COUPE HEALTH

PHARMACY UTILIZATION MANAGEMENT (UM) PROGRAM CRITERIA ACTIVITY

Provider Notification

Policies Effective: 11/7/2022 Notification Posted: September 23, 2022

CONTENTS	PAGE
Aplenzin; Forfivo XL; Wellbutrin SR; Wellbutrin XL (bupropion)	1
Cymbalta, Drizalma Sprinkle (duloxetine)	5
Caplyta (lumateperone)	9
Effexor IR/XR (venlafaxine)	11
Fetzima (Levomilnacipran)	15
Trintellix (vortioxetine)	18
Viibryd (vilazodone)	21

Revisions are effective the first of the month following a 45-day notification and comment period.

UM PROGRAM CRITERIA REVISED			
Aplenzin; Forfivo XL; Wellbutrin SR; Wellbutrin XL (bupropion)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Aplenzin; Forfivo XL; Wellbutrin SR; Wellbutrin XL	1. Updated continuation criteria 2. Removed Viibryd as preferred brand product, as is now available as a generic 3. Defined parameters for failure of trial in fail first criteria		

Prior Authorization Approval Criteria

Aplenzin; Forfivo XL; Wellbutrin SR; Wellbutrin XL (bupropion)

Generic name: bupropion
Brand name: Aplenzin (HBr); Forfivo XL (HCl); Wellbutrin SR (HCl); Wellbutrin XL (HCl)
Medispan GPI: 5830004010**** MON
Medication class: Dopamine/Norepinephrine-Reuptake Inhibitor
FDA-approved uses: Major depressive disorder
Seasonal affective disorder

Usual dose range:

Major depressive disorder

Immediate Release	Initial: 100mg twice daily	Maximum: 450mg/day
12-hour (SR)	Initial: 150mg once daily	Maximum: 400mg/day

24-hour (XL) HCl	Initial: 150mg once daily	Maximum: Wellbutrin XL - 300mg/day Forfivo XL – 450mg/day
24-hour HBr	Initial: 174mg once daily	Maximum: 522mg/day
Seasonal affective disorder		
24-hour (Wellbutrin XL) HCl	Initial: 150mg once daily	Maximum: 300mg/day
24-hour HBr	Initial: 174mg once daily	Maximum: 348mg/day

Duration of Authorization:

Initial:	3 months
Ongoing:	12 months

Estimated Cost:

Criteria for use for Indication Major Depressive Disorder

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 18 years of age or older
- Patient has failure following an adequate trial (defined as a minimum of 4 weeks), contraindication, or intolerance to:
  - At least one generic bupropion product
    -AND-
  - At least one generic SSRI (citalopram (Celexa), escitalopram (Lexapro), fluoxetine (Prozac), fluvoxamine (Luvox), paroxetine (Paxil), sertraline (Zoloft))
    -AND-
  - At least one generic SNRI (desvenlafaxine (Pristiq), duloxetine (Cymbalta), venlafaxine (Effexor))
    -AND-
  - At least one preferred brand antidepressant (Fetzima, Trintellix)
- In patients who have confirmed failure to generic bupropion, and patient is currently stabilized on brand Wellbutrin, Aplenzin, or Forfivo, therapy can be authorized thru grandfathering criteria. Trial dates of generic bupropion trial will be required for review.
- DAW1 is not allowed outside of a confirmed trial of generic venlafaxine

Criteria for use for Seasonal affective disorder

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 18 years of age or older.
- Must be prescribed by, or in consultation with a psychiatrist or mental health professional.
- Prophylactic treatment should be reserved for patients with frequent depressive episodes and/or significant impairment.
- Continue treatment through the winter season and should be tapered and discontinued in early spring.
- Patient has failure following an adequate trial (defined as a minimum of 4 weeks), contraindication, or intolerance to:
  - At least one generic bupropion product
    -AND-
  - At least one generic SSRI (citalopram (Celexa), escitalopram (Lexapro), fluoxetine (Prozac), fluvoxamine (Luvox), paroxetine (Paxil), sertraline (Zoloft))
    -AND-

    - At least one generic SNRI (desvenlafaxine (Pristiq), duloxetine (Cymbalta), venlafaxine (Effexor))
      -AND-
    - At least one preferred brand antidepressant (Fetzima, Trintellix)
- In patients who have confirmed failure to generic bupropion, and patient is currently stabilized on brand Wellbutrin, Aplenzin, or Forfivo, therapy can be authorized thru grandfathering criteria. Trial dates of generic bupropion trial will be required for review.
- DAW1 is not allowed outside of a confirmed trial of generic venlafaxine

