# SmartPA Criteria Proposal

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| **Drug/Drug Class:** | Antipsychotics - 2nd Generation (Atypical) Oral & Transdermal Agents Resource List |
| **First Implementation Date:** | April 6, 2023 |
| **Revised Date:** | July 20, 2023 |
| **Prepared for:** | MO HealthNet |
| **Prepared by:** | MO HealthNet/Conduent |
| **Criteria Status:** | ☐Existing Criteria<br>☒Revision of Existing Criteria<br>☐New Criteria |

## Executive Summary

**Purpose:** The MO HealthNet Pharmacy Program will implement a state-specific resource list.

**Why Issue Selected:** **Antipsychotics** are a class of medication which may be used to treat a variety of behavioral health conditions, including schizophrenia, bipolar disorder, depression, anxiety, and agitation.

**First generation** (also known as typical) antipsychotics have a significant potential to cause extrapyramidal side effects, which are involuntary movement disorders that involve lip smacking, grimacing, muscle spasms, and other actions that may interfere with daily functioning.

**Second generation** (also known as atypical) antipsychotics have a lower likelihood of causing these side effects and are now considered first line therapies for patients who require therapy with an antipsychotic.

MO HealthNet allows access to appropriate medication to all participants. As such, all second generation (atypical) antipsychotic agents are available to MO HealthNet participants based on established criteria within this proposal and are not excluded from coverage. Within this proposal is Resource List A, listing multiple atypical antipsychotic agents with no restrictions to access, based on the relative effectiveness, side effects, mechanism of action, and cost effectiveness.

The medications in Resource List A should be used by providers to select an appropriate antipsychotic for participants as a first line option when an antipsychotic is needed. If the participant is unable to achieve the desired therapeutic benefit with an agent from Resource List A or has intolerable side effects, providers may select an agent from Resource List B. Agents in the Non-Resource List should be utilized when participants are unable to achieve the desired therapeutic benefit from agents in Resource List A or B. If it is not possible to utilize an agent from Resource List A as a first line agent due to unique participant factors, participants will be able to access agents in Resource List B or the Non-Resource List.

Participants who are established on an antipsychotic medication will be able to maintain access to their current therapy regardless of the Resource List placement. All antipsychotics are subject to clinical edits to ensure appropriate utilization.

This proposal does not apply to the first generation (typical) antipsychotics.

**Program-Specific Information:**

| **Resource List A**<br>Transparent approval for these medications is available with no prior authorization or previous atypical antipsychotic medication, as long as the participant meets clinical criteria. | **Non-Resource List**<br>Transparent approval, without prior authorization, is available for these medications if the participant has prior history of 2 previous atypical antipsychotics. Prior Authorization is also available for participants with unique factors without a previous atypical antipsychotic medication. |
|---|---|
| • Aripiprazole Tabs | • Abilify® Tabs<br>• Abilify MyCite® Kits<br>• Aripiprazole ODT**<br>• Aripiprazole Soln** |
| • Clozapine Tabs | • Clozapine ODT**<br>• Clozaril® Tabs<br>• Versacloz® Susp |
| • Fanapt® Tabs/Pack | • *N/A* |
| • Lurasidone Tabs | • Latuda® Tabs |
| • Nuplazid®* Caps/Tabs | • *N/A* |
| • Olanzapine Tabs<br>• Olanzapine ODT<br>• Olanzapine/Fluoxetine Caps | • Lybalvi® Tabs<br>• Symbyax® Caps<br>• Zyprexa® Tabs<br>• Zyprexa® Zydis® Tabs |
| • Paliperidone ER Tabs | • Invega® ER Tabs |
| • Quetiapine Tabs (excluding 150 mg Tab)<br>• Quetiapine ER Tabs | • Quetiapine 150 mg Tabs<br>• Seroquel® Tabs<br>• Seroquel XR® Tabs |
| • Risperidone Tabs<br>• Risperidone ODT<br>• Risperidone Soln | • Risperdal® Tabs<br>• Risperdal® Soln |
| • Saphris® SL Tabs | • Asenapine SL Tabs<br>• Secuado® Patches |
| • Ziprasidone Caps | • Geodon® Caps |
| **Resource List B**<br>Transparent approval, without prior authorization, is available for these medications if the participant has prior history of any atypical antipsychotic. Prior Authorization is also available for a participant with unique factors without a previous atypical antipsychotic medication. | |
| • Caplyta® Caps | • *N/A* |
| • Rexulti® Tabs*** | • *N/A* |
| • Vraylar® Caps/Pack | • *N/A* |

