SmartPA Criteria Proposal

Drug/Drug Class:	Antipsychotics - 2nd Generation (Atypical) Clinical Edit and Reference List
First Implementation Date:	November 24, 2015
Proposed Date:	December 17, 2020
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of 2nd Generation (Atypical) Antipsychotics and to impose a state-specific open access reference drug list

Why Issue Selected: Atypical or 2nd generation antipsychotics are a class of antipsychotic drugs which may be used to treat a variety of psychiatric conditions including schizophrenia, bipolar disorder, depression, anxiety, insomnia, agitation, and aggression. The older typical or 1st generation antipsychotics have a significant potential to cause extrapyramidal side effects and tardive dyskinesia; atypical or 2nd generation antipsychotics have a lower likelihood of these symptoms and are now considered first line therapies. With the implementation of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act, state Medicaid programs have new requirements regarding prescription drug utilization reviews, including a program to monitor and manage the appropriate use of antipsychotic medications (both typical and atypical).

Atypical or 2nd generation antipsychotics are consistently found on our quarterly top 25 drugs by cost. This edit does not restrict access to any atypical or 2nd generation antipsychotic but contains a reference product list. Agents on the reference product list are manufactured by pharmaceutical companies who offered a supplemental rebate to help MO HealthNet control spiraling drug costs. We encourage prescribing providers to use the reference products whenever possible.

Program-Specific Information:	Reference Oral & Transdermal Products	Non-Reference Oral & Transdermal Products
	• Aripiprazole Soln/Tab • Clozapine Tab • **Fanapt® (Vanda Pharmaceuticals Inc.)** • Latuda® (Sunovion Pharmaceuticals Inc) • Olanzapine ODT/Tab • Olanzapine/Fluoxetine Cap • Quetiapine Tab • Quetiapine ER Tab • **Rexulti® (Otsuka America Pharmaceutical Inc.)** • Risperidone ODT/Soln/Tab • Saphris® (Allergan USA Inc) • Vraylar® (Allergan USA Inc) • Ziprasidone Cap	• Abilify® • Abilify MyCite® • Aripiprazole ODT • Caplyta® • Clozapine ODT • Clozaril® • Fazaclo® • Geodon® • Invega® • Nuplazid® • Paliperidone ER Tab • Risperdal® • Secuado® • Seroquel® • Seroquel XR® • Symbyax® • Versacloz® • Zyprexa® • Zyprexa® Zydis®
	Reference Depot Products	**Non-Reference Depot Products**
	• Abilify Maintena® (Otsuka America Pharmaceutical Inc) • Aristada® (Alkermes Inc) • Aristada Initio® (Alkermes Inc) • Invega Sustenna® (Janssen Pharmaceuticals Inc) • Invega Trinza® (Janssen Pharmaceuticals Inc) • Perseris® (Indivior Inc)	• Risperdal Consta® • Zyprexa® Relprevv™

Type of Criteria: ☐ **Increased risk of ADE** ☒ **Reference Drug List**
☒ **Appropriate Indications** ☐ **Clinical Edit**

Data Sources: ☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

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

Approval Criteria

- Claim is within appropriate dosage limitations **AND**
- Participant is aged > 8 years **AND**
- Documented appropriate diagnosis **OR**
- Participant demonstrates compliance to prescribed therapy (90 out of 120 days)
- For Nuplazid: documented diagnosis of hallucinations and delusions associated with Parkinson's disease psychosis
- For Invega Trinza: documented history of > 4 months of Invega Sustenna therapy in the past 5 months
- For Aristada Initio: documented history of ≥ 14 days of oral aripiprazole therapy in the past year

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 exceeds maximum dosing limitations on the following:

Drug Description	Generic Equivalent	Maximum Dosing Limitation
ABILIFY 10 MG	ARIPIPRAZOLE	1 TABLET PER DAY
ABILIFY 15 MG	ARIPIPRAZOLE	1 TABLET PER DAY
ABILIFY 1 MG/ML SOLUTION	**ARIPIPRAZOLE**	**25 ML 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	1 TABLET PER DAY
ABILIFY DISCMELT 10 MG	**ARIPIPRAZOLE**	**2 TABLETS PER DAY**
ABILIFY DISCMELT 15 MG	**ARIPIPRAZOLE**	**2 TABLETS PER DAY**
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**
ABILIFY MYCITE 10 MG	**ARIPIPRAZOLE**	**1 TABLET PER DAY**
ABILIFY MYCITE 15 MG	**ARIPIPRAZOLE**	**1 TABLET PER DAY**
ABILIFY MYCITE 20 MG	**ARIPIPRAZOLE**	**1 TABLET PER DAY**
ABILIFY MYCITE 2 MG	**ARIPIPRAZOLE**	**2 TABLETS PER DAY**
ABILIFY MYCITE 30 MG	**ARIPIPRAZOLE**	**1 TABLET PER DAY**
ABILIFY MYCITE 5 MG	**ARIPIPRAZOLE**	**1 TABLET PER DAY**
ARISTADA ER 1064 MG/3.9 ML SYRN	**ARIPIPRAZOLE LAUROXIL**	**3.9 ML EVERY 48 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 INITIO 675 MG/2.4 ML SYR	**ARIPIPRAZOLE LAUROXIL**	**2.4 ML EVERY 20 DAYS**
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
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 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 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**
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
PERSERIS ER 120 MG SYR KIT	**RISPERIDONE**	**1 PKG EVERY 20 DAYS**
PERSERIS ER 90 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**
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**
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

Disposition of Edit

Denial: Exception code “0681” (Step Therapy)
Rule Type: CE

Default Approval Period

1 year

References

- Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
- USPDI, Micromedex; 2020.
- Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC. Last accessed December 2020.
- Evidence-Based Medicine and Fiscal Analysis: “Antipsychotics, Atypical – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; October 2020.
- Evidence-Based Medicine Analysis: “Atypical Antipsychotics”, UMKC-DIC; November 2020.
- 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