UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Antipsychotics- ARIZONA

Program	Prior Authorization
Medication	Antipsychotics

1. Background:

Preferred Typical Antipsychotics	**Non-Preferred Typical Antipsychotics**
Haldol® (haloperidol) concentrate/tablets* Haldol decanoate® (haloperidol decanoate solution)* Loxitane® (loxapine) capsules* Trilafon (perphenazine) tablets* Mellaril® (thioridazine) tablets* Navane® (thiothixene) capsules* Orap® (pimozide) tablets* Prolixin® (fluphenazine hydrochloride) concentrate/elixir/tablets* Prolixin® (fluphenazine decanoate) solution Stelazine® (trifluoperazine) tablets* Thorazine® (chlorpromazine) tablets/solution*	Triavil® (perphenazine-amitriptyline) tablet*
Preferred Atypical Antipsychotics	**Non-Preferred Atypical Antipsychotics**
Abilify® (aripiprazole) tablets* Clozaril® (clozapine) tablets/orally dispersible tablet * Geodon® (ziprasidone) capsules* Latuda (lurasidone) tablets Risperdal® (risperidone) oral solution/tablets* Risperdal M-Tab® (risperidone) orally disintegrating tablet* Saphris (asenapine) sublingual tablet Seroquel® (quetiapine) tablets* Zyprexa® (olanzapine) tablets* Zyprexa Zydis® (olanzapine) orally dispersible tablet* Abilify Maintena ® (aripiprazole) IM injection Aristada (aripiprazole lauroxil) IM injection Invega Sustenna ® (paliperidone) IM injection Invega Trinza ® (paliperidone) IM injection Risperdal Consta ® (risperidone) IM injection	Invega® (paliperidone) tablet Abilify Discmelt® (aripiprazole) orally disintegrating tablet Abilify Oral Solution® (aripiprazole) Fanapt® (iloperidone) tablets Seroquel XR® (quetiapine extended release) tablet Rexulti (brexpiprazole) tablet Symbyax (fluoxetine/ olanzapine) capsule Vraylar (cariprazine) capsule Zyprexa Relprevv (olanzapine) IM injection

*Only generic versions are covered

UHC C&S Plan Minimum Age Edits: Prior authorization is required for atypical antipsychotic claims for members less than the following ages:

Generic Name	Brand Name	Age Edit
ARIPIPRAZOLE TABLETS	ABILIFY	PA Required for Ages < 6 years
ASENAPINE MALEATE SUBLINGUAL	SAPHRIS	PA Required for Ages < 6 years
CLOZAPINE ORALLY DISPERSABLE TABLET	FAZACLO	PA Required for Ages < 6 years
CLOZAPINE TABLETS	CLOZARIL	PA Required for Ages < 6 years
LURASIDONE HCL TABS	LATUDA	PA Required for Ages < 6 years
OLANZAPINE ORALLY DISPERSABLE TABLET	ZYPREXA ZYDIS	PA Required for Ages < 6 years
OLANZAPINE TABLETS	ZYPREXA	PA Required for Ages < 6 years
QUETIAPINE FUMARATE TABLETS	SEROQUEL	PA Required for Ages < 6 years
RISPERIDONE ORALLY DISPERSABLE TABLET	RISPERIDONE ODT	PA Required for Ages < 6 years
RISPERIDONE ORAL SOLUTION	RISPERDAL	PA Required for Ages < 6 years
RISPERIDONE TABLETS	RISPERDAL	PA Required for Ages < 6 years
ZIPRASIDONE HCL CAPSULES	GEODON	PA Required for Ages < 6 years
ARIPIPRAZOLE LAUROXIL	ARISTADA	PA Required for Ages < 18 years
ARIPIPRAZOLE SUSPENSION	ABILIFY MAINTENA	PA Required for Ages < 18 years
PALIPERIDONE PALMITATE SUSPENSION	INVEGA SUSTENNA	PA Required for Ages < 18 years
PALIPERIDONE PALMITATE SUSPENSION	INVEGA TRINZA	PA Required for Ages < 18 years
RISPERIDONE MICROSPHERES SUSPENSION	RISPERDAL CONSTA	PA Required for Ages < 18 years
CHLORPROMAZINE HCL SOLUTION	VARIOUS	PA Required for Ages < 6 years
CHLORPROMAZINE HCL TABLETS	VARIOUS	PA Required for Ages < 6 years
FLUPHENAZINE HCL CONCENTRATE	VARIOUS	PA Required for Ages < 6 years
FLUPHENAZINE HCL ELIXIR	VARIOUS	PA Required for Ages < 6 years
FLUPHENAZINE HCL TABLETS	VARIOUS	PA Required for Ages < 6 years
HALOPERIDOL LACTATE CONCENTRATE	VARIOUS	PA Required for Ages < 6 years
HALOPERIDOL TABLETS	VARIOUS	PA Required for Ages < 6 years
LOXAPINE SUCCINATE CAPSULES	LOXITANE	PA Required for Ages < 6 years
PERPHENAZINE TABLETS	VARIOUS	PA Required for Ages < 6 years
PIMOZIDE	ORAP	PA Required for Ages < 6 years
THIORIDAZINE HCL TABLETS	VARIOUS	PA Required for Ages < 6 years
THIOTHIXENE CAPSULES	VARIOUS	PA Required for Ages < 6 years
TRIFLUOPERAZINE HCL TABLETS	VARIOUS	PA Required for Ages < 6 years
FLUPHENAZINE DECANOATE SOLUTION	FLUPHENAZINE DECANOATE	PA Required for Ages < 18 years
HALOPERIDOL DECANOATE SOLUTION	HALDOL DECANOATE	PA Required for Ages < 18 years

