

### Atypical Antipsychotics Effective 05/01/2025

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		<input type="checkbox"/> Quantity Limit <input checked="" type="checkbox"/> Step Therapy
Specialty Limitations	N/A		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Contact Information	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
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 one first-line or one second-line medication within the past 180 days

**Third-Line:** Third-line medications will pay if the member has filled at least one second-line or one third-line medication in the past 180 days

FIRST-LINE	SECOND-LINE	THIRD-LINE
Aripiprazole tablet, oral solution, ODT Asenapine SL tablet Clozapine tablet, ODT lurasidone tablet olanzapine tablet, ODT quetiapine tablet quetiapine extended-release tablet risperidone tablet, oral solution, ODT ziprasidone capsule	paliperidone tablet Rexulti (brexpiprazole) tablets Vraylar (cariprazine) capsules	Caplyta (lumateperone) capsules Fanapt (iloperidone) tablet Lybalvi (olanzapine/ samidorphan) tablet Secuado (asenapine) transdermal patch

Erzofri (paliperidone extended-release) injection is indicated for the treatment of:

- Schizophrenia in adults
- Schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants

Erzofri requires prior authorization and is not part of the antipsychotic step therapy program.

For all second- and third-line agents in the antipsychotic step therapy program, 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 criteria listed below.

### **Coverage Guidelines**

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs

### **OR**

Authorization may be granted for members when all the following criteria have been met:

### **Paliperidone tablets**

1. Member meets ONE of the following:
  - a. Member has been started and stabilized on the requested medication (samples are not considered adequate justification for started & stabilized)
  - b. Member has had an inadequate response or intolerance to one of the following medications or clinical rationale why none of the following medications is appropriate for the member:
    - i. Aripiprazole tablet, oral solution, orally disintegrating tablet
    - ii. Asenapine sublingual tablet
    - iii. Clozapine tablet, orally disintegrating tablet
    - iv. Lurasidone tablet
    - v. Olanzapine tablet, orally disintegrating tablet
    - vi. Quetiapine immediate-release or extended-release tablet
    - vii. Risperidone tablet, oral solution, orally disintegrating tablet
    - viii. Ziprasidone capsule
    - ix. Rexulti (brexpiprazole) tablet
    - x. Vraylar (cariprazine) capsule
  - c. Member has a diagnosis of schizoaffective disorder
  - d. Member has a diagnosis of schizophrenia and is 12 years of age or younger

### **Rexulti (brexpiprazole) tablet**

1. Member meets ONE of the following:
  - a. Member has been started and stabilized on the requested medication (samples are not considered adequate justification for started & stabilized)
  - b. Member has had an inadequate response or intolerance to one of the following medications or clinical rationale why none of the following medications is appropriate for the member:
    - i. Aripiprazole tablet, oral solution, orally disintegrating tablet



- ii. Asenapine SL tablet
  - iii. Clozapine tablet, orally disintegrating tablet
  - iv. Lurasidone tablet
  - v. Olanzapine tablet, orally disintegrating tablet
  - vi. Paliperidone extended-release tablet
  - vii. Quetiapine immediate-release or extended-release tablet
  - viii. Risperidone tablet, oral solution, orally disintegrating tablet
  - ix. Ziprasidone capsule
  - x. Vraylar (cariprazine) capsule
- c. Member has a diagnosis of agitation in association with dementia due to Alzheimer's disease

**Vraylar (cariprazine) capsule**

1. Member meets ONE of the following:
- a. Member has been started and stabilized on the requested medication (samples are not considered adequate justification for started & stabilized)
  - b. Member has had an inadequate response or intolerance to one of the following medications or clinical rationale why none of the following medications is appropriate for the member:
    - i. Aripiprazole tablet, oral solution, orally disintegrating tablet
    - ii. Asenapine SL tablet
    - iii. Clozapine tablet, orally disintegrating tablet
    - iv. Lurasidone tablet
    - v. Olanzapine tablet, orally disintegrating tablet
    - vi. Paliperidone extended-release tablet
    - vii. Quetiapine immediate-release or extended-release tablet
    - viii. Risperidone tablet, oral solution, orally disintegrating tablet
    - ix. Ziprasidone capsule
    - x. Rexulti (brexpiprazole) tablet

