

## DRUG QUANTITY MANAGEMENT POLICY - PER RX

**POLICY:** Selective Serotonin Reuptake Inhibitors (SSRI) Antidepressants  
Dispensing Limit  
[Celexa<sup>®</sup> \(citalopram tablets – Forest, generics\)](#)  
[Lexapro<sup>®</sup> \(escitalopram tablets– Forest Pharmaceuticals, generics\)](#)  
[fluvoxamine tablets \(generics – brand name Luvox is obsolete\)](#)  
[Luvox<sup>®</sup> CR \(fluvoxamine extended-release capsules - Jazz  
Pharmaceuticals, generics\)](#)  
[Paxil<sup>®</sup> \(paroxetine hydrochloride tablets – GlaxoSmithKline, generic\)](#)  
[Paxil CR<sup>®</sup> \(paroxetine hydrochloride controlled-release tablets –  
GlaxoSmithKline, generic\)](#)  
[Brisdelle<sup>®</sup> \(paroxetine mesylate capsules – Noven Therapeutics, LLC\)](#)  
[Pexeva<sup>®</sup> \(paroxetine mesylate tablets – Noven Therapeutics, LLC\)](#)  
[Prozac<sup>®</sup> \(fluoxetine capsules, tablets – Lilly, generics\)](#)  
[Fluoxetine 60 mg tablets \(branded product – Edgemont  
Pharmaceuticals\)](#)  
[Sarafem<sup>®</sup> \(fluoxetine capsules, tablets – Lilly, generics\)](#)  
[Prozac<sup>®</sup> Weekly<sup>™</sup> \(fluoxetine delayed release capsules – Lilly,  
generics\)](#)  
[Trintellix<sup>®</sup> \(vortioxetine tablets – Takeda Pharmaceuticals \[formerly  
Brintellix\]\)](#)  
[Viibryd<sup>®</sup> \(vilazodone tablets – Forest\)](#)  
[Zoloft<sup>®</sup> \(sertraline tablets – Pfizer, generics\)](#)

**DATE REVIEWED:** 06/08/2016

### DESCRIPTION

#### **Trintellix 5 mg, 10 mg, and 20 mg**

Maximum quantity per RX = 30 tablets

Trintellix is available as 5 mg, 10 mg, and 20 mg tablets and is indicated for the treatment of *major depressive disorder* (MDD).<sup>1</sup> The recommended starting dose is 10 mg once daily without regard to meals. The dosage should then be increased to a target dose of 20 mg per day, as tolerated. In clinical studies, the dose was increased after one week at 10 mg per day and higher doses demonstrated better treatment effects. 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 patients who do not tolerate higher doses and a maximum dose of 10 mg per day is recommended in known CYP2D6 poor metabolizers. Trintellix can be discontinued abruptly, but it is recommended that doses of 15-20 mg per day be reduced to 10 mg per day for one week prior to full discontinuation, if possible

### CRITERIA

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

*Trintellix 5 mg and 10 mg*

1. Exceptions can be made for patients who require that the dose be divided two times daily. A quantity override may be issued for 60 tablets per dispensing.
2. Exceptions can be made when a patient is taking a dose that does not correspond to a commercially-available dosage form [that is, the dose requires multiple same strength tablets be used AND would otherwise require two (or more) strengths to be used]. Approve a quantity to allow a 30 day supply per dispensing. An example of this situation is a patient taking a dose of 15 mg per day; this dose would require one 5 mg and one 10 mg tablet; approve a quantity of 90 of the 5 mg tablets.

### ***Trintellix 20 mg***

1. Exceptions can be made for patients taking greater than 20 mg daily, if there is documentation that the patient has already been started and stabilized on greater than 20 mg per day or if the patient has been receiving 20 mg daily and the dose is now being increased to greater than 20 mg per day. Approve a quantity sufficient for a 30 day supply per dispensing.

### **REFERENCES**

1. Trintellix® tablets [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; May 2016.

### **Celexa 10 mg, 20 mg, and 40 mg (generic)**

Maximum Quantity per RX = 30 tablets

Celexa 10 mg, 20 mg, and 40 mg are film-coated tablets and the 20 mg and 40 mg are scored. The manufacturer recommended dosing guidelines for initial therapy in *major depressive disorder* (MDD) in adults are 20 mg once daily and the dosage may be increased if necessary to 40 mg once daily.<sup>1</sup> The dosing guidelines state that doses above 40 mg daily are ordinarily not recommended but certain patients may require 60 mg daily. Numerous studies have documented the safety and efficacy of utilizing Celexa 60 mg daily in certain patients (i.e., those with refractory depression, non-responders). In most circumstances, 30 of the 20 mg or 40 mg tablets would supply enough medication for a one month (30 day) supply at the recommended dosages. Exceptions can be made for patients requiring a dose  $\geq$  60 mg daily or who are receiving doses that would require that two different strengths be used.