Off-labeled Use:

Drug therapies must be utilized in accordance with FDA approved indications OR the uses found within the compendia of literature† AND the drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program. Authorization for off-labeled use of medication will be evaluated on an individual basis. Review of an off-labeled request by the UnitedHealthcare Community & State Medical Staff will be predicated on the appropriateness of treatment, scientific evidence and full consideration of medical necessity.

†-compendia of current literature: • American Hospital Formulary Service Drug Information • National Comprehensive Cancer Network Drugs and Biologics Compendium • Thomson Micromedex DrugDex • Clinical Pharmacology

Indications

Bipolar Disorder

- Risperdal is indicated alone, or combination with lithium or valproate, for the short-term treatment of acute manic or mixed episodes associated with Bipolar I Disorder in adults, and alone in children and adolescents aged 10-17 years.

- Abilify is indicated for the treatment of manic or mixed episodes associated with Bipolar I Disorder as monotherapy or adjunctive to lithium or valproate in adults or pediatric patients aged 10-17 years.

- Seroquel and Seroquel XR are indicated for the treatment of depressive episodes associated with bipolar disorder, acute manic episodes associated with bipolar I disorder as either monotherapy or adjunct therapy to lithium or divalproex, and maintenance treatment of bipolar I disorder as adjunct therapy to lithium or divalproex.

- Geodon is indicated as monotherapy for the acute treatment of manic or mixed episodes associated with bipolar I disorder and as an adjunct to lithium or valproate for the maintenance treatment of bipolar I.

- Zyprexa is indicated as monotherapy for the acute treatment of manic or mixed episodes associated with bipolar I disorder and maintenance treatment of bipolar I disorder and as an adjunct to lithium or valproate for the treatment of manic or mixed episodes associated with bipolar I disorders.

Autism

- Risperdal is indicated for the treatment of irritability associated with autistic disorder in children and adolescents aged 5-16 years.

- Abilify is indicated for the treatment of irritability associated with autistic disorder. Efficacy was established in two 8-week trials in pediatric patients (6-17 years) with irritability associated with autistic disorder.

Schizophrenia

- Risperdal is indicated for the treatment of schizophrenia in adults and adolescents aged 13-17 years.
- Risperdal Consta is indicated for the treatment of schizophrenia. The efficacy of risperidone in longer-term use, that is, more than 12 weeks, has not been systematically evaluated in controlled trials.
- Abilify is indicated for the treatment of schizophrenia in adults and adolescents ages 13-17 years.
- Seroquel and Seroquel XR are indicated for the treatment of schizophrenia.
- Geodon is indicated for the treatment of schizophrenia.
- Zyprexa is indicated for acute and maintenance treatment of schizophrenia in adults.
- Clozaril is indicated for the management of severely ill schizophrenic patients who fail to respond adequately to standard drug treatment for schizophrenia.
- Invega Sustenna is indicated for the treatment of schizophrenia and for the treatment of schizoaffective disorder as monotherapy and an adjunct to mood stabilizers and/or antidepressant therapy.
- Abilify Maintena is indicated for the treatment of schizophrenia.

