

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Antipsychotics - 2 <sup>nd</sup> Generation (Atypical) Clinical Edit and Reference List
<b>First Implementation Date:</b>	November 24, 2015
<b>Proposed Date:</b>	December 16, 2021
<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 2<sup>nd</sup> Generation (Atypical) Antipsychotics and to impose a state-specific open access reference drug list

**Why Issue Selected:** Atypical or 2<sup>nd</sup> 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 1<sup>st</sup> generation antipsychotics have a significant potential to cause extrapyramidal side effects and tardive dyskinesia; atypical or 2<sup>nd</sup> 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 2<sup>nd</sup> generation antipsychotics are consistently found on our quarterly top 25 drugs by cost. This edit does not restrict access to any atypical or 2<sup>nd</sup> 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 ODT/Soln/Tab</li> <li>• Clozapine Tab</li> <li>• Fanapt® (Vanda Pharmaceuticals Inc.)</li> <li>• Latuda® (Sunovion Pharmaceuticals Inc)</li> <li>• Olanzapine ODT/Tab</li> <li>• Olanzapine/Fluoxetine Cap</li> <li>• <b>Paliperidone ER Tab</b></li> <li>• Quetiapine Tab</li> <li>• Quetiapine ER Tab</li> <li>• Rexulti® (Otsuka America Pharmaceutical Inc.)</li> <li>• Risperidone ODT/Soln/Tab</li> <li>• Saphris® (Allergan USA Inc)</li> <li>• Vraylar® (Allergan USA Inc)</li> <li>• Ziprasidone Cap</li> </ul>	<ul style="list-style-type: none"> <li>• Abilify®</li> <li>• Abilify MyCite®</li> <li>• <b>Asenapine</b></li> <li>• Caplyta®</li> <li>• Clozapine ODT</li> <li>• Clozaril®</li> <li>• Fazaclo®</li> <li>• Geodon®</li> <li>• Invega®</li> <li>• <b>Lybalvi™</b></li> <li>• Nuplazid®</li> <li>• Risperdal®</li> <li>• Secuado®</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>• <b>Invega Hafyera™ (Janssen Pharmaceuticals Inc)</b></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: 2<sup>nd</sup> 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
- 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**

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- Documented history of ≥ 3 months of Invega Trinza therapy in the past 4 months
- For Nuplazid: documented diagnosis of hallucinations and delusions associated with Parkinson's disease psychosis

## 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 2 MG	ARIPIPRAZOLE	2 TABLETS PER DAY
ABILIFY 5 MG	ARIPIPRAZOLE	2 TABLETS PER DAY
ABILIFY 10 MG	ARIPIPRAZOLE	1 TABLET PER DAY
ABILIFY 15 MG	ARIPIPRAZOLE	1 TABLET PER DAY
ABILIFY 20 MG	ARIPIPRAZOLE	1 TABLET PER DAY
ABILIFY 30 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 2 MG	ARIPIPRAZOLE	2 TABLETS PER DAY
ABILIFY MYCITE 5 MG	ARIPIPRAZOLE	1 TABLET PER DAY
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 30 MG	ARIPIPRAZOLE	1 TABLET PER DAY
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
CAPLYTA 42MG CAPSULE	LUMATEPERONE TOSYLATE	1 CAPSULE PER DAY
FANAPT 1 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
FANAPT 10 MG	ILOPERIDONE	2 TABLETS PER DAY
FANAPT 12 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 HAFYERA 1,092 MG/3.5 ML</b>	<b>PALIPERIDONE PALMITATE</b>	<b>3.5 ML EVERY 152 DAYS</b>

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<b>INVEGA HAFYERA 1,560 MG/5 ML</b>	<b>PALIPERIDONE PALMITATE</b>	<b>5 ML EVERY 152 DAYS</b>
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
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
LATUDA 120 MG	LURASIDONE HYDROCHLORIDE	1 TABLET PER DAY
<b>LYBALVI 5-10 MG TABLET</b>	<b>OLANZAPINE/SAMIDORPHAN</b>	<b>1 TABLET PER DAY</b>
<b>LYBALVI 10-10 MG TABLET</b>	<b>OLANZAPINE/SAMIDORPHAN</b>	<b>1 TABLET PER DAY</b>
<b>LYBALVI 15-10 MG TABLET</b>	<b>OLANZAPINE/SAMIDORPHAN</b>	<b>1 TABLET PER DAY</b>
<b>LYBALVI 20-10 MG TABLET</b>	<b>OLANZAPINE/SAMIDORPHAN</b>	<b>1 TABLET PER DAY</b>
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
SAPHRIS 2.5 MG	ASENAPINE MALEATE	2 TABLETS PER DAY
SAPHRIS 5 MG	ASENAPINE MALEATE	2 TABLETS PER DAY
SAPHRIS 10 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:

MedWatch Form:

Progress Notes:

Other:

## Disposition of Edit

Denial: Exception code "0681" (Step Therapy)

Rule Type: CE

## Default Approval Period

**3 months**

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## References

- USPDI, Micromedex; 2021.
- Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.
- Evidence-Based Medicine and Fiscal Analysis: “Antipsychotics, Atypical – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; October 202.
- Evidence-Based Medicine Analysis: “Atypical Antipsychotics”, UMKC-DIC; October 2021.
- 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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