### **CRITERIA**

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

#### ***Celexa 10 mg (generic)***

1. Exceptions can be made for patients who require that the dose be divided two times daily (10 mg twice daily). A quantity override may be issued for a maximum of 60 tablets per dispensing.
2. Exceptions can be made for patients who are receiving a 30 mg daily dose. A quantity override may be issued for a maximum of 90 tablets per dispensing.
3. Exceptions can be made when a patient is taking a dose that does not correspond to a commercially-available dosage form [that is, the dose requires multiple same strength tablets be used AND would otherwise require two (or more) strengths to be used]. Approve a quantity to allow a 30 day supply per dispensing.

#### ***Celexa 20 mg (generic)***

1. Exceptions can be made for patients taking greater than 40 mg daily, if there is documentation that the patient has already been started and stabilized on greater than 40 mg per day or if the patient has been receiving 40 mg daily and the dose is now being increased to 60 mg daily. A quantity override may be issued for a maximum of 90 tablets per dispensing (Note: the scored 40 mg tablet is available for doses greater than 60 mg per day).

2. Exceptions can be made for patients who require that the dose be divided two times daily (20 mg twice daily). A quantity override may be issued for a maximum of 60 tablets per dispensing.
3. Exceptions can be made when a patient is taking a dose that does not correspond to a commercially-available dosage form [that is, the dose requires multiple same strength tablets be used AND would otherwise require two (or more) strengths to be used]. Approve a quantity override for a maximum of 90 tablets per dispensing.
4. Exceptions can be made for patients who are receiving a 30 mg daily dose. A quantity override may be issued for a maximum of 45 tablets per dispensing of the 20-mg strength.

Examples:

- See #1 above, 60 mg daily dose.
- One 20 mg in morning and one 40 mg in evening.

### ***Celexa 40 mg (generic)***

1. Exceptions can be made for patients who are receiving a 60 mg daily dose and taking one and one-half 40 mg tablets per day (total 45 tablets) for a 30 day supply per dispensing.
2. Exceptions can be made for patients taking *greater than* 60 mg daily if it has been determined that patients have tried 60 mg without adequate results. A quantity override may be issued to allow for a 30 day supply per dispensing.

### **REFERENCE**

1. Celexa® tablets [prescribing information]. St. Louis, MO: Forest Pharmaceuticals; July 2014.

### **Lexapro 5 mg, 10 mg, and 20 mg (generic)**

Maximum Quantity per RX = 30 tablets

Lexapro is available as 5 mg, 10 mg, and 20 mg film-coated tablets and the 10 mg and 20 mg are scored. The manufacturer recommended dosing guidelines for *major depressive disorder* (MDD) in adults and adolescents aged 12 to 17 years of age are 10 mg once daily.<sup>1</sup> In adults, the dosage can be increased if necessary to 20 mg once daily after a minimum of one week. Dosage adjustments up to 20 mg per day in adolescents should be made after a minimum of three weeks. For *generalized anxiety disorder* (GAD), the recommended starting dose in adults is 10 mg once daily. If the dose is increased to 20 mg daily, this should occur after a minimum of one week. Regardless of indication, 10 mg daily is the recommended dose for most elderly patients and patients with hepatic impairment. No dosage adjustment is necessary for patients with mild or moderate renal impairment. Lexapro should be used with caution in patients with severe renal impairment. Therefore, 30 of the 10 mg or 20 mg tablets would supply enough medication for a one month (30 day) supply at the recommended dosage. Exceptions can be made for patients who are receiving doses that would require that two different strengths be used.

### **CRITERIA**

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

### ***Lexapro 5 mg (generic)***

1. Exceptions can be made for patients who require that the dose be divided for 2 times daily administration (5 mg twice daily). A quantity override may be issued for a maximum of 60 tablets per dispensing.
2. Exceptions can be made when a patient is taking a dose that does not correspond to a commercially-available dosage form [that is, the dose requires multiple same strength tablets be used AND would otherwise require two (or more) strengths to be used]. Approve a quantity to allow a 30 day supply per dispensing.

***Lexapro 10 mg (generic)***

1. Exceptions can be made for patients who require that the dose be divided for 2 times daily administration (10 mg twice daily). A quantity override may be issued for a maximum of 60 tablets per dispensing.
2. Exceptions can be made when a patient is taking a dose that does not correspond to a commercially-available dosage form [that is, the dose requires multiple same strength tablets be used AND would otherwise require two (or more) strengths to be used]. Approve a quantity to allow a 30 day supply per dispensing.

***Lexapro 20 mg (generic)***

1. Exceptions can be made for patients taking *greater than* 20 mg daily, if there is documentation that the patient has already been started and stabilized on greater than 20 mg per day or if the patient has been receiving 20 mg daily, and the dose is now being increased to greater than 20 mg per day. A quantity override may be issued to allow for a 30 day supply per dispensing.

