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Drug Quantity Management – Per Rx Antidepressants – Selective Serotonin Reuptake Inhibitors

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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

- Brisdelle® (paroxetine mesylate capsules generic)
- Celexa® (citalopram tablets generic)
- citalopram capsules (Almatica)
- fluvoxamine tablets (generic only)
- fluvoxamine extended-release capsules (generic only)
- Lexapro[®] (escitalopram tablets generic)
- Paxil[®] (paroxetine hydrochloride tablets generic)
- Paxil CR® (paroxetine hydrochloride controlled-release tablets generic)
- Pexeva® (paroxetine mesylate tablets)
- fluoxetine 90 mg delayed-release capsules (generic only)

- Prozac® (fluoxetine capsules generic; fluoxetine tablets [generic only])
- Sarafem® (fluoxetine tablets generic [brand no longer available])
- Trintellix[®] (vortioxetine tablets)
- Viibryd[®] (vilazodone tablets)
- Zercapli[™] (sertraline capsules generic)
- Zoloft[®] (sertraline tablets generic)

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of the selective serotonin reuptake inhibitors. 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 otherwise noted below.

Drug Quantity Limits

Brand (generic)	Dosing	Availability	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Brisdelle® (paroxetine mesylate capsules, generic)	VMS: 7.5 mg QHS	7.5 mg capsules	30 capsules	90 capsules
Celexa® (citalopram tablets, generic)	 MDD (adults): 20 mg QD. May increase to 40 mg QD if needed. Doses > 40 mg per day are ordinarily not recommended but certain individuals may require 60 mg per day. Numerous studies have documented the safety and efficacy of utilizing Celexa 60 mg daily in certain individuals (i.e., those with refractory depression, non-responders). 	10 mg tablets 20 mg tablets 40 mg tablets	30 tablets	90 tablets

Drug Quantity Limits (continued)

Brand (generic)	Dosing	Availability	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
citalopram capsules	**Citalopram capsules should not be used to initiate treatment as the only strength available is 30 mg. Another citalopram product should be used for initial dosing, titration, and any dose other than 30 mg QD** • Dosing of citalopram for MDD in adults is provided above.	30 mg capsules	30 capsules	90 capsules
fluvoxamine		25 mg tablets	30 tablets	90 tablets
tablets		50 mg tablets	60 tablets	180 tablets

(generic only)	OCD (individuals 8 to 17 years of age): Initial dose of 25 mg QHS. Dose is increased in 25 mg increments every 4 to 7 days, as tolerated. If the total daily dose is > 50 mg, give in two divided doses (one	100 mg tablets	90 tablets	270 tablets
	dose may be larger than the other. Dose range of 50 mg to 200 mg per day (used in pediatric OCD clinical trials) Maximum dose in children up to age 11 should not exceed 200 mg per day. Maximum dose for adolescents ages 12-17 is 300 mg per day. OCD (adults): Initial dose of 50 mg QHS. Dose is increased in 50 mg increments every 4 to 7 days, as tolerated. If the total daily dose is >			
	100 mg, give in two divided doses (one dose may be larger than the other). o Maximum dose should not exceed 300 mg per day.			
fluvoxamine extended- release capsules (generic only)	OCD (adults): 100 mg QD with dose increases in 50 mg increments every week, as tolerated. Do not exceed 300 mg per day. OCD (pediatric): the lowest available dose of fluvoxamine CR may not be appropriate for pediatric individuals who are naive to fluvoxamine.	100 mg capsules 150 mg capsules	60 capsules	180 capsules
Lexapro® (escitalopram tablets, generic)	MDD (individuals ≥ 12 years of age): 10 mg QD. Adults: Dose may be increased to 20 mg QD if needed, after a minimum of 1 week (adults) or 3 weeks (adolescents). GAD (adults): 10 mg QD. Dose may be increased to 20 mg QD if needed, after a minimum of 1 week.	5 mg tablets 10 mg tablets 20 mg tablets	30 tablets	90 tablets
Paxil® (paroxetine HCI tablets, generic)	Panic Disorder (Adults)/Elderly (Any Indication)/Severe Renal or Hepatic Impairment (Any Indication): 10 mg QD (initial dose). MDD/OCD/GAD/PTSD/SAD: 20 mg QD (initial dose). Increase dose in 10 mg increments at intervals of at least 1 week, to a maximum daily dose of 60 mg (OCD, panic disorder/SAD), 50 mg (MDD, GAD, PTSD), or 40 mg (elderly or debilitated, severe renal or hepatic impairment).	10 mg tablets 40 mg tablets 20 mg tablets 30 mg tablets	30 tablets 60 tablets	90 tablets 180 tablets

