Oscar Clinical Guideline: Aripiprazole oral disintegrating tablet, solution (PG173, Ver. 2)

Aripiprazole oral disintegrating tablet, solution

- Aripiprazole Oral disintegrating tablet (Abilify Discmelt)
- Aripiprazole Oral solution (Abilify 1mg/mL Solution)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Aripiprazole (Abilify) is an atypical antipsychotic medication classified as a dopamine system stabilizer. Unlike most antipsychotics, which act as full dopamine antagonists, aripiprazole is a partial dopamine agonist. This unique mechanism allows aripiprazole to reduce positive symptoms of schizophrenia and stabilize dopamine activity without causing significant extrapyramidal side effects.

- Abilify (aripiprazole) Oral Tablets, Orally-Disintegrating Tablets, and Oral Solution 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.

    - Irritability Associated with Autistic Disorder.
    - Treatment of Tourette's Disorder.
- In addition to oral tablets, aripiprazole is available in several long-acting injectable formulations, including monthly, 2-month, and 1-2 month extended release intramuscular injections for maintenance therapy of schizophrenia and bipolar I disorder.
- An ingestible digital sensor tablet was also approved to monitor adherence to oral aripiprazole treatment.

The major safety concerns with aripiprazole include increased mortality in elderly dementia patients and increased suicidal ideation in pediatric and young adult patients, warranting boxed warnings for these populations.

Definitions

"**Adjunctive therapy**" is the use of a medication in combination with another medication, often to enhance the main therapy or treat additional symptoms. Aripiprazole is approved as adjunctive therapy for major depressive disorder.

"**Atypical Antipsychotics**" are a group of antipsychotic drugs used to treat psychiatric conditions. Atypical antipsychotics are less likely to produce extrapyramidal side effects (movement disorders) compared to the older typical antipsychotics.

"**Bipolar disorder**" is a mental health condition causing unusual shifts in mood, energy, and activity levels ranging from depressive lows to manic highs.

"**Boxed Warnings**", also known as a black box warning, is the most serious type of warning issued by the Food and Drug Administration (FDA). It is placed on the labeling of prescription drugs that have serious or life-threatening risks.

"**Irritability associated with autistic disorder**" refers to irritability manifesting as aggression, deliberate self-injurious behavior, temper tantrums or quickly changing moods that is associated with autism spectrum disorder.

"**Major depressive disorder**" is a psychiatric disorder characterized by a persistent feeling of sadness, loss of interest in activities, and other debilitating symptoms.

"Postpartum Psychosis" is a rare but serious mental health emergency characterized by sudden onset of psychotic symptoms shortly after childbirth. It is often characterized by acute onset of delusions, disorganized thoughts, hallucinations, and/or agitation. While it may occur as a manifestation of bipolar disorder, it can also present in patients without prior psychiatric history. Early recognition and treatment is critical due to risks to both mother and infant.

"**Schizophrenia**" is a chronic and severe mental disorder characterized by disruptions in thinking, perception, emotions, and behavior. Hallucinations and delusions are common.

"**Tourette's syndrome**" is a neurological disorder characterized by sudden, repetitive, rapid, and unwanted movements or vocal sounds called tics.

Clinical Indications

Medical Necessity Criteria for Initial Authorization

The Plan considers **aripiprazole (Abilify) oral disintegrating tablet and solution** medically necessary when **ALL** of the following criteria are met:

1. Documentation indicating the member's inability or unwillingness to take the tablet form; ***AND***
2. Aripiprazole (oral disintegrating tablet, solution) is being prescribed at a dose and frequency (i.e., once daily, up to a maximum daily dose of 30mg/day) that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication***; AND***
3. The member meets the applicable indication-specific criteria listed below:

Adjunctive Therapy of Major Depressive Disorder

4. The member is 18 years of age or older; ***AND***
5. The member has a diagnosis of major depressive disorder.

Bipolar Disorder

4. The member is 10 years of age or older; ***AND***
5. The member has a diagnosis of bipolar disorder***.***

Irritability Associated with Autistic Disorder

4. The member is between ages 6 to 17 years; ***AND***

5. The member has a diagnosis of irritability associated with autistic disorder (including symptoms of aggression, deliberate self-injurious behavior, temper tantrums, quickly changing moods).

Postpartum Psychosis:

4. The requested medication is prescribed by or in consultation with a psychiatrist; ***AND***
5. The member has postpartum psychosis as evidenced by **ONE** of the following:
    a. New onset psychotic symptoms in the postpartum period; ***or***
    b. Bipolar disorder with postpartum psychotic features; ***AND***
6. Clinical documentation shows **BOTH**:
    a. Acute psychotic symptoms (e.g., delusions, disorganized thoughts, hallucinations); ***and***
    b. At least **ONE** of the following:
        i. Agitation; ***and/or***
        ii. Bizarre behavior; ***and/or***
        iii. Documented significant change from baseline functioning.

Schizophrenia

4. The member is 13 years of age or older; ***AND***
5. The member has a diagnosis of schizophrenia.

Tourette's Syndrome or chronic tic disorders

4. The member is between ages 6 to 18 years; ***AND***
5. The member has a diagnosis of Tourette disorder or chronic tic disorders.

For other off-label uses

4. The member is 18 years of age or older; ***AND***
5. The medication is being requested for treatment of **ONE** of the following:
    a. Agitation or aggression associated with psychiatric conditions (eg, schizophrenia, bipolar disorder), substance intoxication, or other organic causes; ***or***
    b. Agitation/aggression and psychosis related to dementia whose symptoms are dangerous, severe, or cause significant patient distress; ***or***
    c. Delusional infestation (also called delusional parasitosis) **AND** the member is unable to use, or has tried and failed olanzapine and risperidone; ***or***
    d. Treatment-resistant obsessive-compulsive disorder (OCD) in members who have a partial response to initial treatment (e.g., antidepressants such as clomipramine, fluvoxamine, fluoxetine, paroxetine, sertraline); ***or***

e. Reducing tic severity in members with Tourette syndrome.

If the above prior authorization criteria are met, the requested product will be authorized for up to 12-months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if **BOTH** of the following are met:

1. Recent chart documentation (within the last 3 months) shows the member has experienced clinical response to the requested therapy as evidenced by **ONE** of the following:
    a. clinical improvement (e.g., reduction in intensity or severity of symptoms) since starting the requested medication***; or***
    b. stability in condition (e.g., stabilizing mood, return to normal psychosocial functioning) since starting the requested medication; ***AND***
2. The member maintains adherence to the prescribed dosing regimen as evidenced by pharmacy claims record.

Experimental or Investigational / Not Medically Necessary

Aripiprazole (oral disintegrating tablet, solution) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Attention Deficit Hyperactivity Disorder (ADHD).
- Chronic Lower Back Pain (CLBP).
- Eating Disorders, including Anorexia Nervosa (AN).
- for the treatment of chorea associated with Huntington.
- for the treatment of delusional disorder.
- Generalized Anxiety Disorder/Panic Disorder.
- Postpartum Depression.

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