Criteria continuation of therapy

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- Updated chart notes or other clinical documentation confirming efficacy and tolerability of the requested treatment will be required for all renewal reviews. Submitted clinical documentation must be from an encounter after the start date of the current approval.
- Patient demonstrates adequate compliance as defined as an MPR >80%.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Seizure disorder
- History of bulimia or anorexia nervosa
- Patients undergoing abrupt discontinuation of ethanol or sedatives, including benzodiazepines, barbiturates, or antiepileptic drugs
- Use of MAOIs (concurrently or within 14 days of discontinuing either bupropion or the MAOI)
- Initiation of bupropion in a patient receiving linezolid or IV methylene blue.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patients under the age of 18, safety and effectiveness have not been established in pediatric patients
- The treatment of bipolar disorder

Special Considerations:

- In patients with moderately impaired renal function (CrCl 15-60mL/min) - Use with caution; consider a maximum daily dose of 150 mg/day.
- In patients with impaired renal function (CrCl <15mL/min) - Use of alternative agent may be preferred. Use with caution; to limit accumulation of active metabolites, initiate therapy at 100 mg every 48 hours or 150 mg every 72 hours. Titrate gradually based on tolerability and response to a maximum daily dose of 150 mg/day.
- In patients on hemodialysis - Minimally dialyzable (13%); major active metabolite (hydroxybupropion) is not dialyzable.
- In patients of peritoneal dialysis - Not likely to be dialyzable.
- In patients with mild impaired hepatic function (Child-Pugh score 5 to 6) - Use with caution. Manufacturer labeling suggests that a reduction in dose and/or frequency be considered but does not provide specific dosing recommendations. Some experts recommend decreasing the initial dose to 50% of usual dose and reducing dosing frequency. Use of the 450 mg ER tablet is not recommended (Forfivo XL is not available in a lower dose strength).
- In patients with moderate to severe impaired hepatic function (Child-Pugh score 7 to 15) - use with extreme caution. Some experts recommend decreasing the initial dose to 50% of usual dose and reducing dosing frequency.
- Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term trials. These trials did not show an increase in the risk of suicidal thoughts and behavior

with antidepressant use in subjects >24 years of age; there was a reduction in risk with antidepressant use in subjects ≥65 years of age. In patients of all ages who are started on antidepressant therapy, monitor closely for worsening and for emergence of suicidal thoughts and behaviors, particularly during the initial 1 to 2 months of therapy or during periods of dosage adjustments (increases or decreases); advise families and caregivers of the need for close observation and communication with the prescriber. A medication guide concerning the use of antidepressants should be dispensed with each prescription.

- The possibility of a suicide attempt is inherent in major depression and may persist until remission occurs. Worsening depression and severe abrupt suicidality that are not part of the presenting symptoms may require discontinuation or modification of drug therapy. Use caution in high-risk patients during initiation of therapy.
- Prescriptions should be written for the smallest quantity consistent with good patient care. The patient's family or caregiver should be alerted to monitor patients for the emergence of suicidality and associated behaviors such as anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, and mania; patients should be instructed to notify their health care provider if any of these symptoms or worsening depression or psychosis occur.
- May cause a dose-related risk of seizures. Use is contraindicated in patients with a history of seizures or certain conditions with high seizure risk (eg, history of anorexia/bulimia or patients undergoing abrupt discontinuation of ethanol, benzodiazepines, barbiturates, or antiepileptic drugs). 24-hour ER formulations are also contraindicated in patients with certain conditions with high seizure risk (eg, arteriovenous malformation, severe head injury, severe stroke, CNS tumor, and CNS infection). Use caution with concurrent use of antipsychotics, antidepressants, theophylline, systemic corticosteroids, stimulants (including cocaine), anorexiants, or hypoglycemic agents, or with excessive use of ethanol, benzodiazepines, sedative/hypnotics, or opioids. Use with caution in seizure-potentiating metabolic disorders (hypoglycemia, hyponatremia, severe hepatic impairment, and hypoxia). The dose-dependent risk of seizures may be reduced by gradual dose increases and by not exceeding the maximum daily dose. Do not coadminister with other bupropion-containing formulations. Permanently discontinue if seizure occurs during therapy. Chewing, crushing, injecting, or dividing long-acting products may increase seizure risk.
- May precipitate a shift to mania or hypomania in patients with bipolar disorder. Monotherapy in patients with bipolar disorder should be avoided. Combination therapy with an antidepressant and a mood stabilizer may be effective for acute treatment of bipolar major depressive episodes but should be avoided in acute mania or mixed episodes as well as maintenance treatment in bipolar disorder due to the mood-destabilizing effects of antidepressants. Patients presenting with depressive symptoms should be screened for bipolar disorder. Bupropion is not FDA-approved for the treatment of bipolar depression.

