



Clinical Edit Criteria Proposal

Drug/Drug Class: **Atypical Antipsychotic Clinical Edit**
 Date: **January 11, 2018**
 Prepared for:
 Prepared by: **MO HealthNet**

New Criteria

Revision of Existing Criteria

Executive Summary

Purpose: Ensure appropriate and prudent use atypical antipsychotic medications within the MO HealthNet Pharmacy program.

Patient safety is at the heart of MO HealthNet administration and Pharmacy management decision-making. Protecting participants in the Pharmacy program includes assessing for utilization of the atypical antipsychotic medications. By using medical evidence guidelines, this clinical edit is intended to flag potentially inappropriate therapy for these agents. Additionally, some participants are cared for by multiple prescribers and have medications filled at different pharmacies. Without a clinical edit capability, it is almost impossible to prevent duplication within a drug class, dangerous drug interactions, or overmedication. The clinical edit does not replace medical practice and professional judgment. The edit helps to provide an “early warning alert” to the pharmacist filling the prescription and the prescribing physician. Even if the edit is “triggered” and the physician wishes to over-ride the process for medically necessary reasons, as is presently true for all other drug classes the drug can be approved with further medical input through direct communication with the MHD Hotline. As the clinical edits are reviewed and updated, compliance and efficacy with existing medications are always taken into account, helping to ensure a smooth transition for current participants.

Why was this Issue Selected: The Centers for Medicare & Medicaid Services (CMS), Medicaid Integrity Group (MIG) has identified issues with the utilization of the atypical antipsychotic drug therapy class in specific patient populations. The MIG has identified that some providers may have prescribed atypical antipsychotics outside of FDA-approved product labeling for indication, age, dosage, or duration of therapy. Therefore, CMS’s goal is to improve quality of care and enhance patient safety by educating providers on the proper use of atypical antipsychotics in pediatric patients. MO HealthNet will review and implement changes to the approval process to ensure appropriate utilization of atypical antipsychotics across all patient populations.

Setting & Population: All Patients

Type of Criteria: Increased risk of ADE Non-Preferred Agent
 Appropriate Utilization Other:

Data Sources: Only administrative databases Databases + Prescriber-supplied

SFY2017	CLAIMS	SPEND	PERCENTAGE OF TOTAL DRUG SPEND
Atypical Antipsychotics (Oral)	440,551	\$134,264,407	9.53%
Atypical Antipsychotics (Injectables)	28,489	\$41,407,184	2.94%

*Total MHD Drug Spend for SFY17 = **\$1.41 Billion**

Setting & Population

- Drug/drug class for review: Atypical Antipsychotics
- Age range: All patients
- Gender: males and females

Approval Criteria

- Atypical Antipsychotic monotherapy for the treatment of schizophrenia, bipolar disorder, or psychosis
- Appropriate diagnosis (see diagnosis table – Appendix A)
- Doses not exceeding recommended maximum doses (see Table 1)
- Documented compliance to current therapy regimen (adults – 90 days of therapy out of the most recent 120 days)

EFFECTIVE 1/1/2018: Prescribers will be required to submit documentation of recent laboratory testing and monitoring for metabolic syndrome, for APPROVAL of all new and continuing Antipsychotic Drug Therapy. Laboratory testing should include fasting blood glucose, lipid profile (total cholesterol, HDL, LDL, triglycerides), weight and calculation of BMI.

Table of Metabolic Monitoring Parameters Based on American Diabetes Association/American Psychiatric Association Consensus Guidelines

Measure	Baseline	4 Weeks	8 Weeks	12 Weeks	Annually
Personal/family of Diabetes and Hyperlipidemia	X			X	X
Body Mass Index (BMI)	X	X	X	X	X
Waist circumference	X			X	X
Blood pressure	X			X	X
Fasting blood glucose/hemoglobin A1c	X			X	X
Fasting lipid profile	X			X	X

Magellan Health Services. Second Generation Antipsychotic Tip Sheet. N.p.: Magellan Health Services, 12/11. Essential Tools for Atypical Antipsychotics Monitoring. Independence, Dec. 2011. Web. 19 Sept 2012

Approval Diagnoses (Appendix A)		
Condition	Inferred Drugs	Date Range
Acute Psychosis	--	720 days
ADHD	--	720 days
Conduct Disorder/Disturbance	--	720 days
Agitation	--	720 days
Autism	--	720 days
Bipolar	--	720 days
Delirium	--	720 days
Dementia	--	720 days
Depression	--	720 days
Obsessive Compulsive Disorder	--	720 days
Schizophrenia	--	720 days
Singultus	--	720 days
Tourette's Syndrome	--	720 days
Tremor	--	720 days

**Oppositional Defiant Disorder was removed as a qualifying diagnosis in 2016*

Denial Criteria

- **Absence of medical/lab data in claims history documenting metabolic testing (e.g. basic metabolic panel, lipid profile, etc.) or failure to submit with new Rx**
- Use of more than two atypical antipsychotics for more than 60 of the past 90 days
- For under 18 years:
 - Use of more than 2 atypical antipsychotics for more than 30 days
- Use of atypical antipsychotic for children under age 9 years
- Use of atypical antipsychotic at higher than recommended max dose (see Table 1)
- Claim for Invega Trinza without prior history of at least 4 months of Invega Sustenna
- Claim is for non-reference product

Required Documentation

Laboratory results:
MedWatch form:

X

Progress notes:

X

Disposition of Edit

- **Denial:** 681 “Step Therapy”

References

1. Drug Effectiveness Review Project – Drug Class Review: “Second Generation Antipsychotics Report”, Center for Evidence-Based Policy, Oregon Health & Science University; October 2016; Evidence Scan Update, April 2017.
2. Evidence-Based Medicine and Fiscal Analysis: “Antipsychotics Therapeutic Class Review”, Provider Synergies, L.L.C., Mason, OH; August 2017.
3. U.S. Department of Health and Human Services. Agency for Healthcare Research and Quality. (2007, January). Efficacy and Comparative Effectiveness of Off-Label Use of Atypical Antipsychotics: Executive Summary. (AHRQ Pub. No. 07-EHC003-1). Retrieved October 6, 2011, from http://www.effectivehealthcare.ahrq.gov/ehc/products/5/64/Atypical_Executive_Summary.pdf
4. U.S. Department of Health and Human Services. Agency for Healthcare Research and Quality. (2011, September). Off-Label Use of Atypical Antipsychotics: An Update. (AHRQ Publication No. 11-EHC087-EF). Retrieved October 6, 2011, from http://www.effectivehealthcare.ahrq.gov/ehc/products/150/778/CER43_Off-LabelAntipsychotics_20110928.pdf
5. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2015.
6. Drug Facts and Comparisons: eFacts Electronic Edition – On-line; 2017.
7. USPDI, Micromedex, 2017.
8. Clinical Pharmacology Online, 2017.
9. Missouri Behavioral Pharmacy Management Program, CNS/CMT; 2017.

Atypical Antipsychotic Table 1 (Dosing)

Drug name	Maximum Daily Dose
ABILIFY 1 MG/ML SOLUTION	30mg
ABILIFY 10 MG TABLET	30mg
ABILIFY 15 MG TABLET	30mg
ABILIFY 2 MG TABLET	30mg
ABILIFY 20 MG TABLET	30mg
ABILIFY 30 MG TABLET	30mg
ABILIFY 5 MG TABLET	30mg
ABILIFY 9.7 MG/1.3 ML VIAL	30mg
ABILIFY DISCMELT 10 MG TABLET	30mg
ABILIFY DISCMELT 15 MG TABLET	30mg
ABILIFY MAINTENA ER 300 MG VIAL/SYR	300 mg/30 days (1 vial/ 30 days)
ABILIFY MAINTENA ER 400 MG VIAL/SYR	400 mg/30 days (1 vial/30 days)
ARISTADA ER 441 MG/1.6 ML SYRN	441mg/30 days (1 syringe/30 days)
ARISTADA ER 662 MG/2.4 ML SYRN	662mg/30 days (1 syringe/30 days)
ARISTADA ER 882 MG/3.2 ML SYRN	882mg/30 days (1 syringe/30 days)
CLOZAPINE 100 MG TABLET	900mg
CLOZAPINE 200 MG TABLET	900mg
CLOZAPINE 25 MG TABLET	900mg
CLOZAPINE 50 MG TABLET	900mg
CLOZAPINE ODT 100 MG TABLET	900mg
CLOZAPINE ODT 12.5 MG TABLET	900mg
CLOZAPINE ODT 25 MG TABLET	900mg
FANAPT 1 MG TABLET	24mg
FANAPT 10 MG TABLET	24mg
FANAPT 12 MG TABLET	24mg
FANAPT 2 MG TABLET	24mg
FANAPT 4 MG TABLET	24mg
FANAPT 6 MG TABLET	24mg
FANAPT 8 MG TABLET	24mg
FANAPT TITRATION PACK	24mg
FAZACLO 150 MG ODT	900mg
FAZACLO 200 MG ODT	900mg
GEODON 20 MG CAPSULE	240mg
GEODON 20 MG VIAL	40mg
GEODON 40 MG CAPSULE	240mg
GEODON 60 MG CAPSULE	240mg
GEODON 80 MG CAPSULE	240mg
INVEGA ER 1.5 MG TABLET	12mg
INVEGA ER 3 MG TABLET	12mg
INVEGA ER 6 MG TABLET	12mg

Drug name	Maximum Daily Dose
INVEGA ER 9 MG TABLET	12mg
INVEGA SUSTENNA 117 MG PREF SY	234mg/4 weeks
INVEGA SUSTENNA 156 MG PREF SY	234mg/4 weeks
INVEGA SUSTENNA 234 MG PREF SY	234mg/4 weeks
INVEGA SUSTENNA 39 MG PREF SYR	234mg/4 weeks
INVEGA SUSTENNA 78 MG PREF SYR	234mg/4 weeks
INVEGA TRINZA 273 MG/0.875 ML	819MG/12 weeks
INVEGA TRINZA 410 MG/1.315 ML	819MG/12 weeks
INVEGA TRINZA 546 MG/1.75 ML	819MG/12 weeks
INVEGA TRINZA 819 MG/2.625 ML	819MG/12 weeks
LATUDA 120 MG TABLET	160mg
LATUDA 20 MG TABLET	160mg
LATUDA 40 MG TABLET	160mg
LATUDA 80 MG TABLET	160mg
LATUDA 60 MG TABLET	160mg
OLANZAPINE 10 MG TABLET	40 mg
OLANZAPINE 10 MG VIAL	40 mg
OLANZAPINE 15 MG TABLET	40 mg
OLANZAPINE 2.5 MG TABLET	40 mg
OLANZAPINE 20 MG TABLET	40 mg
OLANZAPINE 5 MG TABLET	40 mg
OLANZAPINE 7.5 MG TABLET	40 mg
OLANZAPINE ODT 10 MG TABLET	40 mg
OLANZAPINE ODT 15 MG TABLET	40 mg
OLANZAPINE ODT 20 MG TABLET	40 mg
OLANZAPINE ODT 5 MG TABLET	40 mg
OLANZAPINE-FLUOXETINE 12-25 MG	3 capsules
OLANZAPINE-FLUOXETINE 12-50 MG	1 capsule
OLANZAPINE-FLUOXETINE 3-25 MG	3 capsules
OLANZAPINE-FLUOXETINE 6-25 MG	3 capsules
OLANZAPINE-FLUOXETINE 6-50 MG	1 capsule
QUETIAPINE FUMARATE 100 MG TAB	1200mg
QUETIAPINE FUMARATE 200 MG TAB	1200mg
QUETIAPINE FUMARATE 25 MG TAB	1200mg
QUETIAPINE FUMARATE 300 MG TAB	1200mg
QUETIAPINE FUMARATE 400 MG TAB	1200mg
QUETIAPINE FUMARATE 50 MG TAB	1200mg
REXULTI 0.25 MG TABLET	4 mg
REXULTI 0.5 MG TABLET	4 mg
REXULTI 1 MG TABLET	4 mg
REXULTI 2 MG TABLET	4 mg
REXULTI 3 MG TABLET	4 mg
REXULTI 4 MG TABLET	4mg

Drug name	Maximum Daily Dose
RISPERDAL 0.5 MG TABLET	16mg
RISPERDAL 1 MG TABLET	16mg
RISPERDAL 1 MG/ML SOLUTION	16mg
RISPERDAL 2 MG TABLET	16mg
RISPERDAL 3 MG TABLET	16mg
RISPERDAL 4 MG TABLET	16mg
RISPERIDONE 1 MG/ML DISP SYRINGE ORAL	16mg
RISPERIDONE 2 MG/2 ML DISP SYRINGE ORAL	16mg
RISPERIDONE 3 MG/3 ML DISP SYRINGE ORAL	16mg
RISPERDAL CONSTA 12.5 MG SYR	50mg/2 weeks
RISPERDAL CONSTA 25 MG SYR	50mg/2 weeks
RISPERDAL CONSTA 37.5 MG SYR	50mg/2 weeks
RISPERDAL CONSTA 50 MG SYR	50mg/2 weeks
RISPERDAL M-TAB 0.5 MG ODT	16mg
RISPERDAL M-TAB 1 MG ODT	16mg
RISPERDAL M-TAB 2 MG ODT	16mg
RISPERDAL M-TAB 3 MG ODT	16mg
RISPERDAL M-TAB 4 MG ODT	16mg
RISPERIDONE 0.25 MG ODT	16mg
SAPHRIS 10 MG TAB SL BLK CHERY	20mg
SAPHRIS 5 MG TAB SL BLK CHERRY	20mg
SEROQUEL XR 150 MG TABLET	1200mg
SEROQUEL XR 200 MG TABLET	1200mg
SEROQUEL XR 300 MG TABLET	1200mg
SEROQUEL XR 400 MG TABLET	1200mg
SEROQUEL XR 50 MG TABLET	1200mg
VERSACLOZ 50 MG/ML ORAL SUSPENSION	900 mg
VRAYLAR 1.5 MG/3 MG PACK	6 mg
VRAYLAR 1.5 MG CAPSULE	6 mg
VRAYLAR 3 MG CAPSULE	6 mg
VRAYLAR 4.5 MG CAPSULE	6 mg
VRAYLAR 6 MG CAPSULE	6 mg
ZYPREXA RELPREVV 210 MG VIAL	405mg every 4 weeks
ZYPREXA RELPREVV 300 MG VIAL	405mg every 4 weeks
ZYPREXA RELPREVV 405 MG VIAL	405mg every 4 weeks