MARYLAND Department of Health

# *Tier 2 and Non-Preferred Antipsychotics For Patients Age 18 Years and Older*

The following clinical criteria must be met to obtain prior authorization (PA) for Tier 2 and non-preferred antipsychotics. All other existing policies such as those regarding generic substitution and quantity limit (including dose optimization) continue to apply to these drugs as well.

**Note: Patient will be grandfathered, if patient has been on the prescribed drug for greater than 30 days in the previous 120 days excluding any emergency supplies obtained through the Call center help desk.**

### *Criteria for immediate approval upon review:*

- The medication was started on an inpatient unit/other acute care setting and the patient was discharged within the last 60 days; **OR**
- The prescriber furnishes documentation that the patient has experienced adverse effects, allergic reactions, has a contraindication to, or failed to respond to each of the preferred antipsychotic medications.

### *Other requests will be evaluated based on the following criteria:**

- The patient has FDA indicated diagnosis for the requested medication; AND
- The requested medication complies with FDA-labeling for indication, dosage and administration frequency.
- The patient has had an adequate trial (at least 6 weeks, at the FDA approved recommended dose) of at least one Tier 1 preferred antipsychotic drug that is FDA approved for the indicated diagnosis (please refer to the Maryland Medicaid Pharmacy Program Preferred Drug List).

The use of pharmaceutical samples and emergency supplies authorized by the Program will not be considered when evaluating the patient's medical condition or prior prescription history for drugs that require prior authorization.

All requests are reviewed by a psychiatric clinical pharmacist at the Maryland Medicaid Pharmacy Program or its designee.

### *Requests for specific drugs/dosage forms:*

Alternate dosage form: When a drug is available in an oral tablet or capsule dosage form, all other dosage forms (excluding injectable) will only be approved if the patient has a documented inability to ingest the oral tablet or capsule.

Once daily dosage form: Medications available in an extended duration dosage form or with extended half-lives will only be approved for once daily administration as per FDA labeling.

Paliperidone oral tablet: Authorization will only be approved if the patient has hepatic dysfunction that prevents risperidone metabolism to the active metabolite or a genetic polymorphism for CYP2D6 that classifies the patient as a "slow metabolizer" of risperidone.[1]

[1] Per Package insert for Invega® Sustenna® "For patients who have never taken oral paliperidone or oral or injectable risperidone, tolerability should be established with oral paliperidone or oral risperidone prior to initiating treatment with INVEGA® SUSTENNA®."

Concurrent use of oral and long-acting injectable antipsychotic medication: If a patient has an existing prior authorization for a long-acting injectable antipsychotic at the time authorization is sought for a Tier 2 or non-preferred oral medication (other than any oral overlap required per the package insert), authorization may be denied.

Multiple antipsychotics: If a patient has an existing authorization for a Tier 2 or non-preferred antipsychotic at the time authorization is sought for a second Tier 2 or non-preferred antipsychotic, the authorization for the initially approved antipsychotic will be adjusted to expire 90 days after the approval of the second agent in order to allow an adequate titration period between medications. Two or more Tier 2 or non-preferred antipsychotics will not be authorized for an extended time.

***Please note: Rexulti®, Nuplazid®, Perseris®, and Invega Trinza® have additional Clinical Criteria which can be found at https://mmcp.health.maryland.gov/pap/Pages/Clinical-Criteria.aspx**

Additional monitoring recommendations:

Note: Due to certain risk factors with these agents, the following monitoring parameters are indicated: BMI, BP, Fasting Glucose, Fasting Lipid Profile, EKG (when indicated), and an assessment of abnormal involuntary movements (ex. AIMS or DISCUS) and an assessment of family and personal history for cardiac risk factors.

Recommended Monitoring by the American Diabetes Association and American Psychiatric Association:

| Parameter/Frequency | Baseline | 4 weeks | 8 weeks | 12 weeks | Every 3 months | Yearly |
|---|---|---|---|---|---|---|
| BMI | x | x | x | x | x | x |
| Waist Circumference | x | | | | | x |
| BP | x | | | x | | x |
| FBG/HbA1c | x | | | x | | x |
| Fasting Lipids | x | | | x | | x |

BMI – Body Mass Index = 703 x weight (pounds)/height2 (inches)

BP – Blood Pressure

FBG – Fasting Blood Glucose