High Cost Oral Atypical Antipsychotics (Caplyta, Fanapt, Lybalvi, Rexulti, Vraylar)

Prior Authorization Guideline

Guideline Name	High Cost Oral Atypical Antipsychotics (Caplyta, Fanapt, Lybalvi, Rexulti, Vraylar)

Guideline Note:

Effective Date:	10/1/2024

1 . Criteria

Product Name: Caplyta, Fanapt, Lybalvi, Rexulti, Vraylar	
Diagnosis	Schizophrenia
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of schizophrenia

AND

2 - One of the following:

2.1 Inadequate response (minimum 30-day trial) or adverse reaction to TWO, or contraindication to ALL of the following:

- Aripiprazole
- Clozapine
- Olanzapine
- Quetiapine
- Risperidone
- Ziprasidone

OR

2.2 One of the following:

2.2.1 The patient has been receiving treatment with the requested medication, and is new to the plan (enrollment effective date within the past 90 days)

OR

2.2.2 The patient is currently receiving treatment with the requested medication in the hospital and must continue upon discharge

AND

3 - For Lybalvi requests ONLY, One of the following:

- Patient has a BMI of 30 kg/m2 or greater
- Patient has a BMI of 27 kg/m2 or greater with a weight-related comorbidity (e.g., dyslipidemia, hypertension, type 2 diabetes, sleep apnea)
- Patient has a documented history of weight gain of greater than or equal to 10% of their baseline weight after initiating antipsychotic medication
- Physician has provided clinical rationale for requiring samidorphan in addition to olanzapine therapy

Product Name: Fanapt, Lybalvi, Vraylar	
Diagnosis	Bipolar I Disorder
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of bipolar I disorder

AND

2 - ONE of the following:

2.1 Inadequate response (minimum 30-day trial) or adverse reaction to THREE, or contraindication to ALL of the following:

- Aripiprazole
- Lamotrigine
- Lithium
- Lurasidone
- Olanzapine
- Risperidone
- Valproate

OR

2.2 One of the following:

2.2.1 The patient has been receiving treatment with the requested medication, and is new to the plan (enrollment effective date within the past 90 days)

OR

2.2.2 The patient is currently receiving treatment with requested medication in the hospital and must continue upon discharge

AND

3 - For Lybalvi requests ONLY, One of the following:

- Patient has a BMI of 30 kg/m2 or greater
- Patient has a BMI of 27 kg/m2 or greater with a weight-related comorbidity (e.g., dyslipidemia, hypertension, type 2 diabetes, sleep apnea)
- Patient has a documented history of weight gain of greater than or equal to 10% of their baseline weight after initiating antipsychotic medication
- Physician has provided clinical rationale for requiring samidorphan in addition to olanzapine therapy

Product Name: Caplyta, Vraylar	
Diagnosis	Bipolar Depression

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of bipolar depression

AND

2 - ONE of the following:

2.1 Inadequate response (minimum 30-day trial) or adverse reaction to THREE, or contraindication to ALL of the following:

- Lurasidone
- Quetiapine
- Olanzapine plus fluoxetine
- Valproate monotherapy
- Combination therapy (i.e., lithium plus lamotrigine/valproate, lurasidone plus lithium/valproate, quetiapine plus lithium/valproate)

OR

2.2 One of the following:

2.2.1 The patient has been receiving treatment with the requested medication, and is new to the plan (enrollment effective date within the past 90 days)

OR

2.2.2 The patient is currently receiving treatment with requested medication in the hospital and must continue upon discharge

Product Name: Rexulti, Vraylar	
Diagnosis	Major Depressive Disorder (MDD)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Major depressive disorder (MDD)
- Treatment resistant depression (Applies to Vraylar only)

AND

2 - One of the following:

2.1 BOTH of the following:

2.1.1 Inadequate response (minimum 30-day trial) or adverse reaction to TWO different antidepressants from the following classes (antidepressants MUST be from TWO different classes):

- Selective Serotonin Reuptake Inhibitors (SSRIs)
- Serotonin Norepinephrine Reuptake Inhibitors (SNRIs)
- New Generation Antidepressants (e.g., bupropion, mirtazapine, etc.)
- Tricyclic Antidepressants (TCAs)

AND

2.1.2 Inadequate response (minimum 30-day trial) or adverse reaction to TWO of the following:

- aripiprazole
- quetiapine ER
- risperidone
- Augmented therapy (e.g., addition of lithium, another antidepressant from a different class, thyroid hormone to current antidepressant regimen)

OR

2.2 One of the following:

2.2.1 The patient has been receiving treatment with the requested medication, and is new to the plan (enrollment effective date within the past 90 days)

OR

2.2.2 The patient is currently receiving treatment with the requested medication in the hospital and must continue upon discharge

Product Name: Rexulti	
Diagnosis	Agitation Associated With Dementia Due To Alzheimer's Disease
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - The requested medication is being used for treatment of agitation associated with dementia due to Alzheimer's disease

Product Name: Caplyta, Fanapt, Lybalvi, Rexulti, Vraylar	
Diagnosis	Requests Exceeding Quantity Limit*
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - ONE of the following:

1.1 The requested drug must be used for a Food and Drug Administration (FDA)-approved indication

OR

1.2 The use of this drug is supported by information from one of the following appropriate compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- Micromedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

AND

2 - ONE of the following:

2.1 The drug is being prescribed within the manufacturer's published dosing guidelines

OR

2.2 The requested dose falls within dosing guidelines found in one of the following compendia of current literature:

- Food and Drug Administration (FDA) approved indications and limits
- Published practice guidelines and treatment protocols
- Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits and potential member outcomes
- Drug Facts and Comparisons
- American Hospital Formulary Service Drug Information
- United States Pharmacopeia – Drug Information
- DRUGDEX Information System
- UpToDate
- Micromedex
- Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies
- Other drug reference resources

AND

3 - The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation

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

AND

5 - Physician has provided rationale for needing to exceed the quantity limit (QL) of one of the following:

- For Caplyta requests, QL of 1 capsule/day
- For Fanapt tablet requests, QL of 2 tablets/day
- For Fanapt titration pack requests, QL of 1 pack/180 days
- For Lybalvi requests, QL of 1 tablet/day
- For Rexulti requests, QL of 1 tablet/day
- For Vraylar 1.5 mg and 3 mg requests, QL of 2 capsules/day
- For Vraylar 4.5 mg and 9 mg requests, QL of 1 capsule/day
- For Vraylar therapy pack requests, 2 packs/365 days

Notes	*Prior authorization requests should be reviewed using the above crite ria. This section is for quantity limit requests only.