DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Serotonin and Norepinephrine Reuptake Inhibitors (SNRI) Antidepressants Dispensing Limit

DRUGS AFFECTED: Cymbalta® (duloxetine HCl delayed-release capsules – Lilly, generics)
duloxetine delayed-release 40 mg capsules (generics only, brand Irenka obsolete)
Drizalma Sprinke™ (duloxetine delayed-release capsule - Sun Pharmaceutical Industries, Inc.)
Desvenlafaxine extended-release tablets (Sun Pharmaceuticals /Ranbaxy [brand product])
Desvenlafaxine extended-release tablets (Macoven [brand product])
Khedezla™ (desvenlafaxine extended-release tablets – Pernix Therapeutics, LLC)
Pristiq® (desvenlafaxine succinate extended-release tablets – Wyeth Pharmaceuticals, generics)
venlafaxine HCl tablets, (generics [brand Effexor® now obsolete])
Effexor® XR (venlafaxine HCl extended-release capsules – Wyeth Pharmaceuticals, generics)
Venlafaxine HCl extended-release tablets- generics)
Fetzima® (levomilnacipran HCl extended-release capsules – Forest Pharmaceuticals)
Savella® (milnacipran HCl tablets – Forest Pharmaceuticals)

DATE REVIEWED: 03/19/2021

DESCRIPTION

Cymbalta 20 mg (generic) Maximum Quantity per RX = 60 capsules
Cymbalta 30 mg (generic) Maximum Quantity per RX = 30 capsules
Cymbalta 60 mg (generic) Maximum Quantity per RX = 60 capsules

Cymbalta is available as 20 mg, 30 mg and 60 mg capsules. The manufacturer recommended dosing guidelines for major depressive disorder (MDD) in adults are 40 mg per day given as 20 mg twice daily to 60 mg per day given either once a day or as 30 mg twice daily.[1] Some patients benefit from starting at a dose of 30 mg once daily for one week before increasing the dose to 60 mg per day. The recommended starting dose for fibromyalgia and chronic musculoskeletal pain is 30 mg per day while the starting dose for generalized anxiety disorder (GAD)**,** and diabetic peripheral neuropathic (DPNP) pain is a 60 mg per day given once per day. The maximum maintenance dose for all indications can range up to 60 to 120 mg per day. [1-14] Therefore, 60 of the 20 mg capsules would supply enough medication for a one month (30 day) supply if the dose is 20 mg twice daily or 40 mg once daily; 30 of the 30 mg capsules would supply enough medication for a one month (30 day) supply if the dosage is 30 mg once daily; and 60 of the 60 mg capsules supplies enough medication for a one month (30 day) supply at a dosage of 120 mg daily.

CRITERIA

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

Cymbalta 20 mg (generic)

1. Exceptions can be made for patients who are taking 40 mg twice daily. A quantity override may be issued to allow for a 30 day supply (120 capsules) per dispensing.
2. Exceptions can be made for patients who are taking 20 mg three times daily or who are taking 40 mg and 20 mg daily. A quantity override may be issued to allow for a 30 day supply (90 capsules) 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]. A quantity may be issued to allow for a 30 day supply per dispensing.

Cymbalta 30 mg (generic)
1. Exceptions can be made for patients who are taking 30 mg twice daily. A quantity override may be issued to allow for a 30 day supply (60 capsules) per dispensing.
2. Exceptions can be made for patients taking 30 mg three times daily or 60 mg and 30 mg daily. A quantity override may be issued to allow for a 30 day supply (90 capsules) 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]. A quantity may be issued to allow for a 30 day supply per dispensing.

Cymbalta 60 mg (generic)
No overrides to this quantity limit recommended.

REFERENCES
1. Cymbalta® capsules [prescribing information]. Indianapolis, IN: Eli Lilly and Company; October 2019.

Duloxetine delayed-release 40 mg capsules (generic only, Irenka is obsolete)
Maximum Quantity per RX = 30 capsules

The manufacturer recommended dosing guidelines are the same as described above for Cymbalta.[1] The starting dose for major depressive disorder (MDD) in adults is 40 to 60 mg per day while other indications range from 30 to 60 mg per day. Most indications have a target maintenance dose of 60 mg per day. Therefore, 30 of the 40 mg capsules would supply enough medication for a one month (30 day) supply if the dose is 40 mg once daily. In general, the participant should be referred to higher strength capsules of Cymbalta or generic duloxetine if a quantity greater than 80 mg per day is requested.

