MEDICAL MUTUAL®

Drug Policy

Policy:	**Select Antipsychotics Step Therapy**	**Annual Review Date:** **11/21/2023**
Impacted Drugs:	• **Rexulti (brexpiprazole)** • **Caplyta (lumateperone)**	**Last Revised Date:** **11/21/2023**

OVERVIEW

Rexulti and Abilify are atypical antipsychotics that act as partial agonists of serotonin 5-HT-1A and dopamine D2 receptors, and as antagonists of serotonin 5-HT-2A. Both drugs are indicated for the treatment of major depressive disorder (MDD) as adjunct to antidepressants, and for treatment of schizophrenia. Rexulti is only indicated for use in adults whereas Abilify can be used to treat schizophrenia in pediatric patients as young as 13 years of age. Abilify has the added indications of Gilles de la Tourette's syndrome, psychomotor agitation in Autism, and Bipolar I disorder. Caplyta is also an atypical antipsychotic indicated for the treatment of schizophrenia in adults. The mechanism of action is unknown, however it may be mediated through a combination of antagonist activity at central serotonin 5-HT-2A receptors and postsynaptic antagonist activity at central dopamine D2 receptors. If Neuroleptic Malignant Syndrome is suspected, immediately discontinue Rexulti or Caplyta and provide intensive symptomatic treatment and monitoring. Neither Rexulti nor Caplyta are approved for the treatment of patients with dementia-related psychosis.

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: Patients who are new to therapy with Rexulti or Caplyta will be targeted in this policy.

Preferred Medications

- Abilify
- Aripiprazole

Non-Preferred Medication

- Rexulti
- Caplyta

PREFERRED STEP THERAPY CRITERIA

1. If the patient has tried a preferred medication, then authorization for a non-preferred medication may be given.

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Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

Step Therapy Exception Criteria
In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation

supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Aripiprazole. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 12 June 2019. Accessed on 18 June 2019.
2. Brexpiprazole. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 16 February 2018. Accessed on 18 June 2019.
3. Rexulti [prescribing information]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; March 2020.
4. Abilify [prescribing information]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; February 2018.
5. Caplyta [prescribing information]. New York, NY: Intra-Cellular Therapies, Inc.; December 2019