Clinical Policy: Concomitant Antipsychotic Treatment

Reference Number: AZ.CP.PMN.10
Effective Date: 07.16
Last Review Date: 02.24
Line of Business: Arizona Medicaid (AzCH-CCP and Care1st) Revision Log

See Important Reminder 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.

AHCCCS non-preferred drugs in this class include (but not limited to) - Abilify MyCite, Seroquel ER (quetiapine ER), Saphris.

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

- In case of concomitant use of a long-acting injectable (LAI) second-generation antipsychotic and oral second-generation antipsychotic, use the AHCCCS FFS PA Criteria on Antipsychotics for the LAI antipsychotic, and use this policy AZ.CP.PMN.10 Concomitant Antipsychotic Treatment to review the oral antipsychotic.

- Prescribers must be contracted behavioral health professionals (BHMP).

- For Age Limit review, refer to AHCCCS FFS PA Criteria on Antipsychotics.

Policy/Criteria
Provider must 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:

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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. 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;
4. 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;
5. 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 (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 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	30mg/day oral

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

Drug Name	Indication	Dosing Regimen	Maximum Dose
Lurasidone (Latuda)	Schizophrenia Bipolar depression	Adults: 40-160mg QD Adolescents: 40-80mg QD Adults: 20-120mg QD Children & Adolescents: 20mg-80mg QD	Adults: 160mg/day Adolescents: 80mg/day 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	Adults: 25mg-800mg/day	Adults and Adolescents:

Drug Name	Indication	Dosing Regimen	Maximum Dose
	Bipolar	Adolescents: 25mg-400mg Adults: 50-800mg/day Children & Adolescents: 25mg-600mg/day	800mg/day Children > 10 years: 600mg/day
Risperidone (Risperdal,Risperdal Consta, Perseris)	Schizophrenia	Adults: 2mg-16mg PO/day Adolescents: 0.5mg-6mg PO/day Consta: Adults: 25mg-50mg IM every 2 weeks Perseris: Adults: 90mg or 120mg SC once monthly	16mg/day PO Adolescents: 6mg/day PO 50mg Q 2 weeks 120mg Q 4 weeks
	Bipolar	Adults: 2-6mg/day PO Children & Adolescents: 0.5mg-6mg/day PO	6mg/day PO 50mg IM Q2 weeks 6mg/day PO
Ziprasidone (Geodon)	Schizophrenia Bipolar	Adults: 20mg-80mg BID Adults: 40mg-80mg BID	160mg/day

VI. Product Availability

Drug Name	Availability
Aripiprazole (Abilify, Abilify Maintena, Aristada, Abilify MyCite)	Tablets: 2mg,5mg,10mg,15mg, 20mg Orally disintegrating tablet: 10mg, 15mg Oral solution: 1mg/ml Powder for suspension for injection: Abilify Maintena: 300mg and 400mg 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, Zyprexa Zydis)	Orally disintegrating tablet: 5mg, 10mg, 15mg, 20mg Tablet: 2.5mg, 5mg, 10mg, 15mg, 20mg
Paliperidone(Invega Sustenna, Invega Trinza)	Suspension for injection: **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
Risperidone(Risperdal, Risperdal Consta, Perseris)	Orally disintegrating tablets: 0.25mg, 0.5mg, 1mg, 2mg, 3mg, 4mg Oral solution: 1mg/ml Tablet: 0.25mg, 0.5mg, 1mg, 2mg, 3mg, 4mg

Drug Name	Availability
	Powder for solution for injection (Consta): 12.5mg, 25mg, 37.5mg, 50mg 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 12.9 (Behavioral Health Network provider Service Delivery Requirements-Psychotropic Medication: Prescribing and Monitoring) – revised 02/2023.
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: Elsevier; 2023. Available at: https://www.clinicalkey.com/pharmacology/. Accessed February 9, 2023.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template Added Dosage and Administration; Added Product availability	03.18	07.18
Renamed policy, added new logo and removed Saphris from preferred products; added Abilify MyCite; added Perseris.	07.19	07.19
Annual review: references reviewed and updated; policy formatted.	07.20	07.20
Added Care1st logo. Added verbiage to specify that criteria also applies to Care1st.	5.10.21	04.21
1Q22 Annual Review: no significant changes; References reviewed and updated.	02.11.22	03.22
1Q23 Annual Review: Added guidance in case of concomitant use of a long-acting injectable (LAI) second-generation antipsychotic and oral second-generation antipsychotic, use the AHCCCS FFS PA Criteria on Antipsychotics for the LAI antipsychotic, and use this policy AZ.CP.PMN.10 Concomitant Antipsychotic Treatment to review the oral antipsychotic; For Age Limit review, refer to	02.09.23	02.23

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
AHCCCS FFS PA Criteria on Antipsychotics; References reviewed and updated.		
1Q 2024 Annual review: No significant changes. .	02.01.24	

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.

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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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.