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

Duloxetine delayed-release 40 mg capsules
1. Exceptions can be made for patients who are taking a total dose of 80 mg daily. A quantity override may be issued to allow for a 30 day supply (60 capsules) per dispensing.

REFERENCES
1. Duloxetine 40 mg delayed-release capsules [prescribing information]. Baltimore, MD: Lupin Pharma; February 2021.

Drizalma Sprinkle 20 mg Maximum Quantity per RX = 60 capsules
Drizalma Sprinkle 30 mg Maximum Quantity per RX = 30 capsules
Drizalma Sprinkle 40 mg Maximum Quantity per RX = 30 capsules
Drizalma Sprinkle 60 mg Maximum Quantity per RX = 60 capsules

Drizalma Sprinkle is available as 20 mg, 30 mg, 40 mg and 60 mg capsules. The manufacturer recommended dosing guidelines for major depressive disorder (MDD) in adults are 40 mg per day given as 20 mg twice daily to 60 mg per day given either once a day or as 30 mg twice daily.[1] Some patients benefit from starting at a dose of 30 mg once daily for one week before increasing the dose to 60 mg per day. The recommended starting dose for fibromyalgia and chronic musculoskeletal pain is 30 mg per day while the starting dose for generalized anxiety disorder (GAD)**,** and diabetic peripheral neuropathic (DPNP) pain is a 60 mg per day given once per day. The maximum maintenance dose for all indications can range up to 60 to 120 mg per day. [1-14] Therefore, 60 of the 20 mg capsules would supply enough medication for a one month (30 day) supply if the dose is 20 mg twice daily or 40 mg once daily; 30 of the 30 mg capsules would supply enough medication for a one month (30 day) supply if the dosage is 30 mg once daily; and 60 of the 60 mg capsules supplies enough medication for a one month (30 day) supply at a dosage of 120 mg daily.

CRITERIA

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

Drizalma Sprinkle 20 mg

1. Exceptions can be made for patients who are taking 40 mg twice daily. A quantity override may be issued to allow for a 30 day supply (120 capsules) per dispensing.
2. Exceptions can be made for patients who are taking 20 mg three times daily or who are taking 40 mg and 20 mg daily. A quantity override may be issued to allow for a 30 day supply (90 capsules) 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 OR would otherwise require two (or more) strengths to be used]. A quantity may be issued to allow for a 30 day supply per dispensing.

Drizalma Sprinkle 30 mg

1. Exceptions can be made for patients who are taking 30 mg twice daily. A quantity override may be issued to allow for a 30 day supply (60 capsules) per dispensing.
2. Exceptions can be made for patients taking 30 mg three times daily or 60 mg and 30 mg daily. A quantity override may be issued to allow for a 30 day supply (90 capsules) 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]. A quantity may be issued to allow for a 30 day supply per dispensing.

Drizalma Sprinkle 40 mg

1. Exceptions can be made for patients who are taking a total dose of 80 mg daily. A quantity override may be issued to allow for a 30 day supply (60 capsules) per dispensing.

Drizalma Sprinkle 60 mg

No overrides to this quantity limit recommended.

REFERENCES

1. Drizalma Sprinkle capsules [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; July 2019.

Desvenlafaxine ER, Desvenlafaxine fumarate ER, Khedezla, and Pristiq (generic)
25 mg, 50 mg, and 100 mg tablets Maximum quantity per RX = 30 tablets

Desvenlafaxine ER, Desvenlafaxine fumarate ER, Khedezla, and Pristiq are available as 50 mg and 100 mg tablets and are FDA-labeled for the treatment of major depressive disorder (MDD). Additionally, Pristiq is available as a 25 mg tablet intended for gradual dose tapering or for patients with severe renal impairment. For most patients, the recommended dose is 50 mg once daily. In clinical studies, doses ranging from 50 mg to 400 mg per day were shown to be effective. However, additional benefit at doses greater than 50 mg daily was not shown. In addition, adverse events and discontinuations were more frequent at higher doses. The recommended dose for patients with hepatic impairment is 50 mg per day and dose escalation above 100 mg per day is not recommended. The recommended dose for patients with moderate renal impairment is 50 mg daily. The recommended dose for patients with severe renal impairment or end-stage renal disease (ESRD) is 25 mg per day or 50 mg every other day.