**Caplyta (lumateperone) capsule**

1. Member meets ONE of the following:
- a. Member has been started and stabilized on the requested medication (samples are not considered adequate justification for started & stabilized)
  - b. Member has had an inadequate response or intolerance to one of the following medications or clinical rationale why none of the following medications is appropriate for the member:
    - i. Rexulti (brexpiprazole) tablet
    - ii. Vraylar (cariprazine) capsule
    - iii. Paliperidone extended-release tablet
    - iv. Fanapt (iloperidone) tablet
    - v. Secuado (asenapine) transdermal patch
    - vi. Lybalvi (olanzapine/samidorphan) tablet
  - c. Member has a diagnosis of bipolar II depression and meets ONE of the following:
    - i. Member has had an inadequate response or intolerance to quetiapine



- ii. Member is using Caplyta as an adjunct to lithium or valproate

**Fanapt (iloperidone) tablet**

- 1. Member meets ONE of the following:
  - a. Member has been started and stabilized on the requested medication (samples are not considered adequate justification for started & stabilized)
  - b. Member has had an inadequate response or intolerance to one of the following medications or clinical rationale why none of the following medications is appropriate for the member:
    - i. Rexulti (brexipiprazole) tablet
    - ii. Vraylar (cariprazine) capsule
    - iii. Paliperidone extended-release tablet
    - iv. Caplyta (lumateperone) capsule
    - v. Secuado (asenapine) transdermal patch
    - vi. Lybalvi (olanzapine/samidorphan) tablet

**Secuado (asenapine) transdermal patch**

- 1. Member meets ONE of the following:
  - a. Member has been started and stabilized on the requested medication (samples are not considered adequate justification for started & stabilized)
  - b. Member has had an inadequate response or intolerance to one of the following medications or clinical rationale why none of the following medications is appropriate for the member:
    - i. Rexulti (brexipiprazole) tablet
    - ii. Vraylar (cariprazine) capsule
    - iii. Paliperidone extended-release tablet
    - iv. Caplyta (lumateperone) capsule
    - v. Fanapt (iloperidone) tablet
    - vi. Lybalvi (olanzapine/samidorphan) tablet

**Lybalvi (olanzapine/samidorphan) tablet**

- 1. Member meets ONE of the following:
  - a. Member has been started and stabilized on the requested medication (samples are not considered adequate justification for started & stabilized)
  - b. Member has had an inadequate response or intolerance to one of the following medications or clinical rationale why none of the following medications is appropriate for the member:
    - i. Rexulti (brexipiprazole) tablet
    - ii. Vraylar (cariprazine) capsule
    - iii. Paliperidone extended-release tablet
    - iv. Caplyta (lumateperone) capsule
    - v. Fanapt (iloperidone) tablet
    - vi. Secuado (asenapine) transdermal patch
  - c. Member is being treated for maintenance of bipolar I disorder manic or mixed episodes and has had an inadequate response or intolerance to BOTH of the following medications or clinical rationale why none of the following medications is appropriate for the member:



- i. Asenapine sublingual tablet
- ii. Olanzapine tablet, orally disintegrating tablet

**Erzofri (paliperidone palmitate) extended-release injection**

1. Member meets ONE of the following:
  - a. Member has been started and stabilized on the requested medication (samples are not considered adequate justification for started & stabilized)
  - b. Member has had an inadequate response or intolerance to one of the following medications or clinical rationale why none of the following medications is appropriate for the member:
    - i. Invega Sustenna
    - ii. Invega Trinza
    - iii. Invega Hayfera

**Limitations**

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

Drug Name	Quantity Limit
Abilify Maintena	1 syringe per 28 days
Aripiprazole solution 1mg/ml	150ml per 30 days
Aripiprazole tablets 15mg, 20mg, & 30mg	30 tablets per 30 days
Aripiprazole tablets 2mg, 5mg, & 10mg	60 tablets per 30 days
Aripiprazole tablets ODT	30 tablets per 30 days
Asenapine SL tablet	60 tablets per 30 days
Caplyta 42mg capsules	30 capsules per 30 days
Clozapine tablets 100mg	270 tablets per 30 days
Clozapine tablets 25mg	90 tablets per 30 days
Clozapine tablets 50mg	135 tablets per 30 days
Erzofri extended-release injection	1 syringe per 28 days
Fanapt tablets	60 tablets per 30 days Fanapt starter pack can be filled one time.
Invega Sustenna	1 syringe per 28 days
Invega Trinza	1 syringe per 84 days
Lurasidone tablets 20mg, 40mg, 60mg, & 120mg	30 tablets per 30 days
Lurasidone tablets 80mg	60 tablets per 30 days
Lybalvi tablets 5mg/10mg, 10 mg/10mg, 15mg/10mg, 20mg/10mg	30 tablets per 30 days
Olanzapine tablets 2.5mg & 5mg	60 tablets per 30 days
Olanzapine tablets 7.5mg, 10mg, 15mg, & 20mg	30 tablets per 30 days
Olanzapine tablets ODT	30 tablets per 30 days
Paliperidone tablets ER 1.5mg, 3mg, & 6mg	30 tablets per 30 days
Paliperidone tablets ER 9mg	60 tablets per 30 days
Quetiapine tablets 25mg	120 tablets per 30 days



