Atypical Antipsychotic
Effective 02/01/2021

Plan	☐ MassHealth ☒Commercial/Exchange	**Program Type**	☐ Prior Authorization ☐ Quantity Limit ☒ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Prescriptions that meet the initial step therapy requirements will adjudicate automatically at the point of sale. If the prescription does not meet the initial step therapy requirements, the prescription will deny with a message indicating that prior authorization (PA) is required. Refer to the criteria below and submit a PA request for the members who do not meet the initial step therapy requirements at the point of sale.

Initial Step-Therapy Requirements:
First-Line: Medications listed on first-line are covered without prior-authorization.
Second-Line: Second-line medications will pay if the member has filled at least two different first-line medications or a second-line medication within the past 180 days.

Coverage Guidelines

FIRST-LINE	SECOND-LINE
clozapine olanzapine (Zyprexa) all formulations quetiapine (Seroquel) all formulations risperidone (Risperdal) all formulations ziprasidone all formulations Risperdal Consta (risperidone long-acting) injection Zyprexa Relprevv (olanzapine long-acting) injection Invega Sustenna (paliperidone long-acting) monthly injection 39mg, 78mg, 117mg, 156mg, 234mg strengths	aripiprazole tablets aripiprazole oral solution aripiprazole ODT paliperidone tablets quetiapine XR tablets Caplyta (lumateperone) capsules Saphris (asenapine) SL tablets Latuda (lurasidone) tablets Fanapt (iloperidone) tablets Rexulti (brexpiprazole) tablets Vraylar (cariprazine) capsules Secuado (asenapine) transdermal patch

FIRST-LINE	SECOND-LINE
Invega Trinza (paliperidone long-acting) every 3-month injection 273mg, 410mg, 546mg, & 819mg strengths Abilify Maintena (aripiprazole long-acting) injection	

If a member does not meet the initial step therapy requirements, then approval of a second-line medication will be granted if the member meets the following criteria:

Aripiprazole tablets, aripiprazole oral solution, & aripiprazole ODT

1. Member has been started and stabilized on the requested medication (samples are not considered adequate justification for started & stabilized)

   OR

1. Member will be using as augmentation therapy for depression (e.g., MDD) **AND**
2. Member has had an inadequate response or intolerance to a 30-day trial with two different antidepressants from different therapeutic categories for the current condition (e.g., SSRIs, SNRIs, bupropion, etc.) **AND**
3. Member has had an inadequate response or intolerance to at least one preferred, oral or long-acting injectable, atypical antipsychotic for this indication

   OR

1. Member has a diagnosis of irritability associated with autism disorder **AND**
2. Member has had an inadequate response or intolerance to a trial of risperidone

   OR

1. Member has a diagnosis of another psychiatric diagnosis (e.g., schizophrenia, bipolar, etc.) **AND**
2. Member has had an inadequate response or intolerance to at least two different preferred atypical antipsychotics for this indication, including preferred oral agents and/or long-acting injectable products*

*Note: Members under the age of 12 only need to one trial of a preferred atypical antipsychotic indicated for the diagnosis to satisfy criteria

Seroquel XR tablets

1. Member has been started and stabilized on the requested medication (samples are not considered adequate justification for started & stabilized)

   OR

1. Member will be using as augmentation therapy for depression (e.g., MDD) **AND**
2. Member has had an inadequate response or intolerance to a 30-day trial with two different antidepressants from different therapeutic categories for the current condition (e.g., SSRIs, SNRIs, bupropion, etc.) **AND**
3. Member has had an inadequate response or intolerance to generic quetiapine (Seroquel)

   OR

1. Member has a diagnosis of another psychiatric diagnosis (e.g., schizophrenia, bipolar, etc.) **AND**
2. Member has had an inadequate response or intolerance to generic quetiapine (Seroquel) **AND**
3. Member has had an inadequate response or intolerance to at least one other preferred, oral or long-acting injectable, atypical antipsychotic for this indication*

*Note: A trial of an additional atypical antipsychotic for this indication is not required for members younger than 12

Paliperidone (Invega) tablets

1. Member has been started and stabilized on the requested medication (samples are not considered adequate justification for started & stabilized)

   OR

1. Member is 11 years of age or younger **AND**
2. Member has had an inadequate response or intolerance to risperidone for this indication **AND**
3. Member has had an inadequate response or intolerance to at least one other preferred, oral or long-acting injectable, atypical antipsychotic for this indication

Saphris tablets

1. Member has been started and stabilized on the requested medication (samples are not considered adequate justification for started & stabilized)

   OR

1. Member has had an inadequate response or intolerance to at least two different preferred atypical antipsychotics for this indication, including preferred oral agents and/or long-acting injectable products*

*Note: Members under the age of 12 only need to one trial of a preferred atypical antipsychotic indicated for the diagnosis to satisfy criteria

Latuda, Fanapt, Rexulti, Vraylar, Caplyta & Secuado transdermal patches

1. Member has been started and stabilized on the requested medication (samples are not considered adequate justification for started & stabilized)

   OR

1. Member has had an inadequate response or intolerance to at least two different preferred atypical antipsychotics for this indication, including preferred oral agents and/or long-acting injectable products