References:

1. Wellbutrin (bupropion hydrochloride) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; October 2020.
2. Wellbutrin SR (bupropion hydrochloride) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; October 2020
3. Wellbutrin XL (bupropion hydrochloride) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; July 2021.
4. Forfivo XL (bupropion hydrochloride) [prescribing information]. Pine Brook, NJ: Almatica Pharma, Inc; December 2019.
5. Aplenzin (bupropion hydrobromide) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; July 2021.
6. Grunze H, Vieta E, Goodwin GM, et al; Members of the WFSBP Task Force on Bipolar Affective Disorders. The World Federation of Societies of Biological Psychiatry (WFSBP) guidelines for the biological treatment of bipolar disorders: acute and long-term treatment of mixed states in bipolar disorder. World J Biol Psychiatry. 2018;19(1):2-58.[PubMed 29098925]10.1080/15622975.2017.1384850
7. Yatham LN, Kennedy SH, Parikh SV, et al. Canadian Network for Mood and Anxiety Treatments (CANMAT) and International Society for Bipolar Disorders (ISBD) 2018 guidelines for the management of patients with bipolar disorder. Bipolar Disord. 2018;20(2):97-170.[PubMed 29536616]10.1111/bdi.12609

MedOne P&T Committee approval: Date: 1-1-17

Adopted: 1-1-17
Revised: 9-17-21
9-6-22

Updates:

9-17-21 Updated initial auth from 3 months to 12 months

9-6-22
- Updated continuation criteria
- Removed Viibryd as preferred brand product, as is now available as a generic
- Defined parameters for failure of trial in fail first criteria

Effective Date (most recent revisions): 11-7-22

**Revisions are effective the first of the month following a 45 day notification and comment period.*

NEW UM PROGRAM CRITERIA			
Cymbalta, Drizalma Sprinkle (duloxetine)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Cymbalta, Drizalma Sprinkle (duloxetine)

Generic name: duloxetine
Brand name: Cymbalta, Drizalma
Medispan GPI: 5818002510**** MON
Medication class: Serotonin and Norepinephrine Reuptake Inhibitor
FDA-approved uses:
Fibromyalgia
Generalized Anxiety Disorder
Major Depressive Disorder
Chronic Musculoskeletal Pain
Diabetic peripheral Neuropathy

Usual dose range:

Fibromyalgia – Adult	30mg once daily for 1 week	60mg/day; doses up to 120 mg/day were studied in clinical trials but did not confer any additional benefit.
Fibromyalgia – Pediatric ≥13 years old	30mg once daily for 1 week	60mg/day
Generalized Anxiety Disorder – Adult	60mg once daily	120mg/day
General Anxiety Disorder – Pediatric ≤17 years to ≥7 years old	30mg once daily for 2 weeks	120mg/day
Major Depressive Disorder – Adult	40 to 60mg once daily or divided twice daily	120mg/day
Chronic Musculoskeletal Pain – Adult	30mg once daily for 1 to 2 weeks	60mg/day
Diabetic peripheral Neuropathy - Adult	60mg once daily	60mg/day; doses up to 120 mg/day were studied in clinical trials but did not confer any additional benefit.

Duration of Authorization:
Initial: 3 months
Ongoing: 12 months

Estimated Cost:
$3977.04/year AWP

Criteria for use for Indication Fibromyalgia

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 13 years of age or older.
- Patient has failure following an adequate trial (defined as a minimum of 4 weeks), contraindication, or intolerance to:
    - At least one generic duloxetine product
      -AND-
    - At least one preferred brand antidepressant (Fetzima, Trintellix)
- In patients who have confirmed failure to generic duloxetine, and patient is currently stabilized on brand Cymbalta or Drizalma, therapy can be authorized thru grandfathering criteria. Trial dates of generic duloxetine trial will be required for review.
- DAW1 is not allowed outside of a confirmed trial of generic duloxetine.

Criteria for use for Indication Generalized Anxiety Disorder

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 7 years of age or older.
- Patient failure following an adequate trial (defined as a minimum of 4 weeks), contraindication, or intolerance to:
    - At least one generic duloxetine product
      -AND-
    - At least one generic SSRI (citalopram (Celexa), escitalopram (Lexapro), fluoxetine (Prozac), fluvoxamine (Luvox), paroxetine (Paxil), sertraline (Zoloft))
      -AND-
    - At least one generic alternative antidepressant (bupropion (Wellbutrin), amitriptyline (Elavil), desipramine (Norpramin), nortriptyline (Pamelor), trazodone (Desyrel, Oleptro), mirtazapine (Remeron), Vilazodone (Viibryd)
      -AND-
    - At least one preferred brand antidepressant (Fetzima, Trintellix)
- In patients who have confirmed failure to generic duloxetine, and patient is currently stabilized on brand Cymbalta or Drizalma, therapy can be authorized thru grandfathering criteria. Trial dates of generic duloxetine trial will be required for review.
- DAW1 is not allowed outside of a confirmed trial of generic duloxetine.

Criteria for use for Indication Major Depressive Disorder

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 18 years of age or older.
- Patient has failure following an adequate trial (defined as a minimum of 4 weeks), contraindication, or intolerance to:
    - At least one generic duloxetine product
      -AND-
    - At least one generic SSRI (citalopram (Celexa), escitalopram (Lexapro), fluoxetine (Prozac), fluvoxamine (Luvox), paroxetine (Paxil), sertraline (Zoloft))
      -AND-
    - At least one generic alternative antidepressant (bupropion (Wellbutrin), amitriptyline (Elavil), desipramine (Norpramin), nortriptyline (Pamelor), trazodone (Desyrel, Oleptro), mirtazapine (Remeron),

Vilazodone (Viibryd)
-AND-
- At least one preferred brand antidepressant (Fetzima, Trintellix)

- In patients who have confirmed failure to generic duloxetine, and patient is currently stabilized on brand Cymbalta or Drizalma, therapy can be authorized thru grandfathering criteria. Trial dates of generic duloxetine trial will be required for review.
- DAW1 is not allowed outside of a confirmed trial of generic duloxetine.

Criteria for use for Chronic Musculoskeletal Pain

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 18 years of age or older.
- For chronic low back or non-radicular neck pain, must be used as an adjunct for patients with an inadequate response to nonpharmacologic and nonsteroidal anti-inflammatory (NSAID) drug therapy.
- For osteoarthritis of the knee, reserved for patients with moderate to severe symptoms and an inadequate response to nonpharmacologic interventions and oral NSAIDs or oral NSAIDs are contraindicated.
- Patient has failure following an adequate trial (defined as a minimum of 4 weeks), contraindication, or intolerance to:
  - At least one generic duloxetine product
    -AND-
  - At least one generic prescription strength NSAIDs
- In patients who have confirmed failure to generic duloxetine, and patient is currently stabilized on brand Cymbalta or Drizalma, therapy can be authorized thru grandfathering criteria. Trial dates of generic duloxetine trial will be required for review.
- DAW1 is not allowed outside of a confirmed trial of generic duloxetine.

Criteria for use for Diabetic Peripheral Neuropathy

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 18 years of age or older.
- Patient has failure following an adequate trial (defined as a minimum of 4 weeks), contraindication, or intolerance to:
  - At least one generic duloxetine product
    -AND-
  - At least one anti-convulsant (pregabalin, gabapentin)
- In patients who have confirmed failure to generic duloxetine, and patient is currently stabilized on brand Cymbalta or Drizalma, therapy can be authorized thru grandfathering criteria. Trial dates of generic duloxetine trial will be required for review.
- DAW1 is not allowed outside of a confirmed trial of generic duloxetine.

Criteria continuation of therapy

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- Updated chart notes or other clinical documentation confirming efficacy and tolerability of the requested treatment will be required for all renewal reviews. Submitted clinical documentation must be from an encounter after the start date of the current approval.
- Patient demonstrates adequate compliance as defined as an MPR >80%.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Use of MAOIs (concurrently or within 14 days of discontinuing either bupropion or the MAOI)
- Initiation of bupropion in a patient receiving linezolid or IV methylene blue.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patients under the age of 7, safety and effectiveness have not been established in pediatric patients

Special Considerations:

- When discontinuing antidepressant treatment that has lasted for >3 weeks, gradually taper the dose (eg, over 2 to 4 weeks) to minimize withdrawal symptoms and detect reemerging symptoms. Reasons for a slower taper (eg, over 4 weeks) include use of a drug with a half-life <24 hours (eg, paroxetine, venlafaxine), prior history of antidepressant withdrawal symptoms, or high doses of antidepressants. If intolerable withdrawal symptoms occur, resume the previously prescribed dose and/or decrease dose at a more gradual rate. Select patients (eg, those with a history of discontinuation syndrome) on long-term treatment (>6 months) may benefit from tapering over >3 months.
- Evidence for ideal antidepressant switching strategies is limited; strategies include cross-titration (gradually discontinuing the first antidepressant while at the same time gradually increasing the new antidepressant) and direct switch (abruptly discontinuing the first antidepressant and then starting the new antidepressant at an equivalent dose or lower dose and increasing it gradually). Cross-titration (eg, over 1 to 4 weeks depending upon sensitivity to discontinuation symptoms and adverse effects) is standard for most switches, but is contraindicated when switching to or from an MAOI. A direct switch may be an appropriate approach when switching to another agent in the same or similar class (eg, when switching between 2 SSRIs), when the antidepressant to be discontinued has been used for <1 week, or when the discontinuation is for adverse effects. When choosing the switch strategy, consider the risk of discontinuation symptoms, potential for drug interactions, other antidepressant properties (eg, half-life, adverse effects, and pharmacodynamics), and the degree of symptom control desired.
- May impair cognitive or motor performance; caution operating hazardous machinery or driving.
- Modest increases in serum glucose and HbA1c levels have been observed in some diabetic patients receiving duloxetine for diabetic peripheral neuropathic pain (DPNP).
- May cause orthostatic hypotension/syncope, especially within the first week of therapy and after dose increases. Carefully monitor blood pressure with initiation of therapy, dose increases (especially in patients receiving >60 mg/day), or when using concomitant vasodilators or CYP1A2 inhibitors. Consider dose reduction or discontinuation of duloxetine if orthostatic hypotension or syncope occurs.

References:

8. Cymbalta (duloxetine) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; September 2021.
9. Drizalma Sprinkle (duloxetine delayed-release capsules) [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries Inc; July 2021.
10. American Psychiatric Association (APA). Practice guideline for the treatment of patients with major depressive disorder. 3rd ed. http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf. Published October 2010. Accessed March 27, 2019.

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Adopted: 9-7-22
Revised:
Updates:

Effective Date (most recent revisions): 11-7-22

**Revisions are effective the first of the month following a 45 day notification and comment period.*

NEW UM PROGRAM CRITERIA			
Caplyta (lumateperone)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Caplyta (lumateperone)

Generic name:	lumateperone
Brand name:	Caplyta
Medispan GPI:	594000224001** MONY
Medication class:	Second Generation Atypical Antipsychotic
FDA-approved uses:	**Bipolar I or II Disorder** **Schizophrenia**

Usual dose range:	
Bipolar I or II – monotherapy	42mg once daily, dose titration is not required
Bipolar I or II – adjunctive therapy to lithium or valproate	42mg once daily, dose titration is not required
Schizophrenia	42mg once daily, dose titration is not required

Duration of Authorization:	
Initial:	3 months
Ongoing:	12 months

Estimated Cost: $21,633.55 per patient per year AWP

Criteria for use for Bipolar I or II Disorder

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 18 years of age or older.
- Grandfather criteria allowed as defined as patient is new to the plan and currently stabilized on Caplyta (as evidenced by coverage effective date of less than or equal to 120 days)
    - Please see policy and procedure *"14 – Grandfather Status Authorization"* for additional information.
- Must be prescribed by, or in consultation with a psychiatrist or mental health professional.
- Patient has failure following an adequate trial (defined as a minimum of 4 weeks), contraindication, or intolerance to 2 preferred generic antipsychotics:
    - Aripiprazole (Abilify)
    - Chlorpromazine (Thorazine)
    - Clozapine (Clozaril)
    - Fluphenazine (Prolixin)
    - Haloperidol (Haldol)
    - Loxapine (Loxitane)
    - Olanzapine (Zyprexa)
    - Paliperidone (Invega)
    - Pimozide (Orap)

- Quetiapine IR/ER (Seroquel)
- Risperidone (Risperdal)
- Thiothixene (Navane)
- Trifluoperzine (Stelazine)
- Ziprasidone (Geodon)

-AND-

- Patient has failure following an adequate trial (defined as a minimum of 4 weeks), contraindication, or intolerance to 1 preferred brand antipsychotics:
  - Latuda (lurasidone)
  - Rexulti (brexpiprazole)
  - Vraylar (cariprazine)

-OR-

- Treatment with Caplyta was initiated at a recent behavioral inpatient admission (discharge within the past 3 months) and the member is currently stable on therapy. (Please document date of discharge from inpatient admission).

Criteria for use for Schizophrenia

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 18 years of age or older.
- Grandfather criteria allowed as defined as patient is new to the plan and currently stabilized on Caplyta (as evidenced by coverage effective date of less than or equal to 120 days)
  - Please see policy and procedure *"14 – Grandfather Status Authorization"* for additional information.
- Must be prescribed by, or in consultation with a psychiatrist or mental health professional.
- Patient has failure following an adequate trial (defined as a minimum of 4 weeks), contraindication, or intolerance to 2 preferred generic antipsychotics:
  - Aripiprazole (Abilify)
  - Chlorpromazine (Thorazine)
  - Clozapine (Clozaril)
  - Fluphenazine (Prolixin)
  - Haloperidol (Haldol)
  - Loxapine (Loxitane)
  - Olanzapine (Zyprexa)
  - Paliperidone (Invega)
  - Pimozide (Orap)
  - Quetiapine IR/ER (Seroquel)
  - Risperidone (Risperdal)
  - Thiothixene (Navane)
  - Trifluoperzine (Stelazine)
  - Ziprasidone (Geodon)

-AND-

- Patient has failure following an adequate trial (defined as a minimum of 4 weeks), contraindication, or intolerance to 1 preferred brand antipsychotics:
  - Latuda (lurasidone)
  - Rexulti (brexpiprazole)
  - Vraylar (cariprazine)

-OR-

- Treatment with Caplyta was initiated at a recent behavioral inpatient admission (discharge within the past 3 months) and the member is currently stable on therapy. (Please document date of discharge from inpatient admission).

Criteria continuation of therapy

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- Updated chart notes or other clinical documentation confirming efficacy and tolerability of the requested treatment will be required for all renewal reviews. Submitted clinical documentation must be from an encounter after the start date of the current approval.
- Patient demonstrates adequate compliance as defined as an MPR >80%.

Contraindications:

- History of hypersensitivity to any of the product ingredients.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patient is less than 18, safety and effectiveness not established in pediatric patients.

Special Considerations:

- In patients with moderate or severe hepatic impairment (Child-P B or C) – 21mg once daily
- May cause anticholinergic effects (confusion, agitation, constipation, xerostomia, blurred vision, urinary retention); use with caution in patients with decreased GI motility, urinary retention, benign prostatic hyperplasia, xerostomia, or visual problems.
- May increase the risk for falls due to somnolence, orthostatic hypotension, and motor or sensory instability.
- Use with caution in patients at risk of seizures or with conditions that lower the seizure threshold. Elderly patients may be at increased risk of seizures due to an increased prevalence of predisposing factors.

References:

11. Caplyta (lumateperone tosylate) [prescribing information]. New York, NY: Intra-Cellular Therapies Inc; April 2022.
12. Reus VI, Fochtmann LJ, Eyler AE, et al. The American Psychiatric Association practice guideline on the use of antipsychotics to treat agitation or psychosis in patients with dementia. Am J Psychiatry. 2016;173(5):543-546. http://ajp.psychiatryonline.org/doi/pdf/10.1176/appi.ajp.2015.173501.
13. De Hert M, Detraux J, van Winkel R, Yu W, Correll CU. Metabolic and cardiovascular adverse effects associated with antipsychotic drugs. Nat Rev Endocrinol. 2011;8(2):114-126. doi:10.1038/nrendo.2011.156[PubMed 22009159]
14. Gugger JJ. Antipsychotic pharmacotherapy and orthostatic hypotension: identification and management. CNS Drugs. 2011;25(8):659-671. doi:10.2165/11591710-000000000-00000[PubMed 21790209]

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Updates:
9-6-22 AWP updated as of 9-6-22 pricing
Defined adequate trial for failure of generic trial

Effective Date (most recent revisions): 11-7-22

**Revisions are effective the first of the month following a 45 day notification and comment period.*

NEW UM PROGRAM CRITERIA			
Effexor IR/XR (venlafaxine)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy

Prior Authorization Approval Criteria

Effexor IR/XR (venlafaxine)

Generic name:	venlafaