# Drug Coverage Policy

**Effective Date……04/01/2026**
**Coverage Policy Number…… DQM022**
**Policy Title……Psychiatry – Novel Psychotropics Drug Quantity Management Policy – Per Days**

# Psychiatry – Novel Psychotropics Drug Quantity Management Policy – Per Days

- Abilify® (aripiprazole tablets – Otsuka, generic)
- Caplyta® (lumateperone capsules – Intra-Cellular)
- Fanapt® (iloperidone tablets – Vanda)
- Invega® (paliperidone extended-release tablets – Janssen, generic)
- Latuda® (lurasidone tablets – Sunovion/Sumitomo, generic)
- Lybalvi® (olanzapine and samidorphan tablets – Alkermes)
- Rexulti® (brexpiprazole tablets – Otsuka)
- Vraylar® (cariprazine capsules – Allergan)

***INSTRUCTIONS FOR USE***
*The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not*

*covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.*

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**Overview**
**Indications**
All of the novel psychotropics are indicated for use in **schizophrenia**.[1-17] In addition, all of the agents except Caplyta, paliperidone, Rexulti, and Secuado carry a bipolar disorder indication.

- Aripiprazole and risperidone are indicated for the treatment of irritability associated with autistic disorder in pediatric patients (6 to 17 years of age and 5 to 17 years of age, respectively).
- Aripiprazole, Abilify Mycite, olanzapine, Rexulti, quetiapine extended-release, and Vraylar are indicated as adjunctive treatment for major depressive disorder in patients already taking an antidepressant.
- Aripiprazole is the only agent indicated for the treatment of Tourette's disorder.
- Paliperidone is indicated for the treatment of schizoaffective disorder.
- Aripiprazole, lurasidone, quetiapine, risperidone, and asenapine tablets are approved for use in pediatric patients ≥ 10 years of age with bipolar disorder. Olanzapine is approved for use in patients ≥ 13 years of age with bipolar disorder.
- Aripiprazole, lurasidone, olanzapine, quetiapine, and risperidone are approved for use in patients ≥ 13 years of age with schizophrenia.
- Rexulti has an additional indication for the treatment of agitation associated with dementia due to Alzheimer's disease.
- Fanapt has an additional indication for the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.

**Dosing and Availability**
Refer to Table 1 for the recommended dosing and availability of the novel psychotropics.[1-17]

**Table 1. Novel Psychotropic Dosing and Availability.[1-17]**

| Agent | Dosage Forms | Starting Dose | Usual Therapeutic Dose | Maximum Dose |
|---|---|---|---|---|
| Abilify® (aripiprazole tablets and ODT, generic)[q] | Tablets (2, 5, 10, 15, 20, 30 mg)<br>ODT (10, 15 mg) | 10 to 15 mg QD (S)<br>2 mg QD (SA)<br>15 mg QD (BP)<br>2 mg QD (BPP)<br>2 to 5 mg QD (D)<br>2 mg QD (A)<br>2 mg QD (TD) | 10 to 15 mg QD (S)<br>10 mg QD (SA, BPP)<br>15 mg QD (BP)<br>5 to 10 mg QD (A, D, TD) | 30 mg/d (S, SA, and BP, BPP)<br>15 mg/d (A, D)<br>10 to 20 mg/d (TD) |
| Abilify MyCite® (aripiprazole tablets with sensor) [discontinued 12/2024] | Tablets with sensor (2, 5, 10, 15, 20, 30 mg) | | | |

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|---|---|---|---|---|
| Caplyta® (lumateperone capsules) | Capsules (10.5, 21, 42 mg) | 42 mg QD (S)[†] | 42 mg QD (S)[†] | 42 mg QD (S)[†] |
| Fanapt® (iloperidone tablets) | Tablets (1, 2, 4, 6, 8, 10, 12 mg) | 1 mg BID (S, BP) | 6 to 12 mg BID (S)<br>12 mg BID (BP) | 24 mg/d (S, BP) |
| Geodon® (ziprasidone capsules) | Capsules (20, 40, 60, 80 mg) | 20 mg BID (S)[†]<br>40 mg BID (BP)[†] | 20 to 80 mg BID (S)[†]<br>40 to 80 mg BID (BP)[†] | 200 mg/d (S)<br>160 mg/d (BP) |
| Invega® (paliperidone ER tablets) | ER tablets (1.5 [discontinued], 3, 6, 9 mg) | 6 mg QD (S)<br>3 mg QD (SA) | 3 to 12 mg QD (S) | 12 mg/d (S) |
| Latuda® (lurasidone tablets, generic) | Tablets (20, 40, 60, 80, 120 mg) | 40 mg QD (S)<br>20 mg QD (BP-D) | 40 to 160 mg QD (S)[*]<br>20 to 120 mg QD (BP-D) | 160 mg/d (S)[*]<br>80 mg/d (SA)<br>120 mg/d (BP-D) |
| Lybalvi™ (olanzapine and samidorphan) | Tablets (5/10, 10/10, 15/10, 20/10 mg) | 5/10 or 10/10 mg QD (S)<br>10/10 or 15/10 mg QD (BP)<br>10/10 mg QD (BP-CT) | 10/10 to 20/10 mg QD | 20/10 mg QD |
| Rexulti® (brexpiprazole tablets) | Tablets (0.25, 0.5, 1, 2, 3, 4 mg) | 1 mg QD (S)<br>0.5 mg QD (SP)<br>0.5 to 1 mg QD (D)<br>0.5 mg QD Days 1-7, then 1 mg QD Days 8-14, then 2 mg QD (AD) | 2 to 4 mg QD (S, SP)<br>2 mg QD (D and AD) | 4 mg QD (S, SP)<br>3 mg QD (D and AD) |
| Risperdal®[α] (risperidone tablets)<br>risperidone ODT | Tablets (0.25[Δ], 0.5, 1, 2, 3, 4 mg)<br>ODT (0.25, 0.5, 1, 2, 3, 4 mg) | 2 mg/d given QD or BID (S)<br>0.5 mg QD (SA)<br>2 to 3 mg QD (BP)<br>0.5 mg QD (BPP)<br>0.25 to 0.5 mg QD (A) | 4 to 8 mg/d given QD or BID (S)<br>2 to 8 mg/d to delay relapse (S)<br>1 to 6 mg/d (BP and SA)<br>1 to 2.5 mg/d (BPP)<br>0.5 mg to 3 mg QD (A) | 16 mg/d (S)<br>6 mg/d (BP and SA)<br>2.5 mg/d (BPP) |

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|---|---|---|---|---|
| Saphris® (asenapine tablets, generic) | Sublingual tablets (2.5, 5, 10 mg) | 5 mg BID (S)+<br>2.5 mg BID (, BPP)<br>5 to 10 mg BID (BP)+ | 5 to 10 mg BID (S)+<br>2.5 mg to 10 mg BID (BPP)<br>5 to 10 mg BID (BP)+* | 20 mg/d (S, BPP,and BP) |
| Secuado® (asenapine transdermal system) | Transdermal patches (3.8 mg/24 hours, 5.7 mg/ 24 hours, 7.6 mg/ 24 hours) | 3.8 mg/24 hours QD (S) | 3.8 to 7.6 mg/24 hours QD (S) | 7.6 mg/24 hours QD (S) |
| Seroquel® (quetiapine tablets) | Tablets (25, 50, 100, 200, 300, 400 mg) | 25 mg BID (S, SA)<br>50 mg BID (BP-MA)<br>50 mg HS (BP-D)<br>25 mg BID (BPP) | 150 to 750 mg/d given BID or TID (S)<br>400 to 800 mg/d (SA, BP-MA)<br>400 to 600 mg/d (BPP)<br>300 mg/d HS (BP-D) | 750 mg/d (S)<br>800 mg/d (SA and BP-MA)<br>600 mg/d (BPP)<br>300 mg/d (BP-D) |
| Seroquel XR® (quetiapine ER tablets) | ER tablets (50, 150, 200, 300, 400 mg) | 300 mg QD (S)<br>300 mg QD (BP-MA)<br>50 mg QD (SA, BP-D, BPP, D) | 400 to 800 mg QD (S, SA, BP-MA)<br>400 to 600 mg/d (BPP)<br>300 mg QD (BP-D)<br>150 to 300 mg QD (QD) | 800 mg/d (S, SA and BP-MA)<br>600 mg/d (BPP)<br>300 mg/d (BP-D, D) |
| Vraylar® (cariprazine capsules) | Capsules (1.5, 3, 4.5, 6 mg) | 1.5 mg QD (S, BP, D) | 1.5 to 6 mg QD (S)<br>3 to 6 mg QD (BP)<br>1.5 to 3 mg QD (BP-D, D) | 6 mg QD (S, BP)<br>3 mg QD (BP-D, D) |
| Zyprexa® and Zyprexa Zydis® (olanzapine tablets and ODT) [brand discontinued 9/2023] | Tablets (2.5, 5, 7.5, 10, 15, 20 mg)<br>ODT (5, 10, 15, 20 mg) | 5 to 10 mg QD (S)<br>2.5 to 5 mg QD (SA, BPP)<br>10 to 15 mg QD (BP-M)<br>10 mg QD (BP-CT)<br>5 mg QD (BP-D and D)^<br>2.5 mg QD (BP-DP) ^ | 10 to 15 mg QD (S)<br>10 mg QD (SA, BPP)<br>5 to 20 mg QD (BP)<br>5 to 12.5 mg QD (BP-D)<br>5 to 20 mg QD (D, BP-DP) | 20 mg/d (S, SA and BP)<br>18 mg/d (BP-D, BP-DP)<br>20 mg/d (D) |

[a] This product is also available as an oral solution that is not targeted in this policy; ODT – Orally disintegrating tablets; QD – Once daily; S – Schizophrenia; SA – Schizophrenia in adolescents; BP – Bipolar disorder; BPP – Bipolar disorder in pediatric

patients; D – Depression; A – Irritability associated with autism in pediatric patients; TD – Tourette's disorder; † Take with food; BID – Twice daily; ER – Extended-release; ⁺ Do not eat or drink for 10 minutes after administration; Δ The 0.25 mg brand Risperdal is no longer available; SP – Schizophrenia in pediatrics; MA – Mania; HS – At bedtime; TID – Three times daily; M – Monotherapy; CT – Combination therapy; AD – Agitation due to dementia associated with Alzheimer's disease; ^ With fluoxetine in the evening; BP-DP – Bipolar disorder with depressive episodes in pediatric patients.

*Additional Dosing and Administration Information*

Aripiprazole (Abilify, generic; Abilify Mycite)

When using aripiprazole concomitantly with strong cytochrome P450 (CYP)3A4 inhibitors (e.g., ketoconazole) or CYP2D6 inhibitors (e.g., quinidine, fluoxetine, paroxetine), OR if the patient is a known CYP2D6 poor metabolizer, reduce the aripiprazole dose to one-half the usual dose.[1,2] If the patient is receiving BOTH a strong CYP3A4 inhibitor AND a strong CYP2D6 inhibitor, the aripiprazole dose should be reduced to one-quarter the usual dose. When adding a potential CYP3A4 inducer (e.g., carbamazepine), double the aripiprazole. Aripiprazole orally-disintegrating tablets (ODT) should not be split.

Caplyta

When using Caplyta concomitantly with moderate or strong CYP3A4 inhibitors, the recommended dose of Caplyta is 21 mg and 10.5 mg once daily (QD), respectively.[3] For patients with moderate or severe hepatic impairment (Child-Pugh class B or C), the recommended dose of Caplyta is 21 mg QD.

Fanapt

Fanapt should be started at a low starting dose and titrated slowly to avoid orthostatic hypotension.[4] For the treatment of adults with *schizophrenia*, the recommended starting dose is 1 mg twice daily (BID). Increases to reach the target dose range of 6 to 12 mg BID (total dose 12 to 24 mg daily) may be made with daily dosage increases to 2 mg BID, 4 mg BID, 6 mg BID, 8 mg BID, 10 mg BID and 12 mg BID on days 2, 3, 4, 5, 6, and 7, respectively. For the acute treatment of manic or mixed episodes associated with Bipolar I Disorder, the initial dose is also 1 mg BID, and the dose is titrated with daily dosage increases to 3 mg BID, 6 mg BID, 9 mg BID, and 12 mg BID on Days 2, 3, 4, and 5, respectively. Titration packs are available to accommodate induction dosing. For patients that have had an interval of more than three days off Fanapt, it is recommended that the initiation titration schedule be followed.

Ziprasidone (Geodon, generic)

An increase to a dose greater than 80 mg BID of ziprasidone is not generally recommended and the safety of doses above 100 mg BID has not been evaluated in clinical trials.[5]

Paliperidone (Invega, generic)

Initial dose titration with paliperidone is not required.[6] However, some patients may benefit from lower or higher doses within the dose range of 3 to 12 mg QD. Dose increases should occur in increments of 3 mg per day at intervals of more than 5 days for schizophrenia and 4 days for schizoaffective disorder. The maximum recommended dose is 12 mg per day.

Lybalvi

Dosage may be adjusted at intervals of 5 mg (based on the olanzapine component of Lybalvi) depending upon clinical response and tolerability, up to the maximum recommended dosage of 20 mg/10 mg QD.[8] Lybalvi tablets should be swallowed whole. Patients should not split tablets or combine different strength Lybalvi tablets.

Rexulti

When using Rexulti concomitantly with strong CYP3A4 inhibitors (e.g., ketoconazole) or CYP2D6 inhibitors (e.g., quinidine, fluoxetine, paroxetine), OR the patient is a known CYP2D6 poor metabolizer, reduce the Rexulti dose to one-half the usual dose.[9] If the patient is receiving BOTH

a strong/moderate CYP3A4 inhibitor AND a strong/moderate CYP2D6 inhibitor, the Rexulti dose should be reduced to one-quarter the usual dose. The dose should also be reduced to one-quarter the usual dose if the patient is a known CYP2D6 poor metabolizer and is also receiving a strong/moderate CYP3A4 inhibitor. When adding a strong CYP3A4 inducer (e.g., carbamazepine), the Rexulti dose should be doubled over the course of one to two weeks.

Risperidone tablets (Risperdal, generic) and risperidone ODT
When using concomitantly with CYP2D6 inhibitors (e.g., fluoxetine, paroxetine) the Risperdal dose should be reduced; the maximum dose of Risperdal is 8 mg per day when co-administered with these drugs.[10] When adding enzyme inducers (e.g., carbamazepine, phenytoin, rifampin, phenobarbital), the patient's Risperdal dose may need to be increased up to double the usual dose.

Quetiapine tablets/extended-release tablets (Seroquel/Seroquel XR, generics)
When using concomitantly with CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, ritonavir) the quetiapine dose should be reduced to one sixth the original dose.[13,14] When taking quetiapine in combination with potent CYP3A4 inducers (e.g., carbamazepine, phenytoin, rifampin), the patient's Seroquel dose may need to be increased up to five times the usual dose.

Vraylar
When initiating Vraylar in a patient who is also taking a moderate or strong CYP3A4inhibitor, the dose of Vraylar should be reduced.[15] For schizophrenia or bipolar mania, initiate Vraylar at 1.5 mg every 3 days and then increase to 1.5 mg once every other day, if needed. For bipolar depression or as adjunctive therapy for major depressive disorder, Vraylar should be started at a dose of 1.5mg once every 3 days (strong CYP3A4 inhibitor) or 1.5 mg once every other day (moderate CYP3A4 inhibitor). If a strong or moderate CYP3A4inhibitor is initiated while the patient is already receiving a stable dose of Vraylar, dose adjustments are needed. A dose of 1.5 mg or 3 mg QD should be reduced to 1.5 mg once every 3 days (strong CYP3A4 inhibitor) or 1.5 mg once every other day (moderate CYP3A4 inhibitor). A dose of 4.5 mg or 6 mg QD should be reduced to 1.5 mg once every other day (strong CYP3A4 inhibitor) or 1.5 mg QD (moderate CYP3A4 inhibitor). Concomitant use of Vraylar and a CYP3A4 inducer has not been evaluated and is not recommended.