* Requires diagnosis of Parkinson's disease psychosis
** available to participants < 10 years of age without any pre-requisite therapy
***** available as first line treatment for agitation associated with dementia due to Alzheimer's disease**

**Type of Criteria:**

☐ **Increased risk of ADE** ☒ **Resource List**
☒ **Appropriate Indications** ☐ **Clinical Edit**

**Data Sources:**

☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

## Setting & Population

- Drug class for review: Antipsychotics - 2nd Generation (Atypical) Oral & Transdermal Agents
- Age range: All appropriate MO HealthNet participants aged 8 years and older

## Approval Criteria

Initial Therapy:

- Participant is aged ≥ 9 years (Requests for participants aged < 9 years require manual review by a child psychiatrist) **AND**
- For Nuplazid: documented diagnosis of hallucinations and delusions associated with Parkinson's disease psychosis **OR**
- **For documented diagnosis of agitation associated with dementia due to Alzheimer's disease: Rexulti may be approved as first line therapy without trial of a Resource List A agent OR**
- For all other agents: Documented appropriate diagnosis (i.e., Schizophrenia, Psychotic disorder, Schizoaffective disorders, Manic episode, Bipolar disorder, Depressive episode, Major depressive disorder, Persistent mood [affective] disorders, Postpartum depression, Puerperal psychosis, Obsessive-compulsive personality disorder, Pervasive developmental disorders) **AND**
- Requests for a Resource List B or Non-Resource List agents:
    - Resource List B agents will be transparently approved if the participant has previously received treatment with at least one Resource List A agent based on paid claims history.
    - Non-Resource List agents will be transparently approved if the participant has previously received treatment with at least two Resource List A or B agents based on paid claims history.
    - If the participant previously utilized Resource List A agents for which MO HealthNet does not have paid claims history, the prescriber or pharmacy will need to supply MHD with documentation of previous utilization in order to be approved for a Resource List B or Non-Resource List agent.
    - For liquid or ODT dosage forms: Participants who require a Resource List B or Non-Resource List ODT or liquid agent will be able to access these agents without previously utilizing a Resource List A agent. Examples include participants under the age of 10 years, participants with developmental disabilities, or participants who are otherwise unable to swallow pills.

Continuation of Therapy:

- Participants currently stable on a 2nd generation (atypical) antipsychotic will be able to continue accessing that agent, regardless of Resource List status.
- Participants who successfully utilized a 2nd generation (atypical) antipsychotic previously will be allowed to utilize the same agent subject to clinical edits, regardless of Resource List status.

## Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Participant is aged ≥ 18 years with documented history of > 2 concurrent antipsychotics (typical or atypical) for 60 of the past 90 days
- Participant is aged < 18 years with documented history of > 2 concurrent antipsychotics (typical or atypical) for 30 of the past 90 days
- Claim for Lybalvi: documented therapy with an opioid in the past 45 days
- Claim exceeds maximum dosing limitations on the following:

| Drug Description | Generic Equivalent | Maximum Dosing Limitation |
|---|---|---|
| ABILIFY 1 MG/ML SOLUTION | ARIPIPRAZOLE | 25 ML PER DAY |
| ABILIFY 10 MG | ARIPIPRAZOLE | 1 TABLET PER DAY |
| ABILIFY 15 MG | ARIPIPRAZOLE | 1 TABLET PER DAY |
| ABILIFY 2 MG | ARIPIPRAZOLE | 2 TABLETS PER DAY |
| ABILIFY 20 MG | ARIPIPRAZOLE | 1 TABLET PER DAY |

