SmartPA Criteria Proposal

Drug/Drug Class:	Antipsychotics - 2nd Generation (Atypical) Depot 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 preferred drug 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 a Resource List, 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 the Resource List 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 the Resource List or has intolerable side effects, providers may select an agent from the Non-Resource List. If it is not possible to utilize an agent from the Resource List as a first line agent due to unique participant factors, participants will be able to access agents in 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	Non-Resource List
	• Abilify Maintena® • Aristada® • Aristada Initio® • Invega Hafyera™ • Invega Sustenna® • Invega Trinza® • Perseris® • Risperdal Consta® • Zyprexa® Relprevv™	• *N/A*

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) Depot Agents
- Age range: All appropriate MO HealthNet participants aged **18 years and older**

Approval Criteria

Initial Therapy:

- Participant is aged **≥ 18 years AND**
- Documented appropriate diagnosis **(i.e., Schizophrenia, Schizoaffective disorder, Bipolar disorder)**
- **Requests for Non-Resource List agents:**
  - **Non-Resource List agents will be transparently approved if the participant has previously received treatment with at least one Resource List agent based on paid claims history.**
  - **If the participant previously utilized a Resource List agent 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 Non-Resource List agent.**
- ~~**For Aristada Initio: documented history of ≥ 14 days of oral aripiprazole therapy in the past year**~~
- ~~**For Invega Trinza: documented history of ≥ 4 months of Invega Sustenna therapy in the past 5 months**~~
- ~~**For Invega Hafyera:**~~
  - ~~**Documented history of ≥ 4 months of Invega Sustenna therapy in the past 5 months OR**~~
  - ~~**Documented history of ≥ 3 months of Invega Trinza therapy in the past 4 months**~~

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
- Documented history of > 2 concurrent antipsychotics (typical or atypical) for 60 of the past 90 days
- Claim exceeds maximum dosing limitations on the following:

Drug Description	Generic Equivalent	Maximum Dosing Limitation
ABILIFY MAINTENA ER 300 MG SYR	ARIPIPRAZOLE ER	1 PKG EVERY 20 DAYS
ABILIFY MAINTENA ER 300 MG VIAL	ARIPIPRAZOLE ER	1 PKG EVERY 20 DAYS
ABILIFY MAINTENA ER 400 MG SYR	ARIPIPRAZOLE ER	1 PKG EVERY 20 DAYS
ABILIFY MAINTENA ER 400 MG VIAL	ARIPIPRAZOLE ER	1 PKG EVERY 20 DAYS
ARISTADA ER 441 MG/1.6 ML SYRN	ARIPIPRAZOLE LAUROXIL	1.6 ML EVERY 20 DAYS
ARISTADA ER 662 MG/2.4 ML SYRN	ARIPIPRAZOLE LAUROXIL	2.4 ML EVERY 20 DAYS
ARISTADA ER 882 MG/3.2 ML SYRN	ARIPIPRAZOLE LAUROXIL	3.2 ML EVERY 20 DAYS
ARISTADA ER 1064 MG/3.9 ML SYRN	ARIPIPRAZOLE LAUROXIL	3.9 ML EVERY 48 DAYS
ARISTADA ER INITIO 675 MG/2.4 ML SYR	ARIPIPRAZOLE LAUROXIL	2.4 ML EVERY 20 DAYS
INVEGA HAFYERA 1,092 MG/3.5 ML	PALIPERIDONE PALMITATE	3.5 ML EVERY 152 DAYS
INVEGA HAFYERA 1,560 MG/5 ML	PALIPERIDONE PALMITATE	5 ML EVERY 152 DAYS
INVEGA SUSTENNA 39 MG PREF SYR	PALIPERIDONE PALMITATE	0.25 ML EVERY 20 DAYS
INVEGA SUSTENNA 78 MG PREF SYR	PALIPERIDONE PALMITATE	0.5 ML EVERY 20 DAYS
INVEGA SUSTENNA 117 MG PREF SYR	PALIPERIDONE PALMITATE	0.75 ML EVERY 20 DAYS
INVEGA SUSTENNA 156 MG PREF SYR	PALIPERIDONE PALMITATE	1 ML EVERY 20 DAYS
INVEGA SUSTENNA 234 MG PREF SYR	PALIPERIDONE PALMITATE	1.5 ML EVERY 20 DAYS
INVEGA TRINZA 273 MG/0.875 ML	PALIPERIDONE	0.875 ML EVERY 76 DAYS
INVEGA TRINZA 410 MG/1.315 ML	PALIPERIDONE	1.315 ML EVERY 76 DAYS
INVEGA TRINZA 546 MG/1.75 ML	PALIPERIDONE	1.75 ML EVERY 76 DAYS
INVEGA TRINZA 819 MG/2.625 ML	PALIPERIDONE	2.625 ML EVERY 76 DAYS
PERSERIS ER 90 MG SYR KIT	RISPERIDONE	1 PKG EVERY 20 DAYS
PERSERIS ER 120 MG SYR KIT	RISPERIDONE	1 PKG EVERY 20 DAYS
RISPERDAL CONSTA 12.5 MG SYR	RISPERIDONE	2 PKG EVERY 20 DAYS
RISPERDAL CONSTA 25 MG SYR	RISPERIDONE	2 PKG EVERY 20 DAYS
RISPERDAL CONSTA 37.5 MG SYR	RISPERIDONE	2 PKG EVERY 20 DAYS
RISPERDAL CONSTA 50 MG SYR	RISPERIDONE	2 PKG EVERY 20 DAYS
ZYPREXA RELPREVV 210 MG VIAL	OLANZAPINE PAMOATE	2 PKG EVERY 20 DAYS
ZYPREXA RELPREVV 300 MG VIAL	OLANZAPINE PAMOATE	2 PKG EVERY 20 DAYS
ZYPREXA RELPREVV 405 MG VIAL	OLANZAPINE PAMOATE	1 PKG EVERY 20 DAYS

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: Atypical Antipsychotics (2nd Generation) Depot Products”, Gainwell Technologies; Last updated October 3, 2022.

- Evidence-Based Medicine Analysis: “Atypical Antipsychotics”, UMKC-DIC; September 2022.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.
- 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