Drug Quantity Limits (continued)

Drug Quantity Limits (continued)							
Brand (generic)	Dosing	Availability	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx			
Pexeva [®] (paroxetine mesylate	Panic Disorder (Adults)/Elderly (Any Indication)/Severe Renal or Hepatic Impairment (Any Indication): 10 mg	10 mg tablets 40 mg tablets	30 tablets	90 tablets			
tablets)	QD (initial dose). • MDD/OCD/GAD: 20 mg QD (initial dose). Increase dose in 10 mg	20 mg tablets*	60 tablets	180 tablets			
	increments at intervals of at least 1 week, to a maximum daily dose of 60 mg (OCD, panic disorder), 50 mg (MDD, GAD), or 40 mg (elderly or debilitated, severe renal or hepatic impairment).	30 mg tablets					
Paxil CR® (paroxetine HCI controlled-	Panic Disorder/PMDD/SAD/Elderly or Debilitated (Any Indication)/Severe Renal or Hepatic Impairment (Any	12.5 mg tablets	60 tablets	180 tablets			
release tablets, generic)	Indication): 12.5 mg QD (initial dose). Increase dose in increments of 12.5 mg at intervals of at least 1 week to a	25 mg tablets					
	maximum daily dose of 75 mg (panic disorder), 50 mg (elderly, debilitated, severe renal or hepatic impairment),	37.5 mg tablets					
	37.5 mg (SAD), or 25 mg (PMDD). • MDD: 25 mg QD (initial dose). Increase dose in increments of 12.5						
D @+	mg at intervals of at least 1 week to a maximum daily dose of 62.5 mg.	40					
Prozac ^{®†} (fluoxetine capsules and	MDD/OCD: 20 mg QD (initial dose). Increase to a maximum dose of 80 mg per day if needed.	10 mg capsules and tablets	30 capsules and tablets	90 capsules and tablets			
tablets, generic)	 MDD (≥ 7 years of age to < 18 years of age): 10 mg or 20 mg QD (initial dose). 	20 mg capsules and tablets	No quantity limit	No quantity limit			
	Bulimia nervosa (adults): 60 mg per day (initial dose). It may be advisable	40 mg capsules	60 capsules	180 capsules			
	to titrate to this target dose over a period of several days). • Panic Disorder (Adults): 10 mg QD	60 mg tablets	No quantity limit	No quantity limit			
	(initial dose). After 1 week, increase the dose to 20 mg QD. The dose may be increased again, to a maximum						
	dose of 60 mg per day after several weeks, if necessary. Dosages above 20 mg daily may be						
	given once daily or in 2 divided doses. When used in lower weight children or in evidence-supported off-label						
	situations for children < 7 years of age, therapy can be initiated at 5 to 10 mg QD. Dosage in elderly individuals is						
	often initiated with 10 mg QD. Consider a lower or less frequent dose in individuals with hepatic impairment or						
	other concurrent disease or in those on multiple concomitant medications.						