## Coverage Policy

**POLICY STATEMENT**
This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of the novel psychotropics. In general, the initial quantity limits allow for a 30-day supply of the medication when administered at the maximum recommended dose. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration unless noted below. "One-time" approvals are provided for 30 days in duration. Meeting Drug Quantity Management Program Criteria does not satisfy any other prior authorization or medical necessity criteria requirements.

**Drug Quantity Limits**

| Product | Strength/Dosage Form | Retail Maximum Quantity per 30 Days | Home Delivery Maximum Quantity per 90 Days |
|---|---|---|---|
| Abilify®<br>(aripiprazole tablets, generic) | 5 mg tablets | 30 tablets | 90 tablets |
| Caplyta®<br>(lumateperone capsules) | 10.5 mg capsules<br>21 mg capsules<br>42 mg capsules | 30 capsules | 90 capsules |
| Fanapt®<br>(iloperidone tablets) | 1 mg tablets<br>2 mg tablets<br>4 mg tablets<br>6 mg tablets<br>8 mg tablets<br>10 mg tablets | 120 tablets | 360 tablets |
| | Titration Pack A<br>(contains 2 x 1 mg tablets, 2 x 2 mg tablets, 2 x 4 mg tablets, and 2 x 6 mg tablets = 8 tablets) | 1 pack (8 tablets) | |
| | Titration Pack B<br>(contains 6 x 1 mg, 2 x 2 mg, 2 x 6 mg, and 2 x 8 mg tablets = 12 tablets) | 1 pack (12 tablets) | |
| | Titration Pack C<br>(contains 4 x 1 mg, 2 x 2 mg, and 2 x 6 mg tablets = 8 tablets) | 1 pack (8 tablets) | |
| Invega®<br>(paliperidone extended-release tablets, generic) | 3 mg extended-release tablets | 30 tablets | 90 tablets |
| Latuda®<br>(lurasidone tablets, generic) | 40 mg tablets<br>60 mg tablets | 30 tablets | 90 tablets |
| Lybalvi®<br>(olanzapine and samidorphan tablets) | 5-10 mg tablets<br>10-10 mg tablets<br>15-10 mg tablets<br>20-10 mg tablets | 30 tablets | 90 tablets |

| Product | Strength/Dosage Form | Retail Maximum Quantity per 30 Days | Home Delivery Maximum Quantity per 90 Days |
|---|---|---|---|
| Rexulti®<br>(brexpiprazole tablets) | 0.25 mg tablets<br>0.5 mg tablets<br>1 mg tablets<br>2 mg tablets | 30 tablets | 90 tablets |
| Vraylar®<br>(cariprazine capsules) | 0.5 mg capsules<br>0.75 mg capsules<br>1.5 mg capsules<br>3 mg capsules | 30 capsules | 90 capsules |

**Exceptions to the quantity limits listed above are covered as medically necessary when ONE of the following criteria is met. Any other exception is considered not medically necessary.**

## CRITERIA

Aripiprazole tablets (Abilify, generic)

1. If the patient has been receiving 30 mg per day for at least 4 weeks and the dose is now being increased to > 30 mg per day, approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply per dispensing at home delivery.

2. If the patient has already been started and stabilized on a dose > 30 mg per day, approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply per dispensing at home delivery.

3. If the dose is being doubled to a dose > 30 mg per day because the patient is taking a CYP3A4 inducer (e.g., carbamazepine), approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply per dispensing at home delivery.

4. If the patient's dose is being adjusted and a greater quantity is required to achieve either a lower or higher dose, approve a one-time override for a quantity sufficient to allow for dose titration at retail and at home delivery.

5. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets be used OR would otherwise require two or more strengths to be used), approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply per dispensing at home delivery.
   Note: For example, for a patient receiving aripiprazole 25 mg daily (i.e., five of the 5 mg tablets per day), allow 150 tablets for a 30-day supply per dispensing at retail and 450 tablets for a 90-day supply at home delivery.

6. If the patient has tried once daily therapy, but cannot tolerate it or the patient refuses to try once daily therapy, and requires the drug to be administered more frequently (e.g., divided twice-daily or three-times daily), approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply per dispensing at home delivery.
   Note: For example, for a patient receiving aripiprazole 10 mg twice daily, approve 60 tablets for a 30-day supply per dispensing at retail and 180 tablets for a 90-day supply per dispensing at home delivery.

Caplyta 10.5 mg and 21 mg capsules
No overrides recommended.

Caplyta 42 mg capsules
1. If the patient has been receiving 42 mg per day for at least 4 weeks and the dose is now being increased to > 42 mg per day, approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply per dispensing at home delivery.

2. If the patient has already been started and stabilized on a dose > 42 mg per day, approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply per dispensing at home delivery.

Paliperidone 3 mg extended-release tablets (Invega, generic)
1. If the patient has been receiving 12 mg per day for at least 4 weeks and the dose is now being increased to a dose > 12 mg per day that cannot be achieved using the 6 mg or 9 mg tablet strength, approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply per dispensing at home delivery.

2. If the patient has already been started and stabilized on a dose > 12 mg per day that cannot be achieved using the 6 mg or 9 mg tablet, approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply per dispensing at home delivery.

3. If the patient's dose is being adjusted and a greater quantity is required to achieve either a lower or higher dose, approve a one-time override for a quantity sufficient to allow for dose titration at retail and home delivery.

4. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets be used OR would otherwise require two or more strengths to be used), approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply per dispensing at home delivery.
   Note: For example, for a patient receiving paliperidone 4.5 mg once daily (i.e., three of the 1.5 mg tablets per day), approve 90 tablets for a 30-day supply per dispensing at retail and 270 tablets for a 90-day supply per dispensing at home delivery.

5. If the patient has tried once daily therapy but cannot tolerate it or the patient refuses to try once daily therapy and requires the drug to be administered more frequently

(e.g., twice daily), approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply per dispensing at home delivery.
Note: For example, for a patient receiving paliperidone 3 mg twice daily, approve 60 tablets for a 30-day supply per dispensing at retail and 180 tablets for a 90-day supply per dispensing at home delivery.

Lurasidone 40 mg and 60 mg tablets (Latuda, generic)

**1.** If the patient has been receiving 160 mg per day for at least 4 weeks and the dose is now being increased to a dose > 160 mg per day, approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply per dispensing at home delivery.

**2.** If the patient has already been started and stabilized on a dose > 160 mg per day, approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply per dispensing at home delivery.

**3.** If the patient has tried once daily therapy, but cannot tolerate it or the patient refuses to try once daily therapy and requires the drug to be administered more frequently (e.g., twice daily or three times daily), approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply per dispensing at home delivery.
Note: For example, for a patient receiving Latuda 40 mg twice daily, approve 60 tablets for a 30-day supply per dispensing at retail and 180 tablets as a 90-day supply per dispensing at home delivery.

Lybalvi

**1.** If the patient's dose is being adjusted and a greater quantity is required to achieve either a lower or higher dose, approve a one-time override for a quantity sufficient to allow for dose titration at retail and home delivery.

Rexulti

**1.** If the patient has been receiving 4 mg per day for at least 4 weeks and the dose is now being increased to > 4 mg per day, approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply per dispensing at home delivery.

**2.** If the patient has already been started and stabilized on a dose > 4 mg per day, approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply per dispensing at home delivery.

**3.** If the dose of Rexulti is being doubled to a dose > 4 mg per day because the patient is taking a CYP3A4 inducer (e.g., carbamazepine), approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply per dispensing at home delivery.