Quetiapine tablets 300mg & 400mg	60 tablets per 30 days
Quetiapine tablets 50mg, 100mg, & 200mg	90 tablets per 30 days
Quetiapine tablets ER 150mg & 200mg	30 tablets per 30 days
Quetiapine tablets ER 50mg, 300mg, & 400mg.	60 tablets per 30 days
Rexulti tablets 0.25mg, 0.5mg, & 1mg	30 tablets per 30 days
Rexulti tablets 2mg, 3mg, & 4mg	60 tablets per 30 days
Risperdal Injection 12.5mg	2 injection kits per 28 days
Uzedly injection	1 injection per 28 days
Vraylar capsules 1.5mg	60 tablets per 30 days
Vraylar capsules 3mg, 4.5mg, & 6mg	30 tablets per 30 days
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. Caplyta (lumateperone) [prescribing information]. New York, NY: Intra-Cellular Therapies Inc; December 2019.
4. Fanapt (iloperidone) [prescribing information]. Washington, DC: Vanda Pharmaceuticals Inc; February 2017
5. Invega (paliperidone) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals; July 2018
6. Invega Sustenna (paliperidone palmitate) extended-release injectable suspension [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals; July 2018
7. Latuda (lurasidone) [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc; March 2018
8. Rexulti (brexipiprazole) [prescribing information]. Rockville, MD: Otsuka America Pharmaceutical; February 2018
9. Risperdal (risperidone) tablets, oral solution, and orally disintegrating tablets [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals Inc; July 2018.
10. Risperdal Consta (risperidone) long-acting injection [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals Inc; July 2018
11. Saphris (asenapine) [prescribing information]. Irvine, CA: Allergan USA Inc; January 2017
12. Secuado (asenapine) [prescribing information]. Miami, FL: Noven Therapeutics, LLC; October 2019.
13. Seroquel (quetiapine) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2018.
14. Seroquel XR (quetiapine) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2018
15. Vraylar (cariprazine) [prescribing information]. Irvine, CA: Allergan USA Inc.; November 2018
16. Zyprexa (olanzapine) [prescribing information]. Indianapolis, IN: Lilly USA LLC; March 2018
17. Zyprexa Relprevv (olanzapine) [prescribing information]. Indianapolis, IN: Lilly USA; March 2018.

## 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 Zydys 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.  
 01/19/2022 – Reviewed and Updated; added new medication Invega Hafyera as first line agent. Effective 04/01/2022.  
 09/13/2023 – Reviewed and Updated for Sept P&T; added new medication Uzedy and Abilify Asumtifii as first line agent. Effective 11/1/23.  
 02/12/2025 - Reviewed and updated for February P&T. Updated policy to reflect changes to step therapy program: aripiprazole tablet/oral solution/ODT, asenapine SL tablet, clozapine tablet/ODT, lurasidone tablet, olanzapine tablet/ODT, quetiapine IR tablet, quetiapine ER tablet, risperidone tablet/oral solution/ODT, ziprasidone capsule will be first line; paliperidone ER tablet, Rexulti tablet and Vraylar capsule will be second line; Caplyta, Fanapt, Lybalvi and Secuado will be third line. First line agents are covered without PA, second line agents will pay at the pharmacy if there is a claim in the past 180 days for one first-line or one second-line agent. Third-line agents will pay at the pharmacy if there is a claim in the past 180 days for one second-line or one third-line agent. Prior authorization criteria reflect automatic step requirements, with specific criteria for diagnoses not shared with lookback agents. PA criteria for Erzofri was added to the policy. Effective 05/01/2025.