Limitations

1. Approvals will be granted for 36 months.
2. The following quantity limits apply:

Abilify Maintena	1 syringe per 28 days
Aripiprazole solution 1mg/ml	150ml per month
Aripiprazole tablets 15mg, 20mg, & 30mg	30 tablets per month
Aripiprazole tablets 2mg, 5mg, & 10mg	60 tablets per month
Aripiprazole tablets ODT	30 tablets per month
Caplyta 42mg capsules	30 capsules per month
Clozapine tablets 100mg	270 tablets per month
Clozapine tablets 25mg	90 tablets per month
Clozapine tablets 50mg	135 tablets per month

Fanapt tablets	60 tablets per month Fanapt starter pack can be filled one time.
Invega Sustenna	1 syringe per 28 days
Invega Trinza	1 syringe per 84 days
Latuda tablets 20mg, 40mg, 60mg, & 120mg	30 tablets per month
Latuda tablets 80mg	60 tablets per month
Olanzapine tablets 2.5mg & 5mg	60 tablets per month
Olanzapine tablets 7.5mg, 10mg, 15mg, & 20mg	30 tablets per month
Olanzapine tablets ODT	30 tablets per month
Paliperidone tablets ER 1.5mg, 3mg, & 6mg	30 tablets per month
Paliperidone tablets ER 9mg	60 tablets per month
Quetiapine tablets 25mg	120 tablets per month
Quetiapine tablets 300mg & 400mg	60 tablets per month
Quetiapine tablets 50mg, 100mg, & 200mg	90 tablets per month
Quetiapine tablets ER 150mg & 200mg	30 tablets per month
Quetiapine tablets ER 50mg, 300mg, & 400mg.	60 tablets per month
Rexulti tablets 0.25mg, 0.5mg, & 1mg	30 tablets per month
Rexulti tablets 2mg, 3mg, & 4mg	60 tablets per month
Risperdal Injection 12.5mg	2 injection kits per 28 days
Saphris sublingual	60 tablets per month
Vraylar capsules 1.5mg	60 tablets per month
Vraylar capsules 3mg, 4.5mg, & 6mg	30 tablets per month
Zyprexa Relprevv	2 vials per 28 days

References

1. Abilify (aripiprazole) [prescribing information]. Rockville, MD: Otsuka America Pharmaceutical Inc; February 2018
2. Abilify Maintena® [package insert].Rockville (MD): Otsuka America Pharmaceutical, Inc.; 2015 Jul.
3. Fanapt (iloperidone) [prescribing information]. Washington, DC: Vanda Pharmaceuticals Inc; February 2017
4. Invega (paliperidone) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals; July 2018
5. Invega Sustenna (paliperidone palmitate) extended-release injectable suspension [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals; July 2018
6. Latuda (lurasidone) [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc; March 2018
7. Rexulti (brexpiprazole) [prescribing information]. Rockville, MD: Otsuka America Pharmaceutical; February 2018
8. Risperdal (risperidone) tablets, oral solution, and orally disintegrating tablets [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals Inc; July 2018.
9. Risperdal Consta (risperidone) long-acting injection [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals Inc; July 2018
10. Saphris (asenapine) [prescribing information]. Irvine, CA: Allergan USA Inc; January 2017

11. Seroquel (quetiapine) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2018.
12. Seroquel XR (quetiapine) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2018
13. Vraylar (cariprazine) [prescribing information]. Irvine, CA: Allergan USA Inc.; November 2018
14. Zyprexa (olanzapine) [prescribing information]. Indianapolis, IN: Lilly USA LLC; March 2018
15. Zyprexa Relprevv (olanzapine) [prescribing information]. Indianapolis, IN: Lilly USA; March 2018.
16. US FDA approves dual-chamber syringe for Abilify Maintena (aripiprazole) extended-release injectable suspension for the treatment of schizophrenia [press release]. Princeton (NJ): Otsuka & Lundbeck Pharmaceuticals; Sep 29, 2014 [cited 10/28/14]. Available at: http://www.otsuka-us.com/newsroom/Pages/USNewsReleases.aspx
17. Secuado (asenapine) [prescribing information]. Miami, FL: Noven Therapeutics, LLC; October 2019.
18. Caplyta (lumateperone) [prescribing information]. New York, NY: Intra-Cellular Therapies Inc; December 2019.

Review History

09/24/2007 – Reviewed
09/22/2008 – Update approval to 36 months
09/21/2009 – Reviewed
09/24/2009 – Updated
10/26/2009 – 1.5mg strength and injection
06/21/2010 – Updated
12/15/2010 – Disclaimer
06/27/2011 – Reviewed
02/03/2012 – Olanzapine & MHP notification of Zydis MSC override
04/02/2012 – Geodon & Seroquel generic name changes
03/01/2013 – ST/QL program update to review in CCC; QL for clozapine 50mg tabs; increase risperidone ODT QLs)
07/22/2013 – Abilify Maintena inclusion
11/24/2014 – Updated
06/08/2015 – Abilify tabs generic
08/03/2015 – Invega Trinza added
10/01/2015 – Abilify oral soln generic & Invega generic
11/23/2015 – Reviewed
06/22/2016 – Added Rexulti and Vraylar
11/27/2017 – Reviewed
06/19/2019 – Reviewed
02/27/2020 – additional of Secuado patches to second line
01/20/2021 – Reviewed and updated; added Caplyta as second line agent; added QL for Caplyta; references updated. Effective 02/01/21.

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