**REFERENCE**

1. Lexapro® tablets/oral solution [prescribing information]. St Louis, MO: Forest Pharmaceuticals, Inc.; October 2014.

**Fluvoxamine 25 mg**

Maximum quantity per RX = 30 tablets

**Fluvoxamine 50 mg**

Maximum quantity per RX = 60 tablets

**Fluvoxamine 100 mg**

Maximum quantity per RX = 90 tablets

Fluvoxamine is available as 25 mg, 50 mg, and 100 mg tablets and the 50 mg and 100 mg tablets are scored. Fluvoxamine is indicated for the treatment of *obsessive compulsive disorder* (OCD) in children, adolescents, and adults.<sup>1</sup> The manufacturer recommended dosing guidelines for initial therapy in *children and adolescents* (ages 8-17 years) are 25 mg daily at bedtime and dosage is increased in 25 mg increments every 4 to 7 days, as tolerated. When the total daily dose is greater than 50 mg it is given in two divided doses (one dose may be larger than the other). In controlled clinical trials establishing the effectiveness of fluvoxamine in obsessive compulsive disorder, pediatric patients (ages 8-17) were titrated within a dose range of 50 to 200 mg per day. The maximum dose in children up to age 11 should not exceed 200 mg daily. The maximum dose for adolescents ages 12-17 is 300 mg daily. Hence, 30 of the 25 mg tablets would provide a sufficient number of tablets for initial therapy and titration of the dose.

The manufacturer recommended dosing guidelines for initial therapy in *adults* are 50 mg daily at bedtime and dosage is increased in 50 mg increments every 4 to 7 days, as tolerated. When the total daily dose is greater than 100 mg it should be given in two divided doses (one dose may be larger than the other) and the total daily dosage should not exceed 300 mg in adults. Hence, 60 of the 50 mg tablets would provide a sufficient number of tablets for patients receiving 50 mg twice daily for a one month (30 day) supply of treatment. Likewise, 90 of the 100 mg tablets would provide a sufficient number of tablets for the maximum recommended dose for a one month (30 day) supply of treatment. Patients using a 100, 150 or 200 mg dose should use the 100 mg tablets. Exceptions can be made for patients (adults, children, adolescents) taking a 75 mg dose (one and one half tablets) twice daily or for those taking a 50 mg and 75 mg dose daily. Exceptions can be made for patients who are receiving doses that would require that two different strengths be used.

**CRITERIA**

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

***Fluvoxamine 25 mg***

Express Scripts recommends no overrides to this quantity limit.

### ***Fluvoxamine 50 mg***

1. Exceptions can be made when a patient is taking a dose that does not correspond to a commercially-available dosage form [that is, the dose requires multiple same strength tablets be used AND would otherwise require two (or more) strengths to be used]. Approve a quantity to allow a 30 day supply per dispensing.

Examples:

- for patients taking a 75 mg dose (one and one half tablets) twice daily, a quantity override may be issued to allow 3 tablets per day (total 90 tablets) for a 30 day supply.
- for patients taking 125 mg once daily or taking a 50 mg dose plus a 75 mg dose (two different doses a day), a quantity override may be issued to allow 2 and 1/2 tablets per day (total 75 tablets) for a 30 day supply.
- for patients taking 150 mg once daily, use the 100 mg tablets.

### ***Fluvoxamine 100 mg***

1. Exceptions can be made for patients taking *greater than* 300 mg daily, if there is documentation that the patient has already been started and stabilized on greater than 300 mg per day or if the patient has been receiving 300 mg daily, and the dose is now being increased to greater than 300 mg per day. A quantity override may be issued to allow for a 30 day supply per dispensing.

### **REFERENCE**

1. Fluvoxamine tablets [prescribing information]. Weston, FL: Apotex Corp; August 2015.

### **Luvox CR 100 mg and 150 mg (generic)**

Maximum quantity per RX = 60 capsules

Luvox CR is available as 100 mg and 150 mg extended-release capsules indicated for the treatment of *obsessive compulsive disorder* (OCD).<sup>1</sup> The manufacturer recommended dosing guidelines for initial therapy in *adults* is 100 mg once daily with dose increases in 50 mg increments every week, as tolerated. The total daily dosage should not exceed 300 mg in adults. The lowest available dose of Luvox CR may not be appropriate for pediatric patients who are naive to fluvoxamine. Hence, 60 of the 100 mg or 150 mg capsules would provide a sufficient number of capsules for up to a 200 mg or 300 mg daily dose, respectively, for a one month (30 day) supply of treatment.

### **CRITERIA**

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

### ***Luvox CR 100 mg (generic)***

Express Scripts recommends no overrides to this quantity limit.

### ***Luvox CR 150 mg (generic)***

1. Exceptions can be made for patients taking *greater than* 300 mg daily, if there is documentation that the patient has already been started and stabilized on greater than 300 mg per day or if the patient has been receiving 300 mg daily, and the dose is now being increased to greater than 300 mg per day. A quantity override may be issued to allow for a 30 day supply per dispensing.

