

Drug Quantity Management – Per Rx Psychiatry – Novel Psychotropics

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Product Identifier(s)

Effective 1/1/23 to 3/21/23:

108904, 110564, 109938, 109122, 110230, 110106, 109155, 110612, 110342, 109182, 110298, 110569, 110348, 99175

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34891, 35253, 52158, 79251, 53670, 34952, 35506, 35507, 34892, 35505, 35254, 35674, 35504, 99175

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. 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.

National Formulary Medical Necessity

Drugs Affected

- Abilify® (aripiprazole tablets, generic)
- Abilify Mycite[®] (aripiprazole tablets with sensor)
- aripiprazole orally-disintegrating tablets (generic only)
- Caplyta[®] (lumateperone capsules)
- Fanapt® (iloperidone tablets)
- Geodon® (ziprasidone capsules, generic)
- Invega® (paliperidone extended-release tablets, generic)
- Latuda[®] (lurasidone tablets)
- Lybalvi[™] (olanzapine and samidorphan tablets)
- Rexulti® (brexpiprazole tablet)
- Risperdal® (risperidone tablets, generic)

- risperidone orally-disintegrating tablets (generic only)
- Saphris[®] (asenapine sublingual tablets, generic)
- Secuado® (asenapine transdermal system)
- Seroquel® (quetiapine tablets, generic)
- Quetiapine 150 mg tablets (authorized generic)
- Seroquel XR® (quetiapine extended-release tablets, generic)
- Vraylar® (cariprazine capsules)
- Zyprexa® (olanzapine tablets, generic)
- Zyprexa Zydis® (olanzapine orally disintegrating tablets, generic)

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.

Drug Quantity Limits

Product	Strength/Dosage Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Abilify® (aripiprazole tablets, generic)	2 mg tablets 5 mg tablets 10 mg tablets 15 mg tablets 20 mg tablets 30 mg tablets	30 tablets	90 tablets
Abilify Mycite® (aripiprazole tablets with sensor)	2 mg tablets 5 mg tablets 10 mg tablets 15 mg tablets 20 mg tablets 30 mg tablets Each kit contains 30 tablets and 7 sensor patches.	1 kit (30 tablets and 7 sensor patches)	3 kits (90 tablets and 21 sensor pathes)
aripiprazole orally-disintegrating tablets (generic only)	10 mg orally-disintegrating tablets 15 mg orally-disintegrating tablets	60 tablets	180 tablets
Caplyta [®] (lumateperone capsules)	10.5 mg capsules 21 mg capsules 42 mg capsules	30 capsules	90 capsules
Fanapt [®] (iloperidone tablets)	1 mg tablets 2 mg tablets 4 mg tablets 6 mg tablets 8 mg tablets 10 mg tablets 12 mg tablets	60 tablets	180 tablets
	Titration Pack (contains 2 x 1 mg tablets, 2 x 2 mg tablets, 2 x 4 mg tablets, and 2 x 6 mg tablets)	1 pack (8 tablets)	1 pack (8 tablets)
Geodon® (ziprasidone capsules, generic)	20 mg capsules 40 mg capsules 60 mg capsules 80 mg capsules	60 capsules	180 capsules

Product	Strength/Dosage Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Invega® (paliperidone extended-release tablets, generic)	1.5 mg extended-release tablets 3 mg extended-release tablets 9 mg extended-release tablets	30 tablets	90 tablets
	6 mg extended-release tablets	60 tablets	180 tablets
Latuda [®] (lurasidone tablets)	20 mg tablets 40 mg tablets 60 mg tablets 120 mg tablet	30 tablets	90 tablets
	80 mg tablets	60 tablets	180 tablets
Lybalvi [™] (olanzapine and samidorphan tablets)	5-10 mg tablets 10-10 mg tablets 15-10 mg tablets 20-10 mg tablets	30 tablets	90 tablets
Rexulti® (brexpiprazole tablets)	0.25 mg tablets 0.5 mg tablets 1 mg tablets 2 mg tablets 3 mg tablets 4 mg tablets	30 tablets	90 tablets

