SmartPA Criteria Proposal

Drug/Drug Class:	Antipsychotics - 2nd Generation (Atypical) Oral & Transdermal Agents Resource List
First Implementation Date:	November 24, 2015
Proposed Date:	December 15, 2022
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐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 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** 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 • Abilify MyCite® Kits • Aripiprazole ODT** • Aripiprazole Soln**
• Clozapine Tabs	• Clozapine ODT** • Clozaril® Tabs • Versacloz® Susp
• Fanapt® Tabs/Pack	• *N/A*
• Latuda® Tabs	• *N/A*
• Nuplazid®* Caps/Tabs	• *N/A*
• Olanzapine Tabs • Olanzapine ODT • Olanzapine/Fluoxetine Caps	• Lybalvi® Tabs • Symbyax® Caps • Zyprexa® Tabs • Zyprexa® Zydis® Tabs
• Paliperidone ER Tabs	• Invega® ER Tabs
• Quetiapine Tabs (excluding 150 mg Tab) • Quetiapine ER Tabs	• Quetiapine 150 mg Tabs • Seroquel® Tabs • Seroquel XR® Tabs
• Risperidone Tabs • Risperidone ODT • Risperidone Soln	• Risperdal® Tabs • Risperdal® Soln
• Saphris® SL Tabs	• Asenapine SL Tabs • Secuado® Patches
• Ziprasidone Caps	• Geodon® Caps
Resource List B 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

Type of Criteria:
☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☒ **Resource List**
☐ **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 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
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
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

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.
- Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act 2018. Available at: https://www.congress.gov/bill/115th-congress/house-bill/6
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.