Major Depressive Disorder

- Abilify is indicated for adjunctive treatment of Major Depressive Disorder in adults.
- Seroquel XR is indicated for use as an adjunctive therapy to antidepressants for the treatment of Major Depressive Disorder.

Tourette's Disorder

Abilify is indicated for the treatment of Tourette's disorder.

2. Coverage Criteria:

A.	**<u>Preferred Antipsychotics: Antipsychotic Medications in Children Under 6 Years Old</u>** All of the following:

1. The patient has been diagnosed per current DSM criteria with one of the following disorders:
    a. Bipolar Spectrum Disorder
    b. Schizophrenic Spectrum Disorder
    c. Tourette's or other tic disorder
    d. Autism Spectrum Disorder

-AND-

2. The requesting clinician has documented that psychosocial issues have been evaluated before request for antipsychotic medications

-AND-

3. The requesting clinician has documented non-medication alternatives that have been attempted before request for antipsychotic medications

-AND-

4. The above documentation includes information on the expected outcomes and an evaluation of potential adverse events

-AND-

5. The member does not have a known hypersensitivity to the requested agent

Authorization will be issued for 12 months.

B. <u>Long- Acting Injectable Antipsychotics for Patients <18 Years of Age</u>

a. Invega Sustenna

1. Patient has a diagnosis of schizophrenia or schizoaffective disorder

-AND-

2. Patient is non-compliant with oral atypical antipsychotic dosage forms

-AND-

3. Prescriber attests they are aware of FDA labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary. (Document rationale for use)

b. Risperdal Consta

1. Patient has **one** of the following diagnoses:
   - Schizophrenia or schizoaffective disorder
   - Bipolar disorder

-AND-

2. Patient is non-compliant with oral atypical antipsychotic dosage forms

-AND-

3. Prescriber attests they are aware of FDA labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary. (Document rationale for use)

c. Abilify Maintena

1. Patient has **one** of the following diagnoses:
   - Schizophrenia or schizoaffective disorder
   - Bipolar disorder

-AND-

2. Patient is non-compliant with oral atypical antipsychotic dosage forms

-AND-

3. Prescriber attests they are aware of FDA labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary. (Document rationale for use)

d. Invega Trinza

1. Patient has a diagnosis of schizophrenia or schizoaffective disorder

-AND-

2. Patient has been treated with Invega Sustenna for at least 4 months.

-AND-

3. Prescriber attests they are aware of FDA labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary. (Document rationale for use)

e. Aristada

1. Patient has a diagnosis of schizophrenia or schizoaffective disorder

-AND-

2. Patient is non-compliant with oral atypical antipsychotic dosage forms

-AND-

3. Patient has established tolerability with oral aripriprazole.

-AND-

4. Prescriber attests they are aware of FDA labeling regarding use of long acting injectable antipsychotic products in patients less than 18 years of age and feels the treatment with the requested product is medically necessary. (Document rationale for use)

Initial Authorization will be issued for 6 months; reauthorization will be issued for 12 months.

C. Concomitant Antipsychotic Treatment Beyond 60 Day Cross Taper Window

1. Refractory Schizophrenic Spectrum Disorder

All of the following:

a. The requesting provider has submitted 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 and failure due to **one** of the following:

1. Inadequate response to maximum tolerated doses
2. Adverse reactions
3. Break through symptoms

-AND-

b. The requesting provider has provided supporting documentation that adherence to the treatment regimen has not been a contributing factor to the lack of response in the medication trials

-AND-

c. The member does not have a known hypersensitivity to the requested medication(s).

