

Prior Authorization DRUG Guidelines

Abilify Asimtufii, Abilify Maintena (Aripiprazole - Otsuka
America Pharmaceutical, Inc.)

Date Developed: 10/10/2024

Date Approved by P&T Committee: 02/18/2025

OVERVIEW

Second-generation antipsychotics are serotonin-dopamine antagonists and are also known as atypical antipsychotics. The Food and Drug Administration (FDA) has approved 12 atypical antipsychotics as of the year 2016, including aripiprazole. Second-generation antipsychotics (SGAs) have a decreased risk of extrapyramidal side effects as compared to first-generation antipsychotics. SGAs are associated with significant weight gain and the development of metabolic syndrome. The FDA recommends monitoring personal and family history of diabetes mellitus, dyslipidemia, weight, and height, waist circumference, blood pressure, fasting plasma glucose, and fasting lipid profile for all patients.

NOTE: This policy is for Abilify Long-acting Injectables, specifically Abilify Asimtufii and Abilify Maintena only. For oral Abilify, the patient should use the preferred bioequivalent generic product.

Source:

<https://www.vchealthcareplan.org/providers/docs/padg/NationalPreferredFormularyExceptionCriteria.pdf>

FDA Approved Indications:

ABILIFY ASIMTUFII—may be given for:

- ~~for the~~ treatment of schizophrenia in adults
- alone as maintenance treatment, monotherapy of bipolar I disorder in adults
- Initial therapy [Recommended dosage is 960 mg administered once every 2 months as a single injection. Dose can be reduced to 720 mg in patients with adverse reactions]
 - a. Has tried and tolerated oral aripiprazole for at least two (2) weeks prior to initiating treatment with ABILIFY ASIMTUFII.
 - b. Must be administered as an intramuscular gluteal injection

- c. When injection is initiated in patients receiving oral aripiprazole, administer the first dose along with oral aripiprazole (10 mg to 20 mg) for 14 consecutive days.
 - d. For patients already stable on another oral antipsychotic (and known to tolerate aripiprazole), administer the first injection along with the oral antipsychotic for 14 consecutive days
 - e. For patients receiving Abilify Maintena (once monthly dosing), ABILIFY ASIMTUFII 960 mg may be given (once every 2-month dosing) in place of the next scheduled injection of the Abilify Maintena.
- Maintenance Therapy
 - a. If there are adverse reactions with the ABILIFY ASIMTUFII 960 mg dosage, the dosage may be reduced to 720 mg once every 2 months.
 - c. Patients may be given the ABILIFY ASIMTUFII injection up to 2 weeks before or 2 weeks after the 2-month scheduled timepoint.

ABILIFY MAINTENA may be given for:

- treatment of schizophrenia in adults
- alone as maintenance treatment of bipolar I disorder in adults
- Initial Therapy.
 - a. Has tried and tolerated oral aripiprazole for at least two (2) weeks prior to initiating treatment
 - b. Recommended starting and maintenance dose is 400 mg administered monthly as a single injection. Dose can be reduced to 300 mg in patients with adverse reactions
 - c. For known CYP2D6 poor metabolizers, recommended starting 300 mg administered monthly as a single injection
- Maintenance Therapy
 - Must be administered as an intramuscular gluteal injection
 - a. The recommended starting and maintenance dose is 400 mg monthly (no sooner than 26 days after the previous injection)
 - b. For patients already stable on another oral antipsychotic (and known to tolerate aripiprazole), after the first ABILIFY MAINTENA injection, continue treatment with the antipsychotic for 14 consecutive days to maintain therapeutic antipsychotic concentrations during initiation of therapy.

- c. If there are adverse reactions with the ABILIFY MAINTENA 400 mg dosage, the dosage may be reduced to 300 mg once a month.

Conditions not recommended for approval:

- It is not known if ABILIFY ASIMTUFII or ABILIFY MAINTENA is safe and effective in children under 18 years of age.
- Abilify Asimtufii and Abilify Maintena are not approved for treatment of patients with dementia- related psychosis.

REFERENCES

1. Abilify Asimtufii and Abilify Maintena [prescribing information]. Otsuka America Pharmaceutical, Inc; November 2023.
2. Aripiprazole (oral and long-acting injectable [Abilify Maintena]): Drug information. Up To Date, 2024. Retrieved October 10, 2024 from https://www.uptodate.com/contents/aripiprazole-oral-and-long-acting-injectable-abilify-maintena-drug-information?search=why%20is%20abilify%20indicated&selectedTitle=1%7E69&usage_type=panel&display_rank=1&kp_tab=drug_general&source=panel_search_result.
3. Chokhawala, K., Stevens, L. Antipsychotic Medications. National Library of Medicine, February 2023. Retrieved October 10, 2024 from <https://www.ncbi.nlm.nih.gov/books/NBK519503/>.

Review History:

Policy created by Howard Taekman, MD/Dr. Robert Sterling on 10/10/2024

Date Reviewed/Updated: 2/18/25 by H. Taekman, MD; R. Sterling, MD

Date Approved by P&T Committee: 2/18/25

Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes