



Clinical Policy: Concomitant Antipsychotic Treatment

Reference Number: AZ.CP.PMN.10 Effective Date: 07.16 Last Review Date: 07.20 Line of Business: Arizona Medicaid (AzCH-CCP and Care1st)

Revision Log

See <u>Important Reminder</u> at the end of this policy for important regulatory and legal information.

Description

Concomitant use of more than one second-generation (atypical) antipsychotic

AHCCCS preferred drugs – multiple—refer to AHCCCS Preferred Drug List.

<u>AHCCCS non-preferred drugs</u> in this class include Abilify MyCite, Seroquel ER (quetiapine ER), Saphris.

FDA approved indications

- Cross tapers will automatically be approved for 60 days at the Point of Sale (POS). Providers must submit a prior authorization request for continued utilization of concomitant use of any 2 atypical antipsychotics beyond the 60 days allowed for cross tapering. This policy includes oral dosage forms in combination with injectable dosage forms of the same agent. (i.e. Abilify and Abilify Maintena; risperidone and Risperdal Consta);
- Prescribers must be contracted behavioral health professionals (BHMP).

Policy/Criteria

Provider <u>must</u> submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Provider must provide supporting documentation that adherence to the treatment regimen has not been a contributing factor to the lack of response in the medication trial.

It is the policy of Arizona Complete Health-Complete Care Plan and Care1st that Concomitant is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

- A. Refractory Schizophrenia Spectrum Disorder (must meet all):
 - 1. Diagnosis of schizophrenia, schizoaffective disorder, or schizophreniform disorder;
 - 2. Prescribed by contracted BHMP;
 - 3. Age \geq 18 years;
 - a. If less than 18, see AZ.CP.PMN.08- Antipsychotic Medications in Children Under 18.





- 4. Evidence of adequate trials of at least three (3) individual antipsychotics listed on the AHCCCS Behavioral Health Drug Lists, for 4-6 weeks at maximum tolerated doses;
- 5. Failure due to one of the following (a, b, OR c):
 - a. Inadequate response to maximum tolerated dose;
 - b. Adverse reaction(s);
 - c. Documented break through symptoms;
- 6. Provider must provide supporting documentation that adherence to the treatment regimen has not been a contributing factor to the lack of response in the medication trials.

Approval duration: 6 months

- **B. Refractory Bipolar Disorder with Psychosis and/or Severe Symptoms** (must meet all):
 - 1. Diagnosis of Bipolar Disorder with Psychosis and/or Severe Symptoms;
 - 2. Evidence of adequate trials of at least four (4) evidence based treatment options dependent upon the episode type. Trials may include, but are not limited to combination therapy of antipsychotics and mood stabilizers and/or anticonvulsants. Trials should be 4-6 weeks of maximum tolerated doses, with failure due to:
 - a. Inadequate response to maximum tolerated dose;
 - b. Adverse reaction(s);
 - c. Breakthrough symptoms;
 - 3. Provider must provide supporting documentation that adherence to the treatment regimen has not been a contributing factor to the lack of response in the medication trials.

Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): AZ.CP.PMN.53 for Arizona Medicaid.

II. Continued Therapy

- A. Refractory Schizophrenia spectrum disorders and refractory bipolar disorder with psychosis and/or severe symptoms (must meet all):
 - 1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - 2. Documentation of positive response to therapy.

Approval duration: 6 months

- **B. Refractory Bipolar Disorder with Psychosis and/or Severe Symptoms** (must meet all):
 - 1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;





- 2. Documentation of positive response to therapy **Approval duration: 6 months**
- C. Other diagnoses/indications (must meet 1 or 2):
 - 1. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy AZ.CP.PMN.53 or evidence of coverage documents

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies AZ.CP.PMN.53 for Arizona Medicaid.
- **B.** Prescriptions written by **non**-behavioral health professionals.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key FDA: Food and Drug Administration BHMP: Behavioral Health Medical Professional POS: Point of Sale

Appendix B: Therapeutic Alternatives N/A

Appendix C: Contraindications/Boxed Warnings See individual Package Inserts.

Appendix D: General Information N/A

V. Dosage and Administration *

*Only Preferred or formulary atypical antipsychotics listed.

Drug Name	Indication	Dosing Regimen	Maximum Dose
Aripiprazole (Abilify, Abilify Maintena, Aristada, Abilify MyCite)	Schizophrenia	Adults:10- 30mg PO/day Adolescents: 2- 30mg/day Adults:	30mg/day oral 400mg IM/month
		Maintena:300- 400mg IM/ month	





Drug Name	Indication	Dosing	Maximum Dose
		Regimen	
	Bipolar	Adults: Aristada: 441mg-882mg IM/ 6 weeks 1064mg IM/ 2 months	882mg IM/month Or 1064mg/IM Q2 months.
		Adults: 15mg- 30mg/day	30mg/day oral 400mgIM/month 30mg/day oral
		Children- Adolescents: 2- 30mg PO day	
		Maintena: 300- 400mg IM/month	
		Abilify MyCite: 5mg- 30mg daily	
Clozapine (Clozaril, Fazaclo)	Schizophrenia, schizoaffective	Adults:12.5mg- 450mg/day in divided doses Children & Adolescents: 6.25mg –	Adults:900mg/day Children & Adolescents: 300mg/day
	Bipolar (off label)	300mg/day 50-400mg/day	
Lurasidone (Latuda)	Schizophrenia	Adults: 40- 160mg QD	Adults: 160mg/day
		Adolescents: 40-80mg	Adolescents: 80mg/day