### **REFERENCE**

**Paxil 10 mg and 40 mg (generic)**

Maximum quantity per RX = 30 tablets

**Paxil 20 mg and 30 mg (generic)**

Maximum quantity per RX = 60 tablets

Paxil tablets are available in 10 mg, 20 mg, 30 mg, and 40 mg strengths and the 10 mg and 20 mg tablets are scored. Paxil is taken once daily. The manufacturer recommended dosing guidelines for initial therapy in adults with *panic disorder*, or patients with any indication who are elderly or debilitated, or who have severe renal or hepatic impairment are 10 mg daily.<sup>1</sup> The manufacturer recommended dosing guidelines for initial therapy in adults with *major depressive disorder (MDD)*, *obsessive compulsive disorder (OCD)*, *generalized anxiety disorder (GAD)*, *posttraumatic stress disorder (PTSD)*, or *social anxiety disorder* are 20 mg daily. Doses are increased in 10 mg increments at intervals of at least one week. The dosage may be increased if necessary to a maximum daily dose of 60 mg in patients with OCD, panic disorder and social anxiety disorder; 50 mg daily in patients with MDD, GAD, and PTSD; or 40 mg in patients who are elderly or debilitated, or have severe renal or hepatic impairment.

Hence, 30 of the 10 mg and 40 mg tablets would provide a sufficient number of tablets for initial therapy using the 10 mg tablet or daily maintenance therapy for patients receiving 40 mg daily doses. Patients using higher doses should be referred to other tablet strengths (Paxil 20 mg tablets are scored and can be divided and used for 10 mg incremental increases in dose). Sixty of the 20 mg and 30 mg tablets would provide a sufficient number of tablets for initial therapy and, in some patients, for maintenance therapy for a one month (30 day) supply at the recommended maximum daily dose.

**CRITERIA**

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

***Paxil 10 mg (generic)***

1. Exceptions can be made when a patient is taking a dose that does not correspond to a commercially-available dosage form [that is, the dose requires multiple same strength tablets be used AND would otherwise require two (or more) strengths to be used]. The 20 mg tablets are scored and can be divided. Approve a quantity to allow a 30 day supply per dispensing.

***Paxil 20 mg (generic)***

1. Exceptions can be made for patients who require that the dose be divided for two or three times daily administration. Approve a quantity to allow a 30 day supply per dispensing. An example of this situation is a patient taking a dose of 20 mg in morning and 40 mg in the evening; the patient would require a quantity override to allow 3 tablets per day (total 90 tablets) for a 30 day supply.
2. Exceptions can be made when a patient is taking a dose that does not correspond to a commercially-available dosage form [that is, the dose requires multiple same strength tablets be used AND would otherwise require two (or more) strengths to be used]. The 20 mg tablets are scored and can be divided. Approve a quantity to allow a 30 day supply per dispensing. An example of this situation is a patient taking 50 mg single dose: use two and one-half of 20 mg tablets; the patient would require a quantity override to allow two and one-half tablets per day (total 75 tablets) for a 30 day supply.

***Paxil 30 mg (generic)***

1. Exceptions can be made for patients taking *greater than* 60 mg daily, if there is documentation that the patient has already been started and stabilized on greater than 60 mg per day or if the patient has

been receiving 70 mg or 80 mg daily (i.e., the patient has been receiving 60 mg daily, then 70 mg or 80 mg daily, and is now being increased to 90 mg daily). A quantity override may be issued to allow for a 30 day supply per dispensing.

***Paxil 40 mg (generic)***

1. Exceptions can be made for patients taking *greater than* 60 mg daily, if there is documentation that the patient has already been started and stabilized on greater than 60 mg per day or if the patient has been receiving 60 mg daily and the dose is now being increased. A quantity override may be issued to allow for a 30 day supply per dispensing.

**REFERENCE**

1. Paxil® tablets and oral suspension [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; July 2014.

**Paxil CR 12.5 mg, 25 mg, and 37.5 mg (generic)**

Maximum quantity per RX = 60 tablets

Paxil CR is available in 12.5 mg, 25 mg, and 37.5 mg strengths and is given once daily. The manufacturer recommended dosing guidelines for initial therapy in adults with *panic disorder, premenstrual dysphoric disorder (PMDD), social anxiety disorder*, or patients with any indication who are elderly or debilitated, or have severe renal or hepatic impairment are 12.5 mg daily.<sup>1</sup> The manufacturer recommended dosing guidelines for initial therapy in adults with *major depressive disorder (MDD)* are 25 mg daily. Doses are increased in 12.5 mg increments at intervals of at least one week. The maximum recommended daily dose varies per indication. The dosage may be increased if necessary to a maximum daily dose of 75 mg in patients with panic disorder; 62.5 mg daily in patients with MDD; 37.5 mg in patients with social anxiety disorder; 25 mg in patients being treated for PMDD; or 50 mg in patients who are elderly or debilitated, or have severe renal or hepatic impairment.

Hence, 60 of the 12.5 mg tablets would provide a sufficient number of tablets for initial therapy and to titrate the dose while 60 of the 25 mg and 37.5 mg tablets would provide a sufficient number of tablets for initial therapy and, in some patients, for maintenance therapy for a one month (30 day) supply of treatment. Patients taking 75 mg once daily should use the 37.5 mg tablets.