Authorization will be issued for 12 months

2. Refractory bipolar disorder with psychosis and/or severe symptoms

All of the following:

a. The provider has submitted evidence of at least four (4) evidence based treatment options dependent upon the episode type. Trials should be 4-6 weeks of maximum tolerated doses, with failure due to **one** of the following:
    1. Inadequate response to maximum tolerated doses
    2. Adverse reactions
    3. Break through symptoms

-AND-

b. The requesting provider has provided supporting documentation that adherence to the treatment regimen has not been a contributing factor to the lack of response in the medication trials

-AND-

c. The member does not have a known hypersensitivity to the requested medication(s).

Authorization will be issued for 12 months

D. <u>Non-Preferred Criteria</u>

1. A requested for a non-preferred medication will be approved based on **<u>one</u>** of the following criteria

a. All of the following:

1. <u>One</u> of the following:

(a) Beneficiary must demonstrate failure or intolerance to a majority (not more than three (3)) of the preferred formulary/PDL alternatives for the given diagnosis - **Prior trials of formulary/PDL alternatives must sufficiently demonstrate that the formulary/PDL alternatives are either ineffective or inappropriate at the time of the request.**

-OR-

(b) There are no preferred formulary alternatives for the requested drug.

-AND-

2. One of the following:

(a) The requested drug must be used for an FDA-approved indication

-OR-

(b) The use of this drug is supported by information from the appropriate compendia of current literature.*

-AND-

3. The drug is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in the compendia of current literature.*

-AND-

4. The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program.

-OR-

b. The requested medication is a behavioral health medication and one of the following:

1. The patient has been receiving treatment with the requested non-preferred behavioral health medication and is new to the plan (enrollment effective date within the past 90 days)

-OR-

2. The patient is currently receiving treatment with the requested non-preferred behavioral health medication in the hospital and must continue upon discharge

Authorization will be issued for 12 months.

*****Compendia of current literature: • American Hospital Formulary Service Drug Information • National Comprehensive Cancer Network Drugs and Biologics Compendium • Thomson Micromedex DrugDex • Clinical Pharmacology

3. Reference:

1. Manufacturer Product Information.
2. McClellan J, Kowatch R, Findling RL. Practice parameter for the assessment and treatment of children and adolescents with bipolar disorder. J Am Acad Child Adolesc Psychiatry. 2007;46:107-126.
3. Schur S, Sikich L, Findling, et al. Treatment recommendations for the use of antipsychotics for aggressive youth (TRAAY) Part I: Review. *J Am Acad Child Adolesc Psychiatry*. 2003;2:132-143.
4. Pappadopulos E, MacIntyre J, Crismon L, et al. Treatment recommendations for the use of antipsychotics for aggressive youth (TRAAY) Part II. *J Am Acad Child Adolesc Psychiatry*. 2003; 42(2): 145-161.
5. Kowatch R, DelBello M. The Use of mood stabilizers and atypical antipsychotics in children and adolescents with bipolar disorder. *CNS Spectrums.* 2003; 8(4): 273-280.
6. McClellan J, Werry J. Practice parameter for the assessment and treatment of children and adolescents with schizophrenia. *J Am Acad Child Adolesc Psychiatry.* 2001;40(7): 4S-23S.
7. Stigler K, Posey D, MacDougle C. Drug therapy algorithms target autism's problem behaviors. *Current Psychiatry*. 2003;2(4): 33-48.
8. Pliszka SR, Greenhill LL, Crismon ML et al. The Texas children's medication algorithm project: report of the Texas consensus conference panel on medication treatment of childhood attention-deficit/hyperactivity disorder. Part I. *J Am Acad Child Adolesc Psychiatry.* 2003;39:908-919.
9. Correll, C. Weight Gain and Metabolic Effects of Mood Stabilizers and Antipsychotics in Pediatric Bipolar Disorder: A systematic review and pooled analysis of short-term trials. *J Am Acad Child Adolesc Psychiatry*. 2007;466:687-700.

Program	Prior Authorization –Atypical Antipsychotics
Change Control	
Date	Change
January 2018	New Policy Specific to Arizona.

February 2018	Replaced state mandated long acting injectable criteria with UPC criteria and added language for reviews based on medical necessity for patients <18 years of age.