**4.** If the patient's dose is being adjusted and a greater quantity is required to achieve either a lower or higher dose, approve a one-time override for a quantity sufficient to allow for dose titration at retail and home delivery.

5. If the patient is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets be used OR would otherwise require two or more strengths to be used), approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply per dispensing at home delivery.
   Note: For example, for a patient receiving Rexulti 1.5 mg daily (i.e., three of the 0.5 mg tablets per day), approve 90 tablets for a 30-day supply per dispensing at retail and 270 tablets for a 90-day supply per dispensing at home delivery.

6. If the patient has tried once daily therapy, but cannot tolerate it or the patient refuses to try once daily therapy, and requires the drug to be administered more frequently (e.g., divided twice-daily or three-times daily), approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply per dispensing at home delivery.
   Note: For example, for a patient receiving Rexulti 1 mg twice daily, approve 60 tablets for a 30-day supply per dispensing at retail and 180 tablets for a 90-day supply per dispensing at home delivery.

Vraylar 1.5 mg and 3 mg capsules

1. If the patient has been receiving 6 mg per day for at least 4 weeks and the dose is now being increased to > 6 mg per day, approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply per dispensing at home delivery.

2. If the patient has already been started and stabilized on a dose > 6 mg per day, approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply per dispensing at home delivery.

3. If the patient's dose is being adjusted and a greater quantity is required to achieve either a lower or higher dose, approve a one-time override for a quantity sufficient to allow for dose titration at retail and home delivery.

4. If the patient has tried once daily therapy but cannot tolerate it or the patient refuses to try once daily therapy and requires the drug to be administered more frequently (e.g., twice daily), approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply per dispensing at home delivery.
   Note: For example, for a patient receiving Vraylar 1.5 mg BID, approve 60 capsules for a 30-day supply per dispensing at retail and 180 capsules for a 90-day supply per dispensing at home delivery.

## References


1. Abilify® tablets, orally disintegrating tablets, oral solution, and injection for intramuscular use [prescribing information]. Rockville, MD: Otsuka; January 2025.
2. Abilify Mycite® tablets with sensor [prescribing information]. Rockville, MD: Otsuka; January 2025.
3. Caplyta® capsules [prescribing information]. New York, NY: Intra-Cellular; June 2023.
4. Fanapt® tablets [prescribing information]. Washington, DC: Vanda; June 2025.

5. Geodon® capsules and IM injection [prescribing information]. New York, NY: Pfizer; January 2025.
6. Invega® extended-release tablets [prescribing information]. Titusville, NJ: Janssen; January 2025.
7. Latuda® tablets [prescribing information]. Marlborough, MA: Sunovion; January 2025.
8. Lybalvi™ tablets [prescribing information]. Waltham, MA: Alkermes; February 2025.
9. Rexulti® tablets [prescribing information]. Rockville, MD: Otsuka; May 2025.
10. Risperdal® (tablets/oral solution) and Risperdal® M-Tab® [prescribing information]. Titusville, NJ: Janssen; January 2025.
11. Saphris® sublingual tablets [prescribing information]. Irvine, CA: Allergan; January 2025.
12. Secuado® transdermal system [prescribing information]. Miami, FL: Noven; January 2025.
13. Seroquel® tablets [prescribing information]. Wilmington, DE: AstraZeneca; January 2025.
14. Seroquel XR® extended-release tablets [prescribing information]. Wilmington, DE: AstraZeneca; January 2025.
15. Vraylar® capsules [prescribing information]. Madison, NJ: Allergan; November 2024.
16. Zyprexa®, Zyprexa® Zydis® and Zyprexa® intramuscular [prescribing information]. Indianapolis, IN: Eli Lilly; January 2025.
17. Quetiapine tablets [prescribing information]. East Brunswick, NJ: Rising; April 2025.

## Revision Details

| Type of Revision | Summary of Changes | Date |
|---|---|---|
| New | New policy. | 04/01/2026 |

The policy effective date is in force until updated or retired.