CRITERIA

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

Desvenlafaxine ER, and Khedezla 50 mg
Pristiq (generic) 25 mg and 50 mg

1. Exceptions can be made for patients who require that the dose be divided two times daily. A quantity override may be issued to allow 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]. A quantity override up to 400 mg/day may be issued to allow for a 30 day supply per dispensing.

Desvenlafaxine ER, Khedezla, and Pristiq (generic) 100 mg

1. Exceptions can be made for patients taking *greater than* 100 mg daily, if there is documentation that the patient has already been started and stabilized on greater than 100 mg per day or if the patient has been receiving 100 mg daily and the dose is now being increased. A quantity override up to 400 mg per day may be issued to allow for a 30 day supply per dispensing.

REFERENCES

1. Pristiq® extended-release tablets [prescribing information]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; November 2018.
2. Desvenlafaxine extended-release tablets [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; November 2019.
3. Khedezla™ extended-release tablets [prescribing information]. Morristown, NJ: Pernix Therapeutics, LLC; January 2019.

venlafaxine immediate-release tablets (generic for Effexor)
25 mg, 37.5 mg, 50 mg, 75 mg and 100 mg Maximum quantity per RX = 90 tablets

Venlafaxine is available as 25 mg, 37.5 mg, 50 mg, 75 mg and 100 mg tablets. Venlafaxine is indicated for the treatment of major depressive disorder (MDD). The recommended starting dose for Effexor is 75 mg/day, administered in two or three divided doses taken with food. Depending on tolerability and the need for further clinical effect, the dose may need to be increased to 150 mg/day and can be further increased to 225 mg/day. Dose increases should be in increments up to 75 mg/day and should made in intervals of not less than four days. More severely depressed patients in one study responded to an average dose of 350 mg/day. Certain patients, including more severely depressed patients, may respond to higher doses, up to a maximum of 375 mg/day, generally in three divided doses. For patients with renal impairment it is recommended that the total daily dose be reduced by 25%. For patients undergoing

hemodialysis or those with mild to moderate hepatic impairment it is recommend that the total daily dose be reduced by 50%.

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

venlafaxine 25 mg, 37.5 mg and 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]. A quantity override up to 375 mg/day may be issued to allow for a 30 day supply per dispensing.

venlafaxine 75 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]. A quantity override up to 375 mg/day may be issued to allow for a 30 day supply per dispensing.
2. Exceptions can be made for patients receiving doses *greater than* 300 mg/day, 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 up to 375 mg/day (150 tablets) may be issued to allow for a 30 day supply per dispensing.

venlafaxine 100 mg
No overrides to this quantity limit recommended.

REFERENCES
1. venlafaxine tablets [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; February 2019.

Effexor XR 37.5 mg, 150 mg (generic) Maximum quantity per RX = 30 capsules
Effexor XR 75 mg (generic) Maximum quantity per RX = 90 capsules

Effexor XR is available as 37.5 mg, 75 mg and 150 mg capsules. Effexor XR is indicated for the treatment of major depressive disorder (MDD), generalized anxiety disorder (GAD), social anxiety disorder (also known as social phobia) and panic disorder, with or without agoraphobia. Effexor XR should be administered as a single dose with food either in the morning or evening. The recommended starting dose for MDD and GAD is 75 mg/day. It may be desirable for some patients to start at 37.5 mg/day for four to seven days, to allow new patients to adjust to the medication before increasing to 75 mg/day. For patients not responding to the initial 75 mg/day dose, they may benefit from dose increases up to a maximum of 225 mg/day. Dose increases should be in increments of up to 75 mg/day, as needed, and should made in intervals of not less than four days. In a study of patients with MDD who were more severely depressed, patients responded to an average dose of 350 mg/day (range 150 to 375 mg/day). The recommended dose for social anxiety disorder is 75 mg/day. The recommended initial dose for panic disorder is 37.5 mg/day for seven days. In clinical trials this was followed with doses of 75 mg/day and subsequent dose increases to a maximum of 225 mg/day. Dose increases should be in increments up to 75 mg/day, as needed, and should be made at intervals of not less than seven days. For patients with mild or moderate renal impairment it is recommended that the total daily dose is reduced by 25% to 50%. For patients undergoing hemodialysis, severe hepatic impairment, hepatic cirrosis or those with severe renal impairment it is recommend that the total daily dose be reduced by 50% or more. When discontinuing treatment, reduce the dose gradually.