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|---|---|---|
| ABILIFY 30 MG | ARIPIPRAZOLE | 1 TABLET PER DAY |
| ABILIFY 5 MG | ARIPIPRAZOLE | 2 TABLETS PER DAY |
| ABILIFY DISCMELT 10 MG | ARIPIPRAZOLE | 2 TABLETS PER DAY |
| ABILIFY DISCMELT 15 MG | ARIPIPRAZOLE | 2 TABLETS PER DAY |
| ABILIFY MYCITE 10 MG | ARIPIPRAZOLE | 1 TABLET PER DAY |
| ABILIFY MYCITE 10 MG MAINT KIT | ARIPIPRAZOLE | 1 TABLET PER DAY |
| ABILIFY MYCITE 10 MG START KIT | ARIPIPRAZOLE | 1 TABLET PER DAY |
| ABILIFY MYCITE 15 MG | ARIPIPRAZOLE | 1 TABLET PER DAY |
| ABILIFY MYCITE 15 MG MAINT KIT | ARIPIPRAZOLE | 1 TABLET PER DAY |
| ABILIFY MYCITE 15 MG START KIT | ARIPIPRAZOLE | 1 TABLET PER DAY |
| ABILIFY MYCITE 2 MG | ARIPIPRAZOLE | 2 TABLETS PER DAY |
| ABILIFY MYCITE 2 MG MAINT KIT | ARIPIPRAZOLE | 2 TABLETS PER DAY |
| ABILIFY MYCITE 2 MG START KIT | ARIPIPRAZOLE | 2 TABLETS PER DAY |
| ABILIFY MYCITE 20 MG | ARIPIPRAZOLE | 1 TABLET PER DAY |
| ABILIFY MYCITE 20 MG MAINT KIT | ARIPIPRAZOLE | 1 TABLET PER DAY |
| ABILIFY MYCITE 20 MG START KIT | ARIPIPRAZOLE | 1 TABLET PER DAY |
| ABILIFY MYCITE 30 MG | ARIPIPRAZOLE | 1 TABLET PER DAY |
| ABILIFY MYCITE 30 MG MAINT KIT | ARIPIPRAZOLE | 1 TABLET PER DAY |
| ABILIFY MYCITE 30 MG START KIT | ARIPIPRAZOLE | 1 TABLET PER DAY |
| ABILIFY MYCITE 5 MG | ARIPIPRAZOLE | 1 TABLET PER DAY |
| ABILIFY MYCITE 5 MG MAINT KIT | ARIPIPRAZOLE | 1 TABLET PER DAY |
| ABILIFY MYCITE 5 MG START KIT | ARIPIPRAZOLE | 1 TABLET PER DAY |
| CAPLYTA 10.5 MG CAPSULE | LUMATEPERONE TOSYLATE | 1 CAPSULE PER DAY |
| CAPLYTA 21 MG CAPSULE | LUMATEPERONE TOSYLATE | 1 CAPSULE PER DAY |
| CAPLYTA 42MG CAPSULE | LUMATEPERONE TOSYLATE | 1 CAPSULE PER DAY |
| FANAPT 1 MG | ILOPERIDONE | 2 TABLETS PER DAY |
| FANAPT 10 MG | ILOPERIDONE | 2 TABLETS PER DAY |
| FANAPT 12 MG | ILOPERIDONE | 2 TABLETS PER DAY |
| FANAPT 2 MG | ILOPERIDONE | 2 TABLETS PER DAY |
| FANAPT 4 MG | ILOPERIDONE | 2 TABLETS PER DAY |
| FANAPT 6 MG | ILOPERIDONE | 2 TABLETS PER DAY |
| FANAPT 8 MG | ILOPERIDONE | 2 TABLETS PER DAY |
| INVEGA 1.5 MG | PALIPERIDONE | 1 TABLET PER DAY |
| INVEGA 3 MG | PALIPERIDONE | 1 TABLET PER DAY |
| INVEGA 6 MG | PALIPERIDONE | 2 TABLETS PER DAY |
| INVEGA 9 MG | PALIPERIDONE | 1 TABLET PER DAY |
| LATUDA 120 MG | LURASIDONE HYDROCHLORIDE | 1 TABLET PER DAY |
| LATUDA 20 MG | LURASIDONE HYDROCHLORIDE | 1 TABLET PER DAY |
| LATUDA 40 MG | LURASIDONE HYDROCHLORIDE | 1 TABLET PER DAY |
| LATUDA 60 MG | LURASIDONE HYDROCHLORIDE | 1 TABLET PER DAY |
| LATUDA 80 MG | LURASIDONE HYDROCHLORIDE | 2 TABLETS PER DAY |
| LYBALVI 10-10 MG TABLET | OLANZAPINE/SAMIDORPHAN | 1 TABLET PER DAY |
| LYBALVI 15-10 MG TABLET | OLANZAPINE/SAMIDORPHAN | 1 TABLET PER DAY |
| LYBALVI 20-10 MG TABLET | OLANZAPINE/SAMIDORPHAN | 1 TABLET PER DAY |
| LYBALVI 5-10 MG TABLET | OLANZAPINE/SAMIDORPHAN | 1 TABLET PER DAY |
| REXULTI 0.25 MG TABLET | BREXPIPRAZOLE | 1 TABLET PER DAY |
| REXULTI 0.5 MG TABLET | BREXPIPRAZOLE | 1.5 TABLETS PER DAY |
| REXULTI 1 MG TABLET | BREXPIPRAZOLE | 1.5 TABLETS PER DAY |
| REXULTI 2 MG TABLET | BREXPIPRAZOLE | 1 TABLET PER DAY |
| REXULTI 3 MG TABLET | BREXPIPRAZOLE | 1 TABLET PER DAY |
| REXULTI 4 MG TABLET | BREXPIPRAZOLE | 1 TABLET PER DAY |
| SAPHRIS 10 MG | ASENAPINE MALEATE | 2 TABLETS PER DAY |
| SAPHRIS 2.5 MG | ASENAPINE MALEATE | 2 TABLETS PER DAY |