mg delayed- release	MDD (Adults): 90 mg QW. If a satisfactory response is not maintained, a dosing regimen with daily fluoxetine should be considered.	90 mg delayed- release capsules	4 capsules	12 capsules
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	Drug Quantity Limits (continued)								
Brand (generic)	Dosing	Availability	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx					
Sarafem® (fluoxetine tablets, generic)	PMDD (Adults): 20 mg QD (initial dose) given continuously every day or intermittently during certain days of the menstrual cycle. Increase dose to a maximum of 80 mg per day, if necessary. However, doses above 60 mg per day have not been systematically studied in PMDD.	10 mg tablets/capsul es Each box contains four 7-day blister packs. 20 mg	30 tablets/capsules No quantity limit	90 tablets/capsules No quantity limit					
	Consider a lower or less frequent dose in individuals with hepatic impairment or other concurrent disease or in those on multiple concomitant medications.	tablets/capsul es Each box contains four 7-day blister packs.							
Trintellix® (vortioxetine tablets)	 MDD (Adults): 10 mg QD (initial dose). After 1 week, may increase to a target dose of 20 mg per day, as tolerated. The efficacy and safety of doses above 20 mg per day have not been evaluated. Doses of 5 mg per day may be considered for individuals who do not tolerate higher doses. A maximum dose of 10 mg per day is recommended in known CYP2D6 poor metabolizers. For doses of 15 to 20 mg per day, reduce the dose to 10 mg per day for 1 week prior to full discontinuation, if possible. However, Trintellix may be discontinued abruptly. 	5 mg tablets 10 mg tablets 20 mg tablets	30 tablets	90 tablets					
Viibryd [®] (vilazodone tablets)	MDD (Adults): Target dose is 20 mg to 40 mg QD. Initial dosing is 10 mg QD x 7 days, followed by 20 mg QD.	10 mg tablets 20 mg tablets 40 mg tablets	30 tablets	90 tablets					
	After a minimum of 7 days, the dose may be increased to 40 mg QD.	10/20 mg Titration Pack (30 tablets)	30 tablets	30 tablets					
Zoloft®		25 mg tablets	45 tablets	135 tablets					

(sertraline	MDD/OCD (Adults): 50 mg QD	50 mg tablets	60 tablets	180 tablets
tablets, generic)	PMDD: 50 mg QD, either	100 mg		
	continuously or limited to the luteal	tablets		
	phase of the menstrual cycle. If the			
	dose is titrated up to 100 mg QD			
	during the luteal phase, then 50 mg			
	daily should be utilized for the first 3			
	days of each luteal phase dosing			
	period. • <u>PTSD/SAD (Adults)</u> : 25 mg QD			
	(initial therapy). After 1 week, the			
	dose should be increased to 50 mg			
	QD.			
	OCD (individuals 6 to 12 years of			
	<u>age)</u> : 25 mg QD			
	 OCD (individuals 13 to 17 years of 			
	<u>age)</u> : 50 mg QD.			
	The dosage may be increased if			
	necessary to a maximum daily dose of			
	200 mg in either adults or children (150			
	mg daily in PMDD when dosing is throughout the menstrual cycle).			

Drug Quantity Limits (continued)

Brand (generic)	Dosing	Availability	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Zercapli® (sertraline capsules, branded generic)	MDD/OCD: 150 mg or 200 mg QD. Maximum recommended dose is 200 mg QD. The capsules should not be used to initiate treatment. Another sertraline product should be used for initial dosing, titration, and dosages < 150 mg QD. Sertraline capsules can be initiated in individuals receiving 100 mg or 125 mg of sertraline for at least 1 week.	150 mg capsules 200 mg capsules	30 capsules	90 capsules

VMS – Vasomotor symptoms; QHS – Once daily at bedtime; MDD – Major depressive disorder; QD – Once daily; OCD – Obsessive compulsive disorder; GAD – Generalized anxiety disorder; PTSD – Posttraumatic stress disorder; SAD – Social anxiety disorder; QW – Once weekly; PMDD – Premenstrual dysphoric disorder.

Criteria

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

Paroxetine mesylate 7.5 mg capsules (Brisdelle, generic)

No overrides recommended.

Citalopram 10 mg tablets (Celexa, generic)

- 1. If the individual requires the dose to be divided two times daily, approve a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
- 2. 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 be used), approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
 - <u>Note</u>: For example, for an individual taking 30 mg per day (three 10 mg tablets), approve 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery.

