



# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Atypical (2 <sup>nd</sup> Generation) Antipsychotics Clinical Edit
<b>First Implementation Date:</b>	November 24, 2015
<b>Revised Date:</b>	April 2, 2020
<b>Prepared for:</b>	MO HealthNet
<b>Prepared by:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** Ensure appropriate utilization and control of atypical (2nd Generation) 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
<ul style="list-style-type: none"> <li>• Aripiprazole</li> <li>• Clozapine</li> <li>• Latuda® (Sunovion Pharmaceuticals Inc)</li> <li>• Olanzapine</li> <li>• Olanzapine/Fluoxetine</li> <li>• Paliperidone ER</li> <li>• Quetiapine</li> <li>• Quetiapine ER</li> <li>• Risperidone</li> <li>• <b>Saphris®</b> (Allergan USA Inc)</li> <li>• Vraylar™ (Allergan USA Inc)</li> <li>• Ziprasidone</li> </ul>	<ul style="list-style-type: none"> <li>• Abilify®</li> <li>• Abilify MyCite®</li> <li>• Clozaril®</li> <li>• Fanapt®</li> <li>• Fazaclo®</li> <li>• Geodon®</li> <li>• Invega®</li> <li>• Nuplazid®</li> <li>• Rexulti™</li> <li>• Risperdal®</li> <li>• <b>Secuado®</b></li> <li>• Seroquel®</li> <li>• Seroquel XR®</li> <li>• Symbyax®</li> <li>• Versacloz®</li> <li>• Zyprexa®</li> <li>• Zyprexa® Zydis®</li> </ul>
Reference Depot Products	Non-Reference Depot Products
<ul style="list-style-type: none"> <li>• Abilify Maintena™ (Otsuka America Pharmaceutical Inc)</li> <li>• Aristada® (Alkermes Inc)</li> <li>• Aristada Initio® (Alkermes Inc)</li> <li>• Invega Sustenna® (Janssen Pharmaceuticals Inc)</li> <li>• Invega Trinza® (Janssen Pharmaceuticals Inc)</li> <li>• Perseris™ (Indivior Inc)</li> </ul>	<ul style="list-style-type: none"> <li>• Risperdal Consta®</li> <li>• Zyprexa® Relprevv™</li> </ul>

Type of Criteria:  Increased risk of ADE  
 Appropriate Indications

Reference Drug List  
 Clinical Edit

Data Sources:  Only Administrative Databases

Databases + Prescriber-Supplied

**Setting & Population**

- Drug class for review: Atypical (2<sup>nd</sup> Generation) 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 in the past 2 years **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 no approval criteria are 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:
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Drug Description	Generic Equivalent	Maximum Dosing Limitation
ABILIFY 10 MG	ARIPIRAZOLE	1 TABLET PER DAY
ABILIFY 15 MG	ARIPIRAZOLE	1 TABLET PER DAY
ABILIFY 2 MG	ARIPIRAZOLE	2 TABLETS PER DAY
ABILIFY 20 MG	ARIPIRAZOLE	1 TABLET PER DAY
ABILIFY 30 MG	ARIPIRAZOLE	1 TABLET PER DAY
ABILIFY 5 MG	ARIPIRAZOLE	1 TABLET PER DAY
<b>ABILIFY MAINTENA ER 300 MG SYR</b>	<b>ARIPIRAZOLE ER</b>	<b>1 PKG EVERY 20 DAYS</b>
<b>ABILIFY MAINTENA ER 300 MG VIAL</b>	<b>ARIPIRAZOLE ER</b>	<b>1 PKG EVERY 20 DAYS</b>
<b>ABILIFY MAINTENA ER 400 MG SYR</b>	<b>ARIPIRAZOLE ER</b>	<b>1 PKG EVERY 20 DAYS</b>
<b>ABILIFY MAINTENA ER 400 MG VIAL</b>	<b>ARIPIRAZOLE ER</b>	<b>1 PKG EVERY 20 DAYS</b>
<b>ARISTADA ER 1064 MG/3.9 ML SYR</b>	<b>ARIPIRAZOLE LAUROXIL</b>	<b>3.9 ML EVERY 48 DAYS</b>
<b>ARISTADA ER 441 MG/1.6 ML SYR</b>	<b>ARIPIRAZOLE LAUROXIL</b>	<b>1.6 ML EVERY 20 DAYS</b>
<b>ARISTADA ER 662 MG/2.4 ML SYR</b>	<b>ARIPIRAZOLE LAUROXIL</b>	<b>2.4 ML EVERY 20 DAYS</b>
<b>ARISTADA ER 882 MG/3.2 ML SYR</b>	<b>ARIPIRAZOLE LAUROXIL</b>	<b>3.2 ML EVERY 20 DAYS</b>
<b>ARISTADA ER INITIO 675 MG/2.4 ML SYR</b>	<b>ARIPIRAZOLE LAUROXIL</b>	<b>2.4 ML EVERY 20 DAYS</b>
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
<b>INVEGA SUSTENNA 117 MG</b>	<b>PALIPERIDONE PALMITATE</b>	<b>0.75 ML EVERY 20 DAYS</b>
<b>INVEGA SUSTENNA 156 MG</b>	<b>PALIPERIDONE PALMITATE</b>	<b>1 ML EVERY 20 DAYS</b>
<b>INVEGA SUSTENNA 234 MG</b>	<b>PALIPERIDONE PALMITATE</b>	<b>1.5 ML EVERY 20 DAYS</b>
<b>INVEGA SUSTENNA 39 MG</b>	<b>PALIPERIDONE PALMITATE</b>	<b>0.25 ML EVERY 20 DAYS</b>
<b>INVEGA SUSTENNA 78 MG</b>	<b>PALIPERIDONE PALMITATE</b>	<b>0.5 ML EVERY 20 DAYS</b>
<b>INVEGA TRINZA 273 MG/0.875 ML</b>	<b>PALIPERIDONE</b>	<b>0.875 ML EVERY 76 DAYS</b>
<b>INVEGA TRINZA 410 MG/1.315 ML</b>	<b>PALIPERIDONE</b>	<b>1.315 ML EVERY 76 DAYS</b>
<b>INVEGA TRINZA 546 MG/1.75 ML</b>	<b>PALIPERIDONE</b>	<b>1.75 ML EVERY 76 DAYS</b>
<b>INVEGA TRINZA 819 MG/2.625 ML</b>	<b>PALIPERIDONE</b>	<b>2.625 ML EVERY 76 DAYS</b>
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
<b>PERSERIS ER 120 MG SYR KIT</b>	<b>RISPERIDONE</b>	<b>1 PKG EVERY 20 DAYS</b>
<b>PERSERIS ER 90 MG SYR KIT</b>	<b>RISPERIDONE</b>	<b>1 PKG EVERY 20 DAYS</b>

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RISPERDAL CONSTA 12.5 MG SYR	RISPERIDONE	2 PKG EVERY 20 DAYS
RISPERDAL CONSTA 25 MG	RISPERIDONE	2 PKG EVERY 20 DAYS
RISPERDAL CONSTA 37.5 MG	RISPERIDONE	2 PKG EVERY 20 DAYS
RISPERDAL CONSTA 50 MG	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
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:

## 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; 2019.
- USPDI, Micromedex; 2019.
- Facts and Comparisons eAnswers (online); 2019 Clinical Drug Information, LLC. Last accessed December 2019.
- Evidence-Based Medicine and Fiscal Analysis: "Antipsychotics, Atypical – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; October 2019.
- Evidence-Based Medicine Analysis: "Atypical Antipsychotics", UMKC-DIC; October 2019.
- 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>

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