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

Effexor XR 37.5 mg (generic)
1. Exceptions can be made for patients who are taking Effexor XR twice daily. A quantity override may be issued for a maximum of 60 capsules 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]. A quantity override up to 375 mg/day may be issued to allow for a 30 day supply per dispensing.

Effexor XR 75 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]. A quantity override up to 375 mg/day may be issued to allow for a 30 day supply per dispensing.
2. Exceptions can be made for patients taking doses ***greater than*** 225 mg/day, if there is documentation that the patient has already been started and stabilized on greater than 225 mg per day or if the patient has been receiving 225 mg daily, and the dose is now being increased to greater than 225 mg per day. A quantity override up to 375 mg/day may be issued to allow for a 30 day supply per dispensing.

Effexor XR 150 mg (generic)
1. Exceptions can be made for patients taking doses ***greater than*** 225 mg/day, if there is documentation that the patient has already been started and stabilized on greater than 225 mg per day or if the patient has been receiving 225 mg daily, and the dose is now being increased to greater than 225 mg per day. A quantity override up to 300 mg/day (60 capsules) may be issued to allow for a 30 day supply per dispensing.

REFERENCES
1. Effexor XR® extended-release capsules [prescribing information]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; December 2018.

Venlafaxine extended-release generic tablets
37.5 mg, 75 mg, 150 mg and 225 mg Maximum quantity per RX = 30 tablets

Venlafaxine extended-release tablets are is available as 37.5 mg, 75 mg, 150 mg and 225 mg tablets. Venlafaxine extended-release is indicated for the treatment of major depressive disorder (MDD) and social anxiety disorder (SAD), also known as social phobia. Venlafaxine extended-release tablets should be administered as a single dose with food either in the morning or evening. The recommended starting dose for MDD is 75 mg/day. It may be desirable for some patients to start at 37.5 mg/day for four to seven days, to allow new patients to adjust to the medication before increasing to 75 mg/day. For patients not responding to the initial 75 mg/day dose, they may benefit from dose increases up to a maximum of 225 mg/day. Dose increases should be in increments of up to 75 mg/day, as needed, and should be made in intervals of not less than four days. More severely depressed patients in one study responded to a mean dose of 350 mg/day (range 150 to 375 mg/day). The recommended dose for SAD is 75 mg/day. Each tablet should be swallowed whole and not divided, chewed, crushed or placed in water. For patients with renal impairment it is recommended that the total daily dose be reduced by 25% to 50%. For patients undergoing hemodialysis or those with mild to moderate hepatic impairment it is recommend that the total daily dose be reduced by 50%. For patients with hepatic cirrosis it may be necessary to reduce the dose by more than 50%. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible.

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

Venlafaxine extended-release 37.5 mg
1. Exceptions can be made for patients who are taking venlafaxine extended release tablets 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]. A quantity override up to 375 mg/day may be issued to allow for a 30 day supply per dispensing.

Venlafaxine extended-release 75 mg
1. Exceptions can be made for patients who are taking venlafaxine extended release tablets 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]. A quantity override up to 375 mg/day may be issued to allow for a 30 day supply per dispensing.
3. Exceptions can be made for patients taking doses ***greater than*** 225 mg/day, if there is documentation that the patient has already been started and stabilized on greater than 225 mg per day or if the patient has been receiving 225 mg daily, and the dose is now being increased to greater than 225 mg per day. A quantity override up to 375 mg/day (150 tablets) may be issued to allow for a 30 day supply per dispensing.

Venlafaxine extended-release 150 mg
1. Exceptions can be made for patients who are taking venlafaxine extended-release tablets 300 mg/day (as a single or divided dose). A quantity override may be issued for a maximum of 60 tablets per dispensing.

Venlafaxine extended-release 225 mg
No overrides to this quantity limit recommended.

REFERENCE
1. Venlafaxine Extended-Release tablets [prescribing information]. Bridgewater, NJ: Trigen Laboratories; November 2017.

Fetzima ER 20 mg, 40 mg, 80 mg, and 120 mg Maximum Quantity per RX = 30 capsules
Fetzima Titration Pack Maximum quantity per RX = 1 pack (28 capsules)
Fetzima is available in four capsule strengths (20 mg, 40 mg, 80 mg, and 120 mg) and also comes in a titration pack. The manufacturer recommended dosing guidelines for major depressive disorder in adults range from a daily dose of 40 mg to 120 mg once daily. Fetzima should be initiated at 20 mg once daily for 2 days and then increased to 40 mg once daily. Based on efficacy and tolerability, Fetzima may then be increased in increments of 40 mg at intervals of two or more days. The maximum recommended dose is 120 mg once daily. Therefore, 30 capsules would supply enough medication for a one month (30 day) supply if dosed once daily. The Fetzima titration pack contains two 20 mg capsules and twenty-six 40 mg capsules. Therefore, one titration pack would supply enough medication for a 28 day supply if dosed once daily. The participant should be referred to higher strength capsules if a greater quantity is requested. For patients with moderate renal impairment (creatinine clearance of 30-59 mL/min), the maintenance dose should not exceed 80 mg once daily. For patients with severe renal impairment (creatinine clearance of

15-29 mL/min), the maintenance dose should not exceed 40 mg once daily. FETZIMA is not recommended for patients with end stage renal disease.

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

Fetzima ER 20 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]. A quantity override up to 100 mg/day may be issued to allow for a 30 day supply per dispensing. Examples: patient is taking 60 mg daily – patient would otherwise require one 20 mg plus one 40 mg capsule: approve 90 of the 20 mg capsules; patient is taking 100 mg daily – patient would otherwise require one 20 mg plus one 80 mg capsule: approve 150 of the 20 mg capsules.

Fetzima ER 40 mg
1. Exceptions can be made for patients who require that the dose be divided two or three times daily. A quantity override may be issued to provide a quantity sufficient for a 30 day supply per dispensing.

Fetzima ER 80 mg and 120 mg
No overrides to this quantity limit recommended.

Fetzima Titration Pack
No overrides to this quantity limit recommended.

REFERENCE
1. Fetzima® capsules [prescribing information]. Madison, NJ: Allergan USA, Inc.; October 2019.

Savella 12.5 mg, 25 mg, 50 mg and 100 mg tablets Maximum quantity per RX = 60 tablets
Savella Titration Pack tablets Maximum quantity per RX = 1 pack (55 tablets)
Savella is available in four strengths (12.5 mg, 25 mg, 50 mg and 100 mg tablets) and also comes in a titration pack. Savella is indicated for the management of fibromyalgia. The recommended dose of Savella is 50 mg twice daily. Dosing should be titrated according to the following schedule: Day 1: 12.5 mg once, Days 2-3: 25 mg/day (12.5 mg twice daily), Days 4-7: 50 mg/day (25 mg twice daily), After Day 7: 100 mg/day (50 mg twice daily). Based on individual response, the dose may be increased to 200 mg/day (100 mg twice daily). Doses above 200 mg daily have not been studied. No dosage adjustments are necessary in patients with hepatic impairment or mild renal impairment. Savella should be used in caution in patients with moderate renal impairment. For patients with severe renal impairment, the maintenance dose should be reduced by 50% to 50 mg/day (25 mg twice daily) and based on individual response may be increased to 100 mg/day. Therefore, 60 tablets would supply enough medication for a one month (30 day) supply if dosed twice daily. The titration pack contains a four week (28 day) blister package to achieve dosing up to the recommended dose of 50 mg twice daily. Therefore, one titration pack would supply enough medication for a 28 day supply. The participant should be referred to higher strength tablets if a greater quantity is requested.

CRITERIA
All approvals are provided for *12 months* in duration unless otherwise noted below.

Savella 12.5 mg, 25 mg and 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]. A quantity override up to 200 mg/day may be issued to allow for a 30 day supply per dispensing.

Savella 100 mg

No overrides to this quantity limit recommended.

Savella Titration Pack

No overrides to this quantity limit recommended.

REFERENCE

1. Savella® tablets [prescribing information]. Irvine, CA: Allergan USA, Inc.; December 2017.