OVERVIEW
The approval of generic atypical antipsychotic agents has created an opportunity to improve the cost-effectiveness of treatment and lower prescription costs for patients without compromising efficacy. A logical and evidence-based method must be employed to support and encourage adequate care. A step algorithm provides one such manner by which treatment for bipolar disorder and schizophrenia can be delivered to efficiently improve patient outcomes and control escalating healthcare expenditures.

PHARMACY COVERAGE GUIDELINES
Tufts Health Plan – Network Health may authorize coverage of a non-preferred antipsychotic medication for Together members when all the following criteria for a particular regimen are met and limitations do not apply:

For members less than 6 years of age,
- The member has been evaluated by a specialist AND
- The request is for an FDA approved diagnosis or for an off-label use supported by recognized medical compendia AND
- One of the following:
  - The member was recently hospitalized for a behavioral health condition.
  - The member has a history of severe risk for harm to oneself or others.

For members at least 6 years of age,
- The member is stabilized on the medication OR
- The member was recently started on the requested medication in an acute care setting, residential setting, or partial hospital setting OR
- One of the following drug-specific criteria:

For aripiprazole, one of the following conditions:
- The member is at least 13 years of age with a diagnosis of schizophrenia or is at least 10 years of age with a diagnosis of bipolar disorder AND
- The member tried and failed therapy with two alternative atypical antipsychotic agents or provider indicates the member is at increased risk for adverse clinical outcome* with the use of two alternative agents OR
- The member is at least 6 years of age with a diagnosis of irritability associated with an autistic disorder or behavioral problems associated with an autistic disorder AND
- The member tried and failed therapy with risperidone, or the provider indicates clinically inappropriateness of therapy or there is an increased risk for adverse clinical outcome* with the use of risperidone OR
- The member is at least 6 years of age with a diagnosis of depression with psychotic features or post-traumatic stress disorder (PTSD), or the request is for a member at least 18 years of age with a diagnosis of depression, without psychotic features or PTSD AND
- The use of aripiprazole with adjunctive therapy used concomitantly with an antidepressant agent AND
- One of the following:
  - The member tried and failed therapy with at least two alternative therapies, one course of therapy with an antidepressant agent and one course of therapy with an antidepressant agent used concomitantly with an alternative antipsychotic agent OR
The provider indicates the member is at increased risk for adverse clinical outcome* with the use of alternative regimens OR

- The member is at least 6 years of age with an off-label behavioral health diagnosis AND
- The member tried and failed therapy with two alternative atypical antipsychotic agents.

For iloperidone or paliperidone (oral),
- The member tried and failed therapy with or the provider indicates clinical inappropriateness of therapy with at least two alternative atypical antipsychotic agents, one of which must be risperidone.

For paliperidone (long-acting injection),
- The member has tried and failed therapy with, or the provider indicates a clinical concern with the use of oral paliperidone and with injectable risperidone.

For lurasidone,
- The member tried and failed therapy with or the provider indicates clinical inappropriateness of therapy with at least two alternative atypical antipsychotic agents.

For quetiapine extended-release, one of the following conditions:
- The member is at least 18 years of age with a diagnosis of schizophrenia or bipolar disorder.
- The member has an insufficient response or adverse effects to a trial with immediate-release quetiapine, or the provider indicates the member is at increased risk for adverse clinical outcome* with the use of immediate-release quetiapine OR
- The member is at least 18 years of age with a diagnosis of depression, without psychotic features, PTSD, or trauma-related features.
- Quetiapine extended-release will be used as adjunctive therapy concomitantly with an antidepressant.
- The member tried and failed therapy with at least three antidepressant medications, or the provider indicates clinical inappropriateness of therapy with alternative antidepressant medications OR
- The member is at least 18 years of age with an off-label behavioral health diagnosis.
- The member tried and failed therapy with two alternative atypical antipsychotic agents, one of which must be immediate-release quetiapine, or the provider indicates clinical inappropriateness of therapy with the use of alternative agents.

**LIMITATIONS**

- For the following antipsychotic agents which require prior authorization, coverage is limited as follows:
  - **Aripiprazole tablets** Abilify 1 tablet per day
  - **Aripiprazole Intramuscular Susp.** Abilify Maintena 1 vial per 28 days
  - **Asenapine** Saphris 2 tablets per day
  - **Iloperidone** Fanapt 2 tablets per day
  - **Lurasidone** Latuda 1 tablet per day
  - **Paliperidone** Invega 1 tablet per day
  - **Paliperidone Inj** Invega Sustenna 1 vial per month; 2 vials for 1st month
  - **Quetiapine extended-release** Seroquel XR 50 mg, 300 mg, 400 mg 2 tablets per day
  - **Quetiapine extended-release** Seroquel XR 150 mg, 200 mg 1 tablet per day

- Quantities that exceed the quantity limit will be reviewed according to the Drugs w/ Quantity Limitations criteria.
- The length of approval will be for 2 years; subsequent approval will require the provider to submit information that the member had an office visit and has been re-assessed for this condition within the past year, and continued therapy with this medication is considered medically necessary.
- Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.

**CODES**

None

**REFERENCES**


**APPROVAL HISTORY**
- 06/09/15: Reviewed by the Pharmacy and Therapeutics Committee; consolidated individual guidelines; added criteria for children less than 6 years of age; modified duration approval to 2 years.

**BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION**
Pharmacy Medication Request Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medication Request Guidelines are developed for selected therapeutic classes or drugs found to be safe but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medication Request Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medication Request Guidelines apply to fully insured Tufts Health Together offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the Preferred Drug List (formulary) in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Direct (individual and small-group plan), please refer to the Tufts Health Direct Pharmacy Medical Necessity Guidelines.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines, when applicable, and adherence to plan policies and procedures and claims editing logic.