Citalopram 20 mg tablets (Celexa, generic)

- 1. If the individual requires the dose to be divided two times daily, approve a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
- 2. If the individual is receiving a 30 mg daily dose, approve 45 tablets per dispensing at retail or 135 tablets 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 be used), approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

Citalopram 30 mg capsules

No overrides recommended.

<u>Note</u>: Citalopram capsules should not be used to initiate treatment as the only strength available is 30 mg. Another citalopram product should be used for initial dosing, titration, and any dose other than 30 mg once daily.

Citalopram 40 mg tablets (Celexa, generic)

- 1. If the individual is receiving a 60 mg daily dose, approve up to 45 tablets per dispensing at retail or 135 tablets per dispensing at home delivery.
- 2. If the individual has been receiving 60 mg per day and the dose is now being increased to > 60 mg per day, approve a quantity sufficient to allow for a 30-day supply per dispensing.

Escitalopram 5 mg tablets (Lexapro, generic)

- 1. If the individual requires the dose to be divided two times daily, approve a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
- 2. 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 be used), approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
 - <u>Note</u>: For example, for an individual receiving 15 mg daily, approve 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery.

Escitalopram 10 mg tablets (Lexapro, generic)

- 1. If the individual requires the dose to be divided two times daily, approve a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
- 2. 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 be used), approve for the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
 - <u>Note</u>: For example, for an individual receiving 30 mg daily, approve 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery.

Escitalopram 20 mg tablets (Lexapro, generic)

- 1. If the individual has already been started and stabilized on a dose > 20 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
- 2. If the individual has been receiving 20 mg per day and the dose is now being increased to > 20 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

Fluvoxamine 25 mg tablets

No overrides recommended.

Note: Individuals receiving a dose of 100 mg, 150 mg, or 200 mg should use the 100 mg tablets.

Fluvoxamine 50 mg tablets

1. 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 be used), approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

<u>Note</u>: For example, for an individual receiving 75 mg twice daily (3 tablets per day), approve 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery.

Fluvoxamine 100 mg tablets

- 1. If the individual has already been started and stabilized on a dose > 300 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
- 2. If the individual has been receiving 300 mg per day and the dose is now being increased to > 300 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

Fluvoxamine 100 mg extended-release capsules

No overrides recommended.

Fluvoxamine 150 mg extended-release capsules

- 1. If the individual has already been started and stabilized on a dose > 300 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
- 2. If the individual has been receiving 300 mg per day and the dose is now being increased to > 300 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

Paroxetine 10 mg tablets (Paxil, generic)

1. 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 be used), approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

<u>Note</u>: The 10 mg tablets and 20 mg tablets are scored. For example, if the individual is taking a dose of 10 mg in the morning and 20 mg in the evening (three 10 mg tablets per day), approve 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery.

Paroxetine 20 mg tablets (Paxil, generic)

- If the individual requires the dose to be divided two or three times daily, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
 Note: For example, for an individual taking a dose of 20 mg in the morning and 40 mg in the evening (three 20 mg tablets per day), approve 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery.
- 2. 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 be used), approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply at home delivery.

<u>Note</u>: The 10 mg tablets and 20 mg tablets are scored. For example, if the individual taking a dose of 20 mg in the morning and 40 mg in the evening (three 20 mg tablets per day), approve 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery.

Paroxetine 30 mg tablets (Paxil, generic)

1. 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 be used), approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply at home delivery.

Paroxetine 40 mg tablets (Paxil, generic)

- 1. If the individual has already been started and stabilized on a dose > 60 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
- 2. If the individual has been receiving 60 mg per day and the dose is now being increased to > 60 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

Pexeva 10 mg tablets

1. 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 be used), approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

<u>Note</u>: The 20 mg tablets are scored and can be divided. For example, if the individual was taking a dose of 10 mg in the morning and 20 mg in the evening (three 10 mg tablets per day), then approve 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery.

