UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Atypical Antipsychotics - OHIO

Program	Prior Authorization
Medication	Atypical Antipsychotics
Markets In Scope	Ohio

1. Background:

Preferred Atypical Antipsychotics	**Preferred Atypical Antipsychotics with Prior Authorization**	**Non-Preferred Atypical Antipsychotics**
Risperdal® (risperidone)* Seroquel® (quetiapine)* Geodon® (ziprasidone)* Zyprexa® (olanzapine)* Clozaril® (clozapine)*	Abilify® (aripiprazole)* Abilify Maintena ® (aripiprazole) IM injection Invega Sustenna ® (paliperidone) IM injection Invega Trinza ® (paliperidone) IM injection Risperdal Consta ® (risperidone) IM injection Aristada (aripiprazole lauroxil) IM injection	Invega® (paliperidone) Risperdal M-Tab® (risperidone orally disintegrating tablet) Abilify Discmelt® (aripiprazole) Abilify Oral Solution® (aripiprazole) Zyprexa Zydis® (olanzapine) Fanapt® (iloperidone) Seroquel XR® (quetiapine extended release) Latuda (lurasidone) Rexulti (brexpiprazole) Saphris (asenapine) Vraylar (cariprazine)

*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:

a. Risperidone – 5 years of age
b. Abilify oral tablets – 6 years of age
c. Abilify discmelt, Abilify oral solution: 6 years of age
d. Seroquel, Seroquel XR – 10 years of age
e. Zyprexa – 13 years of age
f. Zyprexa Zydis – 5 years of age
g. Geodon – 18 years of age
h. Invega Sustenna – 18 years of age
i. Risperdal Consta – 18 years of age

j. Clozapine – 18 years of age
k. Abilify Maintena – 18 years of age
l. Invega Trinza- 18 years of age
m. Invega – 12 years of age
n. Aristada – 18 years of age
o. Fanapt- 18 years of age
p. Rexulti-18 years of age
q. Vraylar- 18 years of age
r. Latuda- 13 years of age
s. Saphris- 10 years of age

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

- Risperidone oral solution: 7 years of age

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>Atypical Antipsychotics: Prior Authorization for Minimum Age Edit</u>

1. The patient is unresponsive to other treatment modalities, unless contraindication (i.e. other medications or behavioral modification attempted).

-AND-

2. The patient has tried and failed all available preferred atypical antipsychotics that are FDA approved for the patient's age

-AND-

3. **<u>One</u>** of the following:

   a. Patient has **<u>one</u>** of the following diagnoses: Schizophrenia-spectrum disorder, Autism spectrum disorder, or Bipolar disorder

   -OR-

   b. Patient displays symptoms of aggression as a symptom of developmental delay, autism, Tourette's syndrome or chronic tics, oppositional defiant disorder, or conduct disorder

Authorization will be issued for 12 months.

B. <u>Risperidone Oral Solution: Prior Authorization for Maximum Age Edit</u>

1. One of the following:

a. Requested drug must be used for an FDA-approved indication

-OR-

b. **Both** of the following:
- The use of this drug is supported by information from the appropriate compendia of current literature†
- The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program

-AND-

2. 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-

3. **One** of the following:

a. The patient is unable to swallow the oral solid preferred alternatives

-OR-

b. History of failure, contraindication, or intolerance to a majority (not more than 3) of the oral solid preferred alternatives

Authorization will be issued for 12 months.

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

C. Invega Sustenna

1. Patient has a diagnosis of schizophrenia or schizoaffective disorder

-AND-

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

Authorization will be issued for 12 months.

D. 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

Authorization will be issued for 12 months.

E. 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

Authorization will be issued for 12 months.

F. 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.

Authorization will be issued for 12 months.

G. 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 aripiprazole.

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

H. Abilify (aripiprazole)

a. **One** of the following:

i. **Both** of the following

(a) Patient has **one** of the following diagnoses:

- Schizophrenia or schizoaffective disorder
- Bipolar disorder

-AND-

(b) Patient has a history of failure, contraindication, or intolerance to **two** of the following:

- Quetiapine immediate release tablet
- Risperidone tablets
- Ziprasidone capsule
- Olanzapine tablet

-OR-

ii. **Both** of the following:

(a) Patient has a diagnosis of autism

-AND-

(b) Patient has a history of failure, contraindication, or intolerance to risperidone tablet

-OR-

iii. **All** of the following:

(a) Patient has a diagnosis of major depressive disorder

-AND-

(b) Patient has already established antidepressant treatment (e.g., SSRI)

-AND-

(c) Abilify will be used as adjunct therapy to antidepressant treatment

-OR-

iv. Patient has a diagnosis of Tourette's

-OR-

v. **Both** of the following:
- The use of this drug is supported by information from the appropriate compendia†
- The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program.

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Authorization will be issued for 12 months.

I. Non-Preferred Criteria

1. A request for a non-preferred medication will be approved based on **one** of the following criteria

a. All of the following:

1. One 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. If the request is for a multi-source brand medication, **one** of the following:

- The multi-source brand is being requested because of an adverse reaction, allergy or sensitivity to a generic equivalent
- The multi-source brand is being requested due to a therapeutic failure with the generic equivalent
- The multi-source brand is being requested because transition to a generic equivalent could result in destabilization of the patient
- Special clinical circumstances exist that preclude the use of a generic version of the multi-source brand medication for the patient

-AND-

3. One of the following:

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

-OR-

(b) **Both** of the following:

- The use of this drug is supported by information from the appropriate compendia of current literature.†
- 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. **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:

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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.
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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
2/2018	Ohio specific policy created for 4/1/18 since Ohio will be moving to a Single PDL later in 2018.