Drug Name	Indication	Dosing	Maximum Dose
		Regimen	
	Bipolar depression	QD Adults: 20- 120mg QD Children & Adolescents: 20mg-80mg QD	Adults:120mg/day Children & Adolescents: 80mg/day
Olanzapine (Zyprexa, Zyprexa Zydis)	Schizophrenia Bipolar	Adults: 5mg- 10mg QD Children & Adolescents: 2.5mg-10mg QD Adults: 10- 20mg QD Adolescents: 2.5mg-10mg QD	20mg/day
Paliperidone (Invega Sustenna, Invega Trinza)	Schizophrenia/Schizoaffective disorder	Adults: Sustenna: 39- 234 mg IM Q monthly Trinza: 273- 819mg IM Q 3 months	Sustenna: 234mg IM every month Trinza: 819mg IM every 3 months.
Quetiapine(Seroquel IR)	Schizophrenia Bipolar	Adults: 25mg- 800mg/day Adolescents: 25mg-400mg	Adults and Adolescents: 800mg/day Children > 10 years: 600mg/day





Drug Name	Indication	Dosing Regimen	Maximum Dose
		Adults: 50- 800mg/day	
		Children & Adolescents: 25mg- 600mg/day	
Risperidone (Risperdal,Risperdal Consta, Perseris)	Schizophrenia	Adults: 2mg- 16mg PO/day	16mg/day PO
		Adolescents: 0.5mg-6mg PO/day	Adolescents: 6mg/day PO
		Consta: Adults: 25mg-50mg IM every 2 weeks	50mg Q 2 weeks
		Perseris: Adults: 90mg or 120mg SC once monthly	120mg Q 4 weeks
	Bipolar	Adults: 2- 6mg/day PO	6mg/day PO 50mg IM Q2 weeks
		Children & Adolescents: 0.5mg- 6mg/day PO	6mg/day PO
Ziprasidone (Geodon)	Schizophrenia Bipolar	Adults: 20mg- 80mg BID Adults: 40mg- 80mg BID	160mg/day





VI. Product Availability

Drug Name	Availability	
	Tablets: 2mg,5mg,10mg,15mg, 20mg	
	Orally disintegrating tablet: 10mg, 15mg Oral solution: 1mg/ml	
Aripiprazole (Abilify, Abilify Maintena, Aristada, Abilify	Powder for suspension for injection: Abilify Maintena: 300mg and 400mg	
MyCite)	Suspension for Injection: Aristada 441mg/1.6ml; 662mg/2.4ml; 882mg/3.2ml; 1064mg/3.9ml	
	Tablet with sensor: Abilify MyCite 2mg, 5mg, 10mg, 15mg, 20mg, 30mg	
Clozapine (Clozaril, Fazaclo)	Orally disintegrating tablet: 12.5mg, 25mg, 100mg, 150mg, 200mg	
	Tablets: 12.5mg, 25mg, 50mg, 100mg, 200mg	
Lurasidone(Latuda)	Tablets: 20mg, 40mg, 60mg, 80mg, 120mg	
Olanzapine(Zyprexa,	Orally disintegrating tablet: 5mg, 10mg, 15mg, 20mg	
Zyprexa Zydis)	Tablet: 2.5mg, 5mg, 10mg, 15mg, 20mgSuspension for injection:	
Paliperidone(Invega Sustenna, Invega Trinza)	Sustenna:39mg/0.25ml; 78mg/0.5ml; 117mg/0.75ml; 156mg/1ml; 234mg/1.5ml Trinza: 273mg, 410mg, 546mg, 819mg	
Quetiapine(Seroquel IR)	Tablets: 25mg, 50mg, 100mg, 200mg, 300mg, 400 mg	
	Orally disintegrating tablets: 0.25mg, 0.5mg, 1mg, 2mg, 3mg, 4mg Oral solution: 1mg/ml	
Risperidone(Risperdal, Risperdal Consta, Perseris)	Tablet: 0.25mg, 0.5mg, 1mg, 2mg, 3mg, 4mgPowder for solution for injection (Consta): 12.5mg, 25mg,37.5mg, 50mg	





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Generic Name

Drug Name	Availability
	Extended-release injectable suspension (Perseris): 90mg,
	120mg
Ziprasidone (Geodon)	Capsules: 20mg, 40mg, 60mg, 80mg

VII. References

- 1. Arizona Complete Health-Complete Care Plan Provider Manual Section 3.8 (Behavioral Health Network provider Service Delivery Requirements-Psychotropic Medication: Prescribing and Monitoring 2020 edition.
- 2. Correll CU, Rummel-Kluge C, Corves C, et al. Antipsychotic combinations vs monotherapy in schizophrenia: A meta-analysis of randomized controlled trials. Schizophrenia Bulletin, 2009; **35**: 443-457.
- 3. Essock SM, Schooler NR, Stroup TS, et al. Effectiveness of switching from antipsychotic polypharmacy to monotherapy. Am. J. Psychiatry, 2011; **168**:702-708.
- 4. Tandon R, Belmaker RH, Gattaz WF, et al. World Psychiatric Association Pharmacopsychiatry Section statement on comparative effectiveness of antipsychotics in the treatment of schizophrenia. Schizophrenia Research, 2008; **100**: 20-38.
- 5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: <u>http://www.clinicalpharmacology-ip.com/</u>.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template	03.18	07.18
Added Dosage and Administration; Added Product availability		
Renamed policy, added new logo and removed Saphris from	07.19	07.19
preferred products; added Abilify MyCite; added Perseris.		
Annual review: references reviewed and updated; policy formatted.	07.20	07.20
Added Care1st logo. Added verbiage to specify that criteria also	5.10.21	04.21
applies to Care1st.		

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health





plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.





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