meet all)**:**
- **A.** Previously received medication via health plan benefit or member has previously met all initial approval criteria;
- **B.** If request is for a dose increase, request does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.

**Approval duration: 12 months**

**Workflow Document**

USS.NSMN.01
aripiprazole (Abilify)

## Background

### *Description/Mechanism of Action*

Aripiprazole is a quinolone-derived atypical antipsychotic agent. The exact mechanism of action is unknown. However, it has been proposed that the efficacy of aripiprazole for schizophrenia is mediated through a combination of partial agonist activity at $D_2$ and 5-$HT_{1A}$ receptors and antagonist activity at 5-$HT_{2A}$ receptors. Actions at receptors other than $D_2$, 5-$HT_{1A}$, and 5-$HT_{2A}$ may explain some of the other clinical effects of aripiprazole (e.g., the orthostatic hypotension observed with aripiprazole may be explained by its antagonist activity at adrenergic alpha-1 receptors).

### *FDA Approved Indications*

Abilify is indicated for schizophrenia in adults and adolescents, bipolar mania in adults and pediatric patients as monotherapy or adjunct to lithium or valproate, major depressive disorder in adults as adjunct to antidepressants, irritability associated with autistic disorder in pediatric patients, Tourette's disorder in pediatric patients, and agitation associated with schizophrenia or bipolar mania in adults.

## References

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7. Jankovic J. Tourette syndrome. Nordli DR (Ed), UpToDate, Waltham, MA. Accessed May 23, 2016.
8. Kurlan R. Tourette's syndrome. N Engl J Med. 2010; 363: 2332-2338.

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10. Weissman L, Bridgemohan C. Autism spectrum disorder in children and adolescents: pharmacologic interventions. Augustin M, Patterson MC (Eds), UpToDate, Waltham, MA. Accessed May 23, 2016.

| Reviews, Revisions, and Approvals | Date | Approval Date |
|---|---|---|
| Policy created. | 06/15 | 06/15 |
| Updated to new template (converted algorithm to bulleted criteria, added background and references). Separated criteria by diagnosis. Added additional option for trial/failure of risperidone to Tourette's criteria per literature review. Added criteria set for new patients stable on therapy. | 07/16 | 09/16 |