**CRITERIA**

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

***Paxil CR 12.5 mg (generic)***

1. Exceptions can be made for patients who require that the dose be divided for two or three times daily administration. Approve a quantity to allow a 30 day supply per dispensing. An example of this situation is a patient taking a dose of 25 mg in the morning and 12.5 mg in the evening.
2. Exceptions can be made when a patient is taking a dose that does not correspond to a commercially-available dosage form [that is, the dose requires multiple same strength tablets be used AND would otherwise require two (or more) strengths to be used]. Approve a quantity to allow a 30 day supply per dispensing. An example of this situation is a patient taking a dose of 62.5 mg once daily; this dose would require two 25 mg and one 12.5 mg tablets (approve a quantity of 150 of the 12.5 mg tablets per dispensing).

***Paxil CR 25 mg (generic)***

1. Exceptions can be made when a patient is taking a dose that does not correspond to a commercially-available dosage form [that is, the dose requires multiple same strength tablets be used AND would

otherwise require two (or more) strengths to be used]. Approve a quantity to allow a 30 day supply per dispensing.

2. Exceptions can be made for patients taking *greater than* 75 mg daily, if there is documentation that the patient has already been started and stabilized on greater than 75 mg per day or if the patient has been receiving 75 mg daily and the dose is now being increased. A quantity override may be issued to allow for a 30 day supply per dispensing.

#### ***Paxil CR 37.5 mg (generic)***

1. Exceptions can be made for patients taking *greater than* 75 mg daily, if there is documentation that the patient has already been started and stabilized on greater than 75 mg per day or if the patient has been receiving 75 mg daily and the dose is now being increased. A quantity override may be issued to allow for a 30 day supply per dispensing.

#### **REFERENCE**

1. Paxil CR® controlled-release tablets [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; July 2014.

#### **Brisdelle 7.5 mg**

Maximum quantity per RX = 30 capsules

Brisdelle is available as a 7.5 mg capsule. This lower dose preparation of paroxetine mesylate is used for moderate to severe hot flashes associated with menopause and is not approved for treatment of any psychiatric conditions.<sup>1</sup> The manufacturer recommended dosing guideline for treatment of moderate to severe vasomotor symptoms associated with menopause (VMS) is 7.5 mg once daily, at bedtime. Hence, 30 of the 7.5 mg capsules would provide a sufficient quantity for a one month supply.

#### **CRITERIA**

Express Scripts recommends no overrides to this quantity limit.

#### **REFERENCE**

1. Brisdelle® capsules [prescribing information]. Miami, FL: Noven Therapeutics, LLC; December 2014.

#### **Pexeva 10 mg and 40 mg**

Maximum quantity per RX = 30 tablets

#### **Pexeva 20 mg and 30 mg**

Maximum quantity per RX = 60 tablets

Pexeva is available in 10 mg, 20 mg, 30 mg and 40 mg and the 20 mg strength is scored. Pexeva is taken once daily. The manufacturer recommended dosing guidelines for initial therapy in adults with *panic disorder*, or patients with any indication who are elderly or debilitated, or have severe renal or hepatic impairment are 10 mg daily.<sup>1</sup> The manufacturer recommended dosing guidelines for initial therapy in adults with *major depressive disorder (MDD)*, *obsessive compulsive disorder (OCD)*, and *generalized anxiety disorder (GAD)* are 20 mg daily. Doses are increased in 10 mg increments at intervals of at least one week. The dosage may be increased if necessary to a maximum daily dose of 60 mg in patients with OCD and panic disorder; 50 mg daily in patients with MDD and GAD; or 40 mg in patients who are elderly or debilitated, or have severe renal or hepatic impairment.

Hence, 30 of the 10 mg and 40 mg tablets would provide a sufficient number of tablets for initial therapy using the 10 mg tablet or daily maintenance therapy for patients receiving 40 mg daily doses. Patients using higher doses should be referred to other tablet strengths (Pexeva 20 mg tablets are scored on both sides and can be divided and used for 10 mg incremental increases in dose). Sixty of the 20 mg and 30



mg tablets would provide a sufficient number of tablets for initial therapy and, in some patients, for maintenance therapy for a one month (30 day) supply at the recommended maximum daily dose.

## CRITERIA

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

### *Pexeva 10 mg*

1. Exceptions can be made when a patient is taking a dose that does not correspond to a commercially-available dosage form [that is, the dose requires multiple same strength tablets be used AND would otherwise require two (or more) strengths to be used]. The 20 mg tablets are scored and can be divided. Approve a quantity to allow a 30 day supply per dispensing.

### *Pexeva 20 mg*

1. Exceptions can be made for patients who require that the dose be divided for two or three times daily administration. Approve a quantity to allow a 30 day supply per dispensing. An example of this situation is a patient taking a dose of 20 mg in morning and 40 mg in the evening; the patient would require a quantity override to allow 3 tablets per day (total 90 tablets) for a 30 day supply per dispensing.
2. Exceptions can be made when a patient is taking a dose that does not correspond to a commercially-available dosage form [that is, the dose requires multiple same strength tablets be used AND would otherwise require two (or more) strengths to be used]. The 20 mg tablets are scored and can be divided. Approve a quantity to allow a 30 day supply per dispensing. An example of this situation is a patient taking 50 mg single dose: use two and one-half of 20 mg tablets; the patient would require a quantity override to allow two and one-half tablets per day (total 75 tablets) for a 30 day supply per dispensing.

