nh healthy families™

**PRIOR AUTHORIZATION GUIDELINE**

| | |
|---|---|
| **DEPARTMENT:** Pharmacy | **DOCUMENT NAME:** aripiprazole (Abilify®) |
| **PAGE:** 1 of 4 | **REFERENCE NUMBER:** NH.PPA.17 |
| **EFFECTIVE DATE:** 08/13 | **REPLACES DOCUMENT:** |
| **RETIRED:** | **REVIEWED:** 7/16, 7/17 |
| **PRODUCT TYPE:** All | **REVISED:** 12/14, 8/15 |

**IMPORTANT REMINDER**

This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough review and consideration of generally accepted standards of medical practice, peer-reviewed medical literature, government agency/program approval status, and other indicia of medical necessity.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based in all cases on the applicable contract provisions governing plan benefits ("Benefit Plan Contract") and applicable state and federal requirements, as well as applicable plan-level administrative policies and procedures. To the extent there are any conflicts between this Clinical Policy and the Benefit Plan Contract provisions, the Benefit Plan Contract provisions will control.

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding results. 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.

**Description:** Abilify 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 (eg, the orthostatic hypotension observed with aripiprazole may be explained by its antagonist activity at adrenergic alpha-1 receptors).

**Brand:** aripiprazole (Abilfy®): 2 mg, 5 mg, 10 mg, 15 mg, 20 mg 30 mg oral tablets
aripiprazole (Abilfy®): 10 mg, 15 mg oral dispersible tablets

**Criteria for Approval:**

<u>Schizophrenia, Schizoaffective Disorder, or other psychotic disorder:</u>

A. Diagnosis of schizophrenia spectrum disorder including schizophrenia, schizoaffective disorder,

schizophreniform disorder, or other psychotic disorder **AND**

B. Age ≥ 13 years of age, **AND**
C. Documentation of inefficacy of, intolerability of, or contraindication to **two** preferred atypical antipsychotics
**NOTE**: Drug intolerance represents treatment failure.

Bipolar I disorder:

A. Diagnosis of Bipolar I disorder. **AND**
B. Age ≥ 10 years of age, AND
C. Documentation of inefficacy of, intolerance or contraindication to monotherapy with lithium AND monotherapy with valproic acid AND
D. Documentation of inefficacy of, intolerability or contraindication to one generic atypical antipsychotic .

**E. NOTE**: Drug intolerance or a contraindication to use of valproic acid and lithium represents a treatment failure to each.

Major Depressive Disorder:

A. Diagnosis of major depressive disorder. **AND**
B. Age ≥ 18 years. **AND**
C. Documentation of inefficacy of, or contraindication to maximum tolerated dose of TWO formulary antidepressants (SSRI, SNRI, TCA, bupropion, mirtazapine, etc.) with one of those trials being augmented by one formulary generic atypical antipsychotic (quetiapine or olanzapine).

Irritability associated with autistic disorder:

A. Diagnosis of autistic disorder. **AND**
B. Age ≥ 6 years of age and ≤ 17 years of age. **AND**
C. Trial and failure of or intolerance to risperidone.

*NOTE: For all indications above, Abilify can be approved if meeting the diagnostic and age criteria with a comorbidity*

*of metabolic syndrome, diabetes mellitus, OR with a BMI > 30. All patients stabilized on Abilify therapy for 30 days or more should be continued for 6 months.*

**Approval:** Initial Approval: 12 months. The Discmelt formulation requires additional rationale supporting use over oral therapy.
Continued Approval: 12 months.

**Special Instructions**

> Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Aripiprazole is not approved for the treatment of patients with dementia-related psychosis.
> Though indicated as an adjunct in the treatment of depression, patients with major depressive disorder, both adults and pediatric patients, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications; this risk may persist until significant remission occurs.
> Aripiprazole may have the potential to impair judgment, thinking, or motor skills. Caution patients about operating hazardous machinery, including automobiles, until they are reasonably certain that therapy with aripiprazole does not affect them adversely.

**References:**

1. Abilify prescribing information. Accessed July, 2014. http://www.abilify.com/pdf/pi.aspx

**Revision Log**

| Revision | Date |
|---|---|
| Updated language to improve clarity of guideline. No major changes to criteria. | 12/14 |
| Added "other psychotic disorder" to FDA labeled indication | 07/15 |
| Changed trial of 3 atypical antipsychotics to two under Schizophrenia, Schizoaffective Disorder, or other psychotic disorder AND removed requirement of 4 week trial | 07/15 |
| Annual Review, No changes made | 07/16 |
| Changed antidepressant trial from 3 to 2 AND changed trial | 07/15 |

| | |
|---|---|
| for 3 months to 1 month for Major Depressive Disorder criteria | |
| Removed 1 month length of trial for MDD criteria, item C. | 08/15 |
| Annual Review No Changes | 07/16 |
| Annual Review, No changes | 07/17 |

## POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file
V.P., Pharmacy Operations: Approval on file
Sr. V.P., Chief Medical Officer: Approval on file