Pexeva 20 mg tablets

- If the individual requires the dose to be divided two or three times daily, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or 90-day supply per dispensing at home delivery.
 Note: For example, for an individual taking a dose of 20 mg in the morning and 40 mg in the evening (three 20 mg tablets per day), approve 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery.
- 2. 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 be used), approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

 Note: For example, for an individual receiving Pexeva 50 mg daily (i.e., two and one-half of the 20 mg
 - tablets per day), approve 75 of the 20 mg tablets for a 30-day supply per dispensing. The 20 mg tablets are scored and can be divided. For example, for an individual taking a dose of 20 mg in the morning and 40 mg in the evening (three 20 mg tablets per day), approve 90 tablets for a 30-day supply per dispensing.

Pexeva 30 mg tablets

1. 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 be used), approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

Pexeva 40 mg tablets

- 1. If the individual has already been started and stabilized on a dose > 60 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
- 2. If the individual has been receiving 60 mg per day and the dose is now being increased to > 60 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

Paroxetine 12.5 mg controlled-release tablets (Paxil CR, generic)

- 1. If the individual requires the dose to be divided two or three times daily, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

 Note: For example, for an individual taking a dose of 25 mg in the morning and 12.5 mg in the evening (three 12.5 mg tablets per day), approve 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery.
- 2. 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 be used), approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply at home delivery.

<u>Note</u>: For example, for an individual receiving 62.5 mg once daily (i.e., five of the 12.5 mg tablets), approve 150 tablets per dispensing at retail or 450 tablets per dispensing at home delivery.

Paroxetine 25 mg controlled-release tablets (Paxil CR, generic)

1. 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 be used), approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

Note: An individual taking 75 mg once daily should use the 37.5 mg controlled-release tablets.

Paroxetine 37.5 mg controlled-release tablets (Paxil CR, generic)

- 1. If the individual has already been started and stabilized on a dose > 75 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
- 2. If the individual has been receiving 75 mg per day and the dose is now being increased to > 75 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

Fluoxetine 10 mg tablets and capsules (Prozac, Sarafem, generic)

Note: Sarafem 10 mg tablets share the same coding values with fluoxetine 10 mg capsules/tablets and Sarafem 20 mg tablets share the same coding with fluoxetine 20 mg capsules/tablets. An individual taking a single daily dose of 20 mg or 40 mg should use the 20 mg (tablets/capsules) or 40 mg (capsules) strengths, respectively. While Sarafem tablets are packaged blister packs of 28-day supplies, the packages *are* breakable, if the prescriber writes for a 30-day supply and the dispensing pharmacist wishes to break a package. Further, Sarafem can be dosed continuously.

- 1. If the individual requires the dose to be divided two or three times daily, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

 Note: For example, for an individual taking a dose of 10 mg twice daily, approve up to 60 tablets or capsules per dispensing at retail or 180 tablets or capsules per dispensing at home delivery.
- 2. 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 be used), approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

<u>Note</u>: For example, if the individual is taking 30 mg daily, either once daily or as a divided dose (i.e., 20 mg in the morning and 10 mg in the evening [three capsules or tablets per day]), approve 90 capsules or tablets per dispensing at retail or 270 capsules or tablets per dispensing at home delivery.

Fluoxetine 40 mg capsules (generic)

- 1. If the individual has already been started and stabilized on a dose > 80 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
- 2. If the individual has been receiving 80 mg per day and the dose is now being increased to > 80 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

Fluoxetine 20 mg capsules and 60 mg tablets

No overrides recommended.

Fluoxetine 90 mg delayed release capsules (Prozac Weekly, generic)

- 1. If the individual has already been receiving 90 mg twice weekly, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
- 2. If the individual has been receiving 90 mg once weekly and the dose is now being increased to 90 mg twice weekly, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

Trintellix 5 mg and 10 mg tablets

- 1. If the individual requires the dose to be divided two times daily, approve dispensing 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
- 2. 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 be used), approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
 - <u>Note</u>: For example, for an individual receiving Trintellix 15 mg per day (i.e., three 5 mg tablets), approve 90 of the 5 mg tablets for a 30-day supply per dispensing.