### *Pexeva 30 mg*

1. Exceptions can be made for patients taking *greater than* 60 mg daily, if there is documentation that the patient has already been started and stabilized on greater than 60 mg per day or if the patient has been receiving 70 mg or 80 mg daily (i.e., the patient has been receiving 60 mg daily, then 70 mg or 80 mg daily, and is now being increased to 90 mg daily). A quantity override may be issued to allow for a 30 day supply per dispensing.

### *Pexeva 40 mg*

1. Exceptions can be made for patients taking *greater than* 60 mg daily, if there is documentation that the patient has already been started and stabilized on greater than 60 mg per day or if the patient has been receiving 60 mg daily and the dose is now being increased. A quantity override may be issued to allow for a 30 day supply per dispensing.

## REFERENCE

1. Pexeva<sup>®</sup> tablets [prescribing information]. Miami, FL: Noven Therapeutics, LLC; July 2014.

### Prozac 10 mg (generic)

Maximum quantity per RX = 30 capsules, tablets

### Prozac 20 mg (generic)

No DQM Limit

### Prozac 40 mg (generic)

Maximum quantity per RX = 60 capsules

### Fluoxetine 60 mg tablet (brand)

No DQM Limit

### Sarafem (brand) 10 mg

Maximum quantity per RX = 30 tablets

### Sarafem (brand) 20 mg

No DQM Limit

Note: Sarafem 10 mg shares the same coding values with fluoxetine 10 mg capsule/tablets (likewise with Sarafem and fluoxetine 20 mg). 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.

Prozac capsules are available in 10 mg, 20 mg, and 40 mg strengths. Generic fluoxetine is available in the 10 mg and 20 mg strengths as both capsules and tablets and as 40 mg capsules.<sup>2</sup> Fluoxetine is also available in a 60 mg tablet [brand product] that has the same FDA-labeled indications as Prozac.<sup>3</sup> The manufacturer recommended dosing guidelines<sup>1</sup> for initial therapy in adults with *major depressive disorder* and in *obsessive compulsive disorder* (OCD) are 20 mg daily and the dosage is increased if necessary to a maximum daily dose of 80 mg. In children and adolescents with major depressive disorder the initial dose is 10 or 20 mg daily and in OCD the initial dose is 10 mg daily. For *bulimia nervosa* in adults, the recommended dose is 60 mg daily and it may be advisable to titrate to this target dose over a period of several days. For *panic disorder* in adults, the initial dose is 10 mg daily, and after one week, the dose should be increased to 20 mg daily; the dose may be increased again to a maximum of 60 mg daily after several weeks if necessary. Dosages above 20 mg daily may be given once daily or in 2 divided doses. Prozac is indicated for children age 7 years and up, but when used in lower weight children or in evidence-supported off-label situations for younger children, therapy can be initiated at 5 to 10 mg daily.<sup>4</sup> Dosage in *elderly patients* is often initiated with 10 mg daily. A lower or less frequent dosage should be considered in patients with hepatic impairment or other concurrent disease or in those on multiple concomitant medications.

Hence, 30 of the 10 mg capsules/tablets would provide a sufficient number of capsules/tablets for titration of the dose and for maintenance therapy when the dosage is 10 mg daily. Patients using a single daily 20 mg or 40 mg dose should use the 20 mg or 40 mg capsules respectively. Hence, 60 of the 40 mg capsules would provide a sufficient number of capsules for the maximum recommended dose for a one month (30 day) supply of treatment. Patients using 60 mg or 80 mg doses (either once daily or in divided doses) should use the 20 mg or 40 mg capsule or 60 mg tablet.

Sarafem tablets are available in 10 mg and 20 mg strengths, in boxes containing four 7-day blister packs. The manufacturer recommended dosing guidelines for initial therapy in premenstrual dysphoric disorder in adults are 20 mg daily given continuously every day or intermittently (i.e., starting a daily dose 14 days prior to the anticipated onset of menstruation and through the first full day of menses and repeating with each new cycle), and the dosage is increased if necessary to a maximum daily dose of 80 mg.<sup>1</sup> Fluoxetine doses above 60 mg daily have not been systematically studied in patients with premenstrual dysphoric disorder. A lower or less frequent dosage should be considered in patients with hepatic impairment or other concurrent disease or in those on multiple concomitant medications. Hence, 30 of the 10 mg capsules would provide a sufficient number of capsules for titration of the dose and for maintenance therapy when the dosage is 10 mg daily. Patients using a single daily 20 mg, 40 mg, or 80 mg doses or those taking 60 mg or 80 mg doses (either once daily or in divided doses) should use the 20 mg tablet.