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| SAPHRIS 5 MG | ASENAPINE MALEATE | 2 TABLETS PER DAY |
| SECUADO 3.8 MG/24 HR PATCH | ASENAPINE | 1 PATCH PER DAY |
| SECUADO 5.7 MG/24 HR PATCH | ASENAPINE | 1 PATCH PER DAY |
| SECUADO 7.6 MG/24 HR PATCH | ASENAPINE | 1 PATCH PER DAY |
| VRAYLAR 1.5 MG CAPSULE | CARIPRAZINE | 1 CAPSULE PER DAY |
| VRAYLAR 3 MG CAPSULE | CARIPRAZINE | 1 CAPSULE PER DAY |
| VRAYLAR 4.5 MG CAPSULE | CARIPRAZINE | 1 CAPSULE PER DAY |
| VRAYLAR 6 MG CAPSULE | CARIPRAZINE | 1 CAPSULE PER DAY |

## Required Documentation

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|---|---|---|---|
| Laboratory Results: | | Progress Notes: | |
| MedWatch Form: | | Other: | X |

## Default Approval Period

3 months

## References


- Evidence-Based Medicine and Fiscal Analysis: “Therapeutic Class Review: CENTRAL NERVOUS SYSTEM: Antipsychotics, Atypical (2nd Generation) Oral and Transdermal Products”, Gainwell Technologies; Last updated November 4, 2022.
- Evidence-Based Medicine Analysis: “Atypical Antipsychotics”, UMKC-DIC; September 2022.
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- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.