Trintellix 20 mg tablets

- 1. If the individual has already been started and stabilized on a dose > 20 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
- 2. If the individual has been receiving 20 mg per day and the dose is now being increased to > 20 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

Viibryd 10 mg and 20 mg tablets

- 1. If the individual requires the dose to be divided two times daily, approve a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
- 2. 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 should be used), approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
 - <u>Note</u>: For example, if the individual is 30 mg per day, approve 90 of the 10 mg tablets per dispensing at retail or 270 tablets per dispensing at home delivery.

Viibryd 40 mg tablets

- 1. If the individual has already been started and stabilized on a dose > 40 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
- 2. If the individual has been receiving 40 mg per day and the dose is now being increased to > 40 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

Viibryd Starter Kits

No overrides recommended.

Sertraline 25 mg tablets (Zoloft, generic)

No overrides recommended.

Sertraline 50 mg tablets (Zoloft, generic)

- 1. If the individual requires the dose to be divided two or three times daily, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
- 2. 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 be used), approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.
 - <u>Note</u>: For example, if an individual is taking a dose of 125 mg per day (two and one-half 50 mg tablets per day), approve 75 tablets per dispensing at retail or 225 tablets per dispensing at home delivery.

Sertraline 100 mg tablets (Zoloft, generic)

1. If the individual has already been started and stabilized on a dose > 200 mg per day, approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

2. If the individual has been receiving 200 mg per day and the dose is now being increased to > 200 mg per day (e.g., 250 mg or 300 mg per day), approve the requested quantity, not to exceed a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

Sertraline 150 mg and 200 mg capsules (Zercapli, generic) No overrides recommended.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

The FDA-approved indications of the selective serotonin reuptake inhibitors (SSRIs) are in Table 1.

Table 1. FDA-Approved Indications of the SSRIs. 1-17

Brand (generic)	MDD	OCD	Panic Disorde r	Bulimia Nervos a	PTSD	SAD	GAD	PMDD	VMS
Brisdelle [®]									Х
(paroxetine mesylate capsules, generic)									
Celexa [®]	Х								
(citalopram tablets, generic)									
citalopram capsules	Х								
fluvoxamine tablets		Χ [†]							
(generic only)									
fluvoxamine extended-release		Χ [†]							
capsules									
(generic only)									
Lexapro [®]	Χα						Х		
(escitalopram tablets, generic)									
Paxil [®]	Х	Х	X		Х	Х	Х		
(paroxetine HCl tablets, generic)									
Pexeva®	Х	Х	Х				Х		
(paroxetine mesylate tablets)									

Table 1 (continued). FDA-Approved Indications of the SSRIs.¹⁻¹⁷

Brand (generic)	MDD	OCD	Panic Disorde r	Bulimia Nervos a	PTSD	SAD	GAD	PMDD	VMS
Paxil CR® (paroxetine HCl controlled-release tablets, generic)	Х		Х			Х		Х	
Prozac [®] (fluoxetine capsules and tablets, generic)	Χ [†]	Χ [†]	X	X					
fluoxetine 90 mg delayed-release capsules (generic only)	X*								
Sarafem [®] (fluoxetine tablets, generic)								Х	
Trintellix® (vortioxetine tablets)	Х								
Viibryd® (vilazodone tablets)	Х								
Zoloft® (sertraline tablets, generic)	Х	Χ [†]	Х		Х	Х		Х	
Zercapli [™]	Х	Χ [†]							

(sertraline capsules, generic)					
(55.4.4					1

SSRIs – Selective serotonin reuptake inhibitors; MDD – Major Depressive Disorder; OCD – Obsessive compulsive disorder; PTSD – Posttraumatic stress disorder; SAD – Social anxiety disorder; GAD – Generalized anxiety disorder; PMDD – Premenstrual dysphoric disorder; VMS – Vasomotor symptoms; † FDA-approved indication includes children and adolescents; ^α FDA-approved indication includes adults and adolescents 12 to 17 years of age; * Approved for the prevention of relapse during the continuation treatment phase of depression.