## **CRITERIA**

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

### ***Prozac 10 mg (generic) and Sarafem (brand) 10 mg***

1. Exceptions can be made for patients who require that the dose be divided for two or three times daily administration. Approve a quantity to allow a 30 day supply per dispensing. An example of this situation is a patient taking a dose of 10 mg twice or three times daily, a quantity override would be required to allow 2 or 3 capsules/tablets per day for a 30 day supply per dispensing.

2. Exceptions can be made when a patient is taking a dose that does not correspond to a commercially-available dosage form [that is, the dose requires multiple same strength tablets be used AND would otherwise require two (or more) strengths to be used]. Approve a quantity to allow a 30 day supply per dispensing. Examples of this situation: a) patient is taking 30 mg daily – either once daily or as a divided dose such as one 20 mg dose in the morning plus one 10 mg dose in the evening, a quantity override would be required to allow 3 capsules/tablets per day (total 90 of the 10 mg capsules/tablets) for a 30 day supply; b) patient is taking 50 mg once daily or in divided doses, a quantity override would be required to allow 5 capsules/tablets per day (total 150) for a 30 day supply; c) patient is taking 70 mg daily, a quantity override would be required to allow 7 capsules/tablets per day (total 210 of the 10 mg capsules/tablets) for a 30 day supply per dispensing.

#### ***Prozac 40 mg (generic)***

1. Exceptions can be made for patients taking *greater than* 80 mg daily, if there is documentation that the patient has already been started and stabilized on greater than 80 mg per day or if the patient has been receiving 80 mg daily and the dose is now being increased. A quantity override may be issued to allow for a 30 day supply per dispensing.

#### **REFERENCES**

1. Prozac® capsules [prescribing information]. Indianapolis, IN: Eli Lilly and Company; October 2014.
2. Fluoxetine tablets [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA; December 2015.
3. Fluoxetine 60 mg tablets [prescribing information]. Austin, TX: Edgemont Pharmaceuticals, LLC; April 2016.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc; 2015. Available at <http://www.clinicalpharmacology-ip.com/Default.aspx>. Accessed on: April 20, 2016. Search term: fluoxetine.

#### **Prozac Weekly 90 mg (generic)**

Maximum quantity per RX = 4 capsules

Prozac Weekly capsules are a delayed release product intended for once weekly administration. The recommended dosage for *major depressive disorder* (MDD) in adults is one 90 mg capsule once weekly.<sup>1</sup> Hence, 4 capsules are a 28 day supply. If a satisfactory response is not maintained with Prozac Weekly, a daily dosing regimen with once daily Prozac should be considered.

#### **CRITERIA**

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

#### ***Prozac Weekly 90 mg (generic)***

1. Exceptions can be made for patients taking 90 mg twice weekly, if there is documentation that the patient has been receiving 90 mg twice weekly or if the patient has been receiving 90 mg once weekly and the dose is now being increased. A quantity override may be issued to allow for a 30 day supply per dispensing.

#### **REFERENCES**

- Prozac® Weekly delayed release capsules [prescribing information]. Indianapolis, IN: Eli Lilly and Company; February 2016.  
Sarafem® tablets [prescribing information]. Rockaway, NJ: Warner Chilcott, Inc.; October 2014.

#### **Viibryd 10 mg, 20 mg, and 40 mg**

Maximum Quantity per RX = 30 tablets

#### **Viibryd Starter Kits**

Maximum Quantity per RX=1 Kit

Viibryd is available as 10 mg, 20 mg, and 40 mg tablets and is also available in two different starter kits. One kit contains seven 10 mg tablets and twenty-three 20 mg tablets. The other kit contains seven 10 mg tablets, seven 20 mg tablets, and sixteen 40 mg tablets. The recommended target dose is 20 mg to 40 mg once daily. The manufacturer recommended dosing guidelines for initial therapy in *major depressive*

*disorder* (MDD) in adults are 10 mg once daily for seven days, followed by 20 mg once daily. The dose may be increased to 40 mg once daily after a minimum of seven days.<sup>1</sup> Dosage adjustments are not necessary in patients with mild, moderate, or severe renal impairment or patients with mild or moderate hepatic impairment. Viibryd has not been studied in patients with severe hepatic impairment. In most circumstances, 30 of the 10 mg, 20 mg or 40 mg tablets would supply enough medication for a one month (30 day) supply at the recommended dosages. One starter kit supplies enough medication for a one month (30 day) supply to properly titrate patients to a dose of 20 mg or 40 mg daily.

## CRITERIA

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

### ***Viibryd 10 mg and 20 mg***

1. Exceptions can be made for patients who require that the dose be divided for 2 times daily administration (i.e., 10 mg twice daily, 20 mg twice daily). A quantity override may be issued for a maximum of 60 tablets per dispensing.
2. Exceptions can be made when a patient is taking a dose that does not correspond to a commercially-available dosage form [that is, the dose requires multiple same strength tablets be used AND would otherwise require two (or more) strengths to be used]. Approve a quantity to allow a 30 day supply per dispensing. Examples include: 30 mg daily, 50 mg daily, 60 mg daily.