Drug Quantity Limits (continued)

Product	Strength/Dosage Form	Retail Maximum Quantity	Home Delivery Maximum Quantity
		per Rx	per Rx
Risperdal [®]	0.25 mg tablets	60 tablets	180 tablets
(risperidone tablets, generic)	0.5 mg tablets		
	1 mg tablets		
	2 mg tablets		
	3 mg tablets		
	4 mg tablets		
risperidone orally-disintegrating	0.25 mg orally-disintegrating	60 tablets	180 tablets
tablets (generic only)	tablets		
	0.5 mg orally-disintegrating tablets		
	1 mg orally-disintegrating tablets		
	2 mg orally-disintegrating		
	tablets		
	3 mg orally-disintegrating tablets		
	4 mg orally-disintegrating		
	tablets		
Saphris [®]	2.5 mg sublingual tablets	60 tablets	180 tablets
(asenapine sublingual tablets,	5 mg sublingual tablets		
generic)	10 mg sublingual tablets		
Secuado [®]	3.8 mg/24 hours	30 transdermal	90 transdermal
(asenapine transdermal system)	5.7 mg/24 hours	systems	systems
	7.6 mg/24 hours		
Quetiapine tablets	150 mg tablets	90 tablets	270 tablets
(authorized generic)			

Product	Strength/Dosage Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Seroquel [®] (quetiapine tablets, generic)	25 mg tablets 50 mg tablets	90 tablets	270 tablets
(440.442.000 (440.400)	100 mg tablets		
	200 mg tablets		
	300 mg tablets 400 mg tablets	60 tablets	180 tablets
Seroquel XR®	50 mg extended-release	60 tablets	180 tablets
(quetiapine extended-release	tablets		
tablets, generic)	300 mg extended-release		
	tablets		
	400 mg extended-release		
	tablets	20 4-1-4-	00 4-1-1-4-
	150 mg extended-release tablets	30 tablets	90 tablets
	200 mg extended-release		
	tablets		
Vraylar® (cariprazine capsules)	1.5 mg capsules	30 capsules	90 capsules
viayiai (campiazine capcaice)	3 mg capsules	oo capcaico	00 04604.00
	4.5 mg capsules		
	6 mg capsules		
	1.5 mg capsules blister pack (7 capsules)	7 capsules (1 pack)	7 capsules (1 pack)
	1.5 mg capsules and 3 mg	7 capsules (1 pack)	7 capsules (1 pack)
	capsules mixed blister pack		, , ,
	(1 x 1.5 mg capsules and 6 x		
	3 mg capsules)		
Zyprexa [®]	2.5 mg tablets	30 tablets	90 tablets
(olanzapine tablets, generic)	5 mg tablets		
	7.5 mg tablets		
	10 mg tablets		
	15 mg tablets		
	20 mg tablets		

Drug Quantity Limits (continued)

Product	Strength/Dosage Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Zyprexa Zydis [®] (olanzapine orally disintegrating tablets, generic)	5 mg orally-disintegrating tablets 10 mg orally-disintegrating tablets 15 mg orally-disintegrating tablets 20 mg orally-disintegrating tablets	30 tablets	90 tablets

<u>Criteria</u>

Cigna covers quantities as medically necessary when the following criteria are met:

All approvals are provided for 3 years in duration unless otherwise noted below.

Aripiprazole tablets (Abilify, generic) and Abilify Mycite

1. If the individual 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 individual 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 individual 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 individual'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 individual 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.
 - <u>Note</u>: For example, for an individual 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 individual has tried once daily therapy, but cannot tolerate it or the individual 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.
 - <u>Note</u>: For example, for an individual 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.

Aripiprazole orally-disintegrating tablets (ODT) [generic only]

- 1. If the individual 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 individual 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 individual 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 individual has tried once daily therapy, but cannot tolerate it or the individual 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 an individual receiving aripiprazole ODT 10 mg three times daily, 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.

Caplyta 10.5 mg and 21 mg capsules

No overrides recommended.

Caplyta 42 mg capsules

1. If the individual 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 individual 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.

Fanapt tablets (NOT the titration pack)

- 1. If the individual has been receiving 24 mg per day for at least 4 weeks and the dose is now being increased to > 24 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 individual has already been started and stabilized on a dose > 24 mg per day, approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and 90-day supply per dispensing at home delivery.
- 3. If the individual'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 individual 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 AND 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 an individual receiving Fanapt 4 mg in the morning and 2 mg in the evening (i.e., three of the 2 mg tablets per day), allow 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 individual has tried twice daily therapy, but cannot tolerate it or the individual refuses to try twice daily therapy and requires the drug to be administered more frequently (e.g., 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.

<u>Note</u>: For example, for an individual receiving Fanapt 4 mg three times daily, approve 90 tablets for a 30-day supply per dispensing at retail and 270 tablets for a 90-days supply per dispensing at home delivery.

Fanapt Titration Pack

No overrides recommended.

ziprasidone capsules (Geodon, generic)

- 1. If the individual has been receiving 160 mg per day for at least 4 weeks and the dose is now being increased to > 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 deliver.
- 2. If the individual 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 individual'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 individual has tried twice daily therapy, but cannot tolerate it or the individual refuses to try twice daily therapy and requires the drug to be administered more frequently (e.g., 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.

<u>Note</u>: For example, for an individual receiving ziprasidone 20 mg three times daily, allow 90 tablets for a 30-day supply per dispensing at retail and 270 tablets for a 90-day supply per dispensing at home delivery.

Paliperidone 1.5 mg and 3 mg extended-release tablets (Invega, generic)

- 1. If the individual 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 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 individual has already been started and stabilized on a dose > 12 mg per day that cannot be achieved using the 6 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 individual'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 individual 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.
 - <u>Note</u>: For example, for an individual 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 individual has tried once daily therapy, but cannot tolerate it or the individual 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.
 - <u>Note</u>: For example, for an individual 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.

Paliperidone 6 mg extended-release tablets (Invega, generic)

- 1. If the individual 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 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 individual has already been started and stabilized on a dose > 12 mg per day that cannot be achieved using the 6 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.

Paliperidone 9 mg extended-release tablets (Invega, tablets)

- 1. If the individual 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 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 individual has already been started and stabilized on a dose > 12 mg per day that cannot be achieved using the 6 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 individual 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.
 - <u>Note</u>: For example, for an individual 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.

Latuda 20 mg tablets

- 1. If the individual 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 individual 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 individual 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.
 - <u>Note</u>: For example, for an individual receiving Latuda 100 mg once daily (i.e., five of the 20 mg tablets per day), approve 150 tablets for a 30-day supply per dispensing at retail and 450 tablets for a 90-day supply per dispensing at home delivery.
- 4. If the individual has tried once daily therapy, but cannot tolerate it or the individual 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.
 - <u>Note</u>: For example, for an individual receiving Latuda 20 mg twice daily, allow 60 tablets for a 30-day supply per dispensing at retail and 180 tablets as a 90-day supply per dispensing at home delivery.

Latuda 40 mg, 60 mg, and 80 mg tablets

- 1. If the individual 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 individual 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 individual has tried once daily therapy, but cannot tolerate it or the individual 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.
 - <u>Note</u>: For example, for an individual 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.

Latuda 120 mg tablets

- 1. If the individual 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 individual 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.

Lybalvi

1. If the individual'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 individual 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 individual 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 individual 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 individual'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 individual 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 an individual 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 individual has tried once daily therapy, but cannot tolerate it or the individual 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 an individual 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.

Risperidone tablets (Risperdal, generics) and risperidone orally-disintegrating tablets (generic)

- If the individual requires a dose > 8 mg per day, approve up to 120 tablets per dispensing for a 30-day supply at retail and 360 tablets per dispensing for a 90-day supply at home delivery.
 Note: This allows for up to a dose of 16 mg per day.
- 2. If the individual has been receiving 16 mg per day for at least 4 weeks and the dose is now being increased to > 16 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 individual has already been started and stabilized on a dose > 16 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.
- 4. If the dose of risperidone (Risperdal tablets, generic; risperidone orally-disintegrating tablets) is being doubled to a dose > 16 mg per day because the individual is taking an enzyme 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.
- If the individual'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.
- 6. If the individual 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.

<u>Note</u>: For example, for an individual receiving risperidone 4 mg in the morning and 2 mg in the evening (i.e., three of the 2 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.

7. If the individual has tried once daily or twice daily therapy, but cannot tolerate it or the individual refuses to try once daily or twice daily therapy, and requires the drug to be administered more frequently (e.g., 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.

<u>Note</u>: For example, for an individual receiving risperidone 4 mg three times daily, allow 90 tablets for a 30-day supply per dispensing at retail and 270 tablets for a 90-day supply per dispensing at home delivery.

Asenapine 2.5 mg tablets (Saphris, generic)

1. If the individual'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.

Asenapine 5 mg tablets (Saphris, generic)

- 1. If the individual has been receiving 20 mg per day for at least 4 weeks and the dose is now being increased to a dose > 20 mg per day that cannot be achieved using the 10 mg 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 individual has already been started and stabilized on a dose > 20 mg per day that cannot be achieved using the 10 mg 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.
- 3. If the individual 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 an individual receiving asenapine 10 mg in the morning and 5 mg in the evening (i.e., three of the 5 mg tablets per day), approve a total of 90 of the 5 mg tablets for a 30-day supply per dispensing at retail and 270 of the 5 mg tablets for a 90-day supply per dispensing at home delivery.
- 4. If the individual has tried twice daily therapy, but cannot tolerate it or the individual refuses to try twice daily therapy, and requires the drug to be administered more frequently (e.g., 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.

<u>Note</u>: For example, for an individual receiving asenapine 5 mg three times daily, allow 90 tablets for a 30-day supply per dispensing at retail and 270 tablets for a 90-day supply per dispensing at home delivery.

Asenapine 10 mg tablets (Saphris, generic)

- 1. If the individual has been receiving 20 mg per day for at least 4 weeks and the dose is now being increased to a dose > 20 mg per day that cannot be achieved using the 10 mg 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 individual has already been started and stabilized on a dose > 20 mg per day that cannot be achieved using the 10 mg 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.

<u>Secuado 3.8 mg/24 hr, 5.7 mg/24 hr, 7.6 mg/24 hr transdermal systems</u> No overrides recommended.

Quetiapine tablets 25 mg, 50 mg, 100 mg, and 200 mg (Seroquel, generic) and Quetiapine 150 mg tablets

- 1. If the individual requires a dose > 600 mg per day that cannot be achieved using the 300 mg or 400 mg tablet strengths, 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 individual'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.
- 3. If the individual 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.
 - <u>Note</u>: For example, for an individual is receiving quetiapine 75 mg twice daily (i.e., six of the 25 mg tablets per day), approve a total of 180 tablets for a 30-day supply per dispensing at retail and a 540 tablets for a 90-day supply per dispensing at home delivery.

Quetiapine 300 mg and 400 mg tablets (Seroquel, generic)

- 1. If the individual has been receiving 800 mg per day for at least 4 weeks and the dose is now being increased to a dose > 800 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 individual has already been started and stabilized on a dose > 800 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 quetiapine is being increased because the individual is taking an enzyme 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 individual'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 a 90-day supply per dispensing at home delivery.

Quetiapine 50 mg extended-release tablets (Seroquel XR, generic)

- 1. If the individual'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.
- 2. If the individual has tried once daily or twice daily therapy, but cannot tolerate it or the individual refuses to try once daily or twice daily therapy, and requires the drug to be administered more frequently (e.g., three-times daily), approve a quantity sufficient to allow for a 30-day supply per dispensing at retail and a 90-day supply at home delivery.
 - <u>Note</u>: For example, for an individual receiving quetiapine 50 mg extended-release tablets three times daily, 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.

Quetiapine 150 mg and 200 mg extended-release tablets (Seroquel XR, generic)

- 1. If the individual has been receiving 800 mg per day for at least 4 weeks and the dose is now being increased to a dose > 800 mg per day that cannot be achieved using the 300 mg or 400 mg tablet strengths, 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 individual has already been started and stabilized on a dose > 800 mg per day that cannot be achieved using the 300 mg or 400 mg tablet strengths, 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 individual's dose is being increased to a dose > 800 mg per day because the individual is taking an enzyme inducer (e.g., carbamazepine) and the new dose cannot be achieved using the 300 mg or 400 mg tablet strengths, 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 individual'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 individual has tried once daily therapy, but cannot tolerate it or the individual 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.
 - <u>Note</u>: For example, for an individual receiving quetiapine 200 mg extended-release tablets 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.

Quetiapine 300 mg and 400 mg extended-release tablets (Seroquel XR, generic)

- 1. If the individual has been receiving 800 mg per day for at least 4 weeks and the dose is now being increased to > 800 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 individual has already been started and stabilized on a dose > 800 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 individual's dose is being increased to a dose > 800 mg per day because the individual is taking an enzyme 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 individual'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.

Vraylar 1.5 mg and 3 mg capsules

- 1. If the individual 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 individual 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 individual'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 individual has tried once daily therapy, but cannot tolerate it or the individual 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.
 - <u>Note</u>: For example, for an individual receiving Vraylar 1.5 mg BID, 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 4.5 mg and 6 mg capsules

- 1. If the individual 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 individual 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.

Vraylar Blister Pack and Mixed Blister Pack

No overrides recommended.

Olanzapine 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg tablets (Zyprexa, generic)

- 1. If the individual has been receiving 20 mg per day for at least 4 weeks and the dose is now being increased to > 20 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 individual has already been started and stabilized on a dose > 20 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 individual'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 individual 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.
 - <u>Note</u>: For an individual receiving olanzapine 12.5 mg once daily (i.e., five of the 2.5 mg tablets per day, allow a total of 150 tablets for a 30-day supply per dispensing at retail and 450 tablets for a 90-day supply per dispensing at home delivery.
- 5. If the individual has tried once daily therapy, but cannot tolerate it or the individual 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.
 - <u>Note</u>: For example, for an individual receiving olanzapine 5 mg twice daily, allow 60 tablets for a 30-day supply per dispensing at retail and 180 tablets for a 90-day supply per dispensing at home delivery.

Olanzapine 5 mg, 10 mg, 15 mg and 20 mg orally-disintegrating tablets (Zyprexa Zydis, generic)

- 1. If the individual has been receiving 20 mg per day for at least 4 weeks and the dose is now being increased to > 20 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 individual has already been started and stabilized on a dose > 20 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 individual'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 individual has tried once daily therapy, but cannot tolerate it or the individual 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.

<u>Note</u>: For example, for an individual receiving olanzapine orally-disintegrating tablet 5 mg twice daily, allow 60 orally-disintegrating tablets for a 30-day supply per dispensing at retail and 180 orally-disintegrating tablets for a 90-day supply per dispensing at home delivery.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

Indications

All of the novel psychotropics are indicated for use in **schizophrenia**.¹⁻¹⁷ In addition, all of the agents except Caplyta, paliperidone, Fanapt, 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, and quetiapine extended-release are indicated as adjunctive treatment for major depressive disorder in patients already taking an antidepressant.
- o Aripiprazole is the only agent indicated for the treatment of Tourette's disorder.
- o Paliperidone is indicated for the treatment of schizoaffective disorder.
- Aripiprazole, Latuda, 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, Latuda, olanzapine, quetiapine, and risperidone are approved for use in patients ≥ 13 years of age with schizophrenia.

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. 1-16

Agent	Dosage Forms	Starting Dose	Usual Therapeutic	Maximum Dose
Abilify® (aripiprazole tablets and ODT, generic) ^α	Tablets (2, 5, 10, 15, 20, 30 mg) ODT (10, 15 mg)	10 to 15 mg QD (S) 2 mg QD (SA) 15 mg QD (BP) 2 mg QD (BPP)	Dose 10 to 15 mg QD (S) 10 mg QD (SA, BPP) 15 mg QD (BP) 5 to 10 mg QD (D, TD)	30 mg/d (S, SA, and BP, BPP) 15 mg/d (D) 10 to 20 mg/d (TD)
Abilify MyCite® (aripiprazole tablets with sensor)	Tablets with sensor (2, 5, 10, 15, 20, 30 mg)	2 to 5 mg QD (D) 2 mg QD (A) 2 mg QD (TD)		
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)	6 to 12 mg BID (S)	24 mg/d (S)
Geodon® (ziprasidone capsules)	Capsules (20, 40, 60, 80 mg)	20 mg BID (S) [†] 40 mg BID (BP) [†]	20 to 80 mg BID (S) [†] 40 to 80 mg BID (BP) [†]	200 mg/d (S) 160 mg/d (BP)
Invega [®] (paliperidone ER tablets)	ER tablets (1.5, 3, 6, 9 mg)	6 mg QD (S) 3 mg QD (SA)	3 to 12 mg QD (S)	12 mg/d (S)
Latuda [®] (lurasidone tablets)	Tablets (20, 40, 60, 80, 120 mg)	40 mg QD (S) 20 mg QD (BP-D)	40 to 160 mg QD (S)* 20 to 120 mg QD (BP- D)	160 mg/d (S) [*] 80 mg/d (SA) 120 mg/d (BP-D)

Agent	Dosage Forms	Starting Dose	Usual Therapeutic Dose	Maximum Dose
Lybalvi [™] (olanzapine and samidorphan)	Tablets (5/10, 10/10, 15/10, 20/10 mg)	5/10 or 10/10 mg QD (S) 10/10 or 15/10 mg QD (BP) 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) 0.5 to 1 mg QD (D)	2 to 4 mg QD (S) 2 mg QD (D)	4 mg QD (S) 3 mg QD (D)
Risperdal®a (risperidone tablets) risperidone ODT	Tablets (0.25 ^Δ , 0.5, 1, 2, 3, 4 mg) ODT (0.25, 0.5, 1, 2, 3, 4 mg)	BID (S)	4 to 8 mg/d given QD or BID (S) 2 to 8 mg/d to delay relapse (S) 1 to 6 mg/d (BP) 1 to 2.5 mg/d (BPP) 0.5 mg to 3 mg QD (A)	16 mg/d (S) 6 mg/d (BP) 2.5 mg/d (BPP)
Saphris® (asenapine tablets)	Sublingual tablets (2.5, 5, 10 mg)	5 mg BID (S) ⁺ 2.5 mg BID (SA, SP, BPP) 10 mg BID (BP) ⁺	5 to 10 mg BID (S) ⁺ 2.5 mg to 10 mg BID (SA, SP, BPP) 5 to 10 mg BID (BP) ^{+*}	20 mg/d (S, SA, SP 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) 50 mg BID (BP-MA) 50 mg HS (BP-D) 25 mg BID (BPP)	150 to 750 mg/d given BID or TID (S) 400 to 800 mg/d (SA, BP-MA) 400 to 600 mg/d (BPP) 300 mg/d HS (BP-D)	750 mg/d (S) 800 mg/d (SA and BP- MA) 600 mg/d (BPP) 300 mg/d (BP-D)

Table 1 (continued). Novel Psychotropic Dosing and Availability. 1-16

Agent	Dosage Forms	Starting Dose	Usual Therapeutic Dose	Maximum Dose
Seroquel XR [®] (quetiapine ER tablets)	ER tablets (50, 150, 200, 300, 400 mg)	300 mg QD (S) 300 mg QD (BP-MA) 50 mg QD (SA, BP-D, BPP, D)	400 to 800 mg QD (S, SA, BP-MA)	800 mg/d (S, SA and BP-MA) 600 mg/d (BPP) 300 mg/d (BP-D, D)
Vraylar [®] (cariprazine capsules)	Capsules (1.5, 3, 4.5, 6 mg)	1.5 mg QD (S, BP)	1.5 to 6 mg QD (S) 3 to 6 mg QD (BP) 1.5 to 3 mg QD (BP-D)	6 mg QD (S, BP) 3 mg QD (BP-D)
Zyprexa® and Zyprexa Zydis® (olanzapine tablets and ODT)	Tablets (2.5, 5, 7.5, 10, 15, 20 mg) ODT (5, 10, 15, 20 mg)	5 to 10 mg QD (S) 2.5 to 5 mg QD (SA, BPP) 10 to 15 mg QD (BP-M) 10 mg QD (BP-CT) 5 mg QD (BP-D and D) ² 2.5 mg QD (BP-DP) ²	10 to 15 mg QD (S) 10 mg QD (SA, BPP) 5 to 20 mg QD (BP) 5 to 12.5 mg QD (BP- D) 5 to 20 mg QD (D, BP-	20 mg/d (S, SA and BP) 18 mg/d (BP-D, BP-DP) 20 mg/d (D)

^α 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; [△] 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; [△] 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), the aripiprazole dose should be doubled. 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, respectively.³ For patients with moderate or severe hepatic impairment (Child-Pugh class B or C), the recommended dose of Caplyta is 21 mg once daily.

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. Increases to reach the target dose range of 6 to 12 mg twice daily (total dose 12 to 24 mg daily) may be made with daily dosage increases to 2 mg twice daily, 4 mg twice daily, 6 mg twice daily, 8 mg twice daily, 10 mg twice daily and 12 mg twice daily on days 2, 3, 4, 5, 6, and 7, respectively. To accommodate this titration, Fanapt is supplied as a titration pack, containing 2 x 1 mg tablets, 2 x 2 mg tablets, 2 x 4 mg tablets, and 2 x 6 mg tablets. 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 once daily. 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 once daily.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. 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. 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 (Seroquel, generic) and Quetiapine extended-release tablets (Seroquel XR, generic) 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.

References

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- 16. Zyprexa®, Zyprexa® Zydis® and Zyprexa® intramuscular [prescribing information]. Indianapolis, IN: Eli Lilly and Company; April 2020.
- 17. Quetiapine tablets [prescribing information]. East Brunswick, NJ: Rising; March 2022.

Revision History

Type of Revision	Summary of Changes	Approval Date
Early Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.	08/31/2022
	The approval durations in the policy were changed from 3 years to 1 year.	
	Caplyta 10.5 mg and 21 mg capsules: New quantity limits were added for 30 capsules per Rx at retail and 90 capsules per Rx at home delivery. No clinical overrides apply.	
Selected Revision	Quetiapine 150 mg tablet (authorized generic): New quantity limits were added for 90 tablets per Rx at retail and 270 tablets per Rx at home delivery. Override criteria apply for patients who require a dose > 600 mg per day that cannot be achieved using the 300 mg or 400 mg tablet strengths, if the dose is being adjusted and a greater quantity is needed to achieve either a higher or lower dose, or if the patient is taking a dose that does not correspond to a commercially-	09/21/2022
	available dosage form.	

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