Dosing and Availability

Dosing and availability for the SSRIs is in the Drug Quantity Limits table.

References

- 1. Brisdelle[®] capsules [prescribing information]. Roswell, GA: Sebela; September 2021.
- 2. Celexa® tablets [prescribing information]. Madison, NJ: Allergan; February 2022.
- 3. Lexapro® tablets/oral solution [prescribing information]. Madison, NJ: Allergan; September 2021.
- 4. Fluvoxamine tablets [prescribing information]. Weston, FL: Apotex; November 2021.
- Fluvoxamine extended-release capsules [prescribing information]. Parsippany, NJ: Actavis; November 2017.
- 6. Paxil® tablets [prescribing information]. Weston, FL: Apotex; September 2021.
- 7. Paxil CR® controlled-release tablets [prescribing information]. Weston, FL: Apotex; September 2021.
- 8. Pexeva® tablets [prescribing information]. Roswell, GA: Sebela; September 2021.
- 9. Prozac® capsules [prescribing information]. Indianapolis, IN: Eli Lilly; October 2021.
- 10. Fluoxetine tablets [prescribing information]. North Wales, PA: Teva; February 2022.
- 11. Sarafem® tablets [prescribing information]. Irvine, CA: Allergan; September 2021.
- 12. Fluoxetine delayed-release capsules [prescribing information]. Bachupally, India: Dr. Reddy's; June 2021.
- 13. Trintellix® tablets [prescribing information]. Lexington, MA: Takeda; September 2021.
- 14. Viibryd® tablets [prescribing information]. Madison, NJ: Allergan; September 2021.
- 15. Zoloft® tablets [prescribing information]. New York, NY: Pfizer Roerig; September 2021.
- 16. Sertraline capsules [prescribing information]. Morristown, NJ: Almatica; October 2021.
- 17. Citalopram capsules [prescribing information]. Morristown, NJ: Almatica; February 2022.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	Approval duration was changed to 1 year (previously 3 years).	12/14/2022
	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.	
	Viibryd 10/20 mg Titration Pack: Home delivery quantity limit was changed to 30 tablets per dispensing (previously 90 tablets per dispensing).	
	Citalopram 10 mg tablets (Celexa, generic): Override for a patient who requires the dose to be divided two times daily was changed to approve a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery. Previously, this override provided for up to 60 tablets per dispensing.	
	Citalopram 20 mg tablets (Celexa, generic): The override for a patient who has been started and stabilized on a dose > 40 mg per day and the override for a patient who has been receiving 40 mg per day and the dose is now being increased to 60 mg per day were removed. Additionally, the override for a patient who requires the dose to be divided two times daily was changed to approve a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery. Previously, this override provided for up to 60 tablets per dispensing.	
	Escitalopram 10 mg tablets (Lexapro, generic): Override for a patient who requires the dose to be divided two times daily was changed to approve a 30-day	

supply per dispensing at retail or a 90-day supply per dispensing at home delivery. Previously, this override provided for up to 60 tablets per dispensing.

Paroxetine 30 mg tablets (Paxil, generic) and Pexeva 30 mg tablets: The override for a patient who has been started and stabilized on a dose > 60 mg per day and the override for a patient who has received 60 mg per day, then has been receiving either 70 mg or 80 mg per day and the dose is being increased to 90 mg per day were removed. An override was added for a patient who is taking a dose that does not correspond to a commercially-available dosage form.

• Paroxetine 25 mg controlled-release tablets (Paxil CR, generic): The override for a patient who has been started and stabilized on a dose > 75 mg per day and the override for a patient who has been receiving 75 mg per day and the dose is now being increased to > 75 mg per day were removed.

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