### ***Viibryd 40 mg***

1. Exceptions can be made for patients taking *greater than* 40 mg daily, if there is documentation that the patient has already been started and stabilized on greater than 40 mg per day or if the patient has been receiving 40 mg daily, and the dose is now being increased to greater than 40 mg per day. A quantity override may be issued to allow for a 30 day supply per dispensing.

### ***Viibryd Starter Kits***

Express Scripts recommends no overrides to this quantity limit.

## REFERENCE

1. Viibryd® tablets [prescribing information]. Cincinnati, OH: Forest Pharmaceuticals; March, 2015.

### **Zoloft 25 mg (generics)**

Maximum quantity per RX = 30 tablets

### **Zoloft 50 mg and 100 mg (generics)**

Maximum quantity per RX = 60 tablets

Zoloft is available as 25 mg, 50 mg, and 100 mg tablets and all strengths are scored. The manufacturer recommended dosing guidelines for initial therapy in *major depressive disorder* (MDD) and in *obsessive compulsive disorder* (OCD) in adults are 50 mg daily.<sup>1</sup> In *premenstrual dysphoric disorder* (PMDD), the initial dose is 50 mg daily, either as a daily dose throughout the menstrual cycle or limited to the luteal phase of the menstrual cycle; if the dose is titrated up to 100 mg daily during the luteal phase, then 50 mg daily should be utilized for the first 3 days of each luteal phase dosing period. The manufacturer recommended dosing guidelines for initial therapy in *panic disorder*, *posttraumatic stress disorder* (PTSD), and *social anxiety disorder* in adults is 25 mg once daily; after one week, the dose should be increased to 50 mg once daily. In children and adolescents with OCD the initial daily dose is 25 mg once daily for children ages 6 to 12 years and 50 mg once daily for adolescents 13 to 17 years of age. 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). Doses are given once daily. Zoloft is extensively metabolized in the liver; use in patients with liver disease should be approached with

caution. Lower or less frequent dosing should be used. No special dosing requirements exist for renal impairment.

Hence, 30 of the 25 mg tablets would provide a sufficient number of tablets for titration of the dose and for maintenance therapy when the dosage is 25 mg. Sixty of the 50 mg tablets would provide a sufficient number of tablets for patients receiving 75 mg (one and one half tablets) daily or 100 mg daily for a one month (30 day) supply of treatment. Sixty of the 100 mg tablets would provide a sufficient number of tablets for the maximum recommended dose for a one month (30 day) supply of treatment.

## CRITERIA

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

### **Zoloft 25 mg (generics)**

Express Scripts recommends no overrides to this quantity limit.

### **Zoloft 50 mg (generics)**

1. Exceptions can be made for patients who require that the dose be divided for two or three times daily administration. Approve a quantity to allow a 30 day supply per dispensing.
2. Exceptions can be made when a patient is taking a dose that does not correspond to a commercially-available dosage form [that is, the dose requires multiple same strength tablets be used AND would otherwise require two (or more) strengths to be used]. Approve a quantity to allow a 30 day supply per dispensing. An example of this situation is a patient taking a dose of 125 mg per day; this dose would require one 25 mg and one 100 mg tablet; approve a quantity of 75 of the 50 mg tablets (two and one-half 50 mg tablets per day).

### **Zoloft 100 mg (generics)**

1. Exceptions can be made for patients taking *greater than* 200 mg daily, if there is documentation that the patient has already been started and stabilized on greater than 200 mg per day or if the patient has been receiving 200 mg daily, and the dose is now being increased to greater than 200 mg per day (e.g., 250 mg, 300 mg). A quantity override may be issued to allow for a 30 day supply per dispensing.

## REFERENCE

1. Zoloft® tablets, oral concentrate [prescribing information]. New York, NY: Pfizer Roerig; August 2014.

## HISTORY

Type of Revision	Summary of Changes*	Date
Annual Revision	<p>All SSRI policies within former “Select per Rx” program consolidated into one policy called “Depression – SSRI_DQM – Per Rx” (for AUM packaging purposes, these are now all under the “Per Rx” program within the therapeutic category “Depression”. No changes to limits or criteria except as noted below for Sarafem/Selfemra:</p> <ul style="list-style-type: none"> <li>• Brintellix</li> <li>• Celexa (citalopram)</li> <li>• Lexapro (escitalopram)</li> <li>• Luvox CR, fluvoxamine</li> <li>• Paxil, Paxil CR (paroxetine), Pexeva, Brisdelle</li> <li>• Prozac (fluoxetine, Sarafem, Selfemra) – Note: Selfemra is now</li> </ul>	01/22/2015

	<p>obsolete and removed from the policy with this revision. The DQM limit for Sarafem 20 mg was retired and the limit for Sarafem 10 mg was increased from 28 per Rx to 30 per Rx.</p> <ul style="list-style-type: none"> <li>• Viibryd</li> <li>• Zoloft (sertraline)</li> </ul>	
Selected revision	Add language regarding Viibryd 20 mg dose	03/23/2015
Selected revision	Add language regarding Viibryd 10 mg-20 mg Starter Kit	09/09/2015
Annual revision	Reviewed by Clinical Specialists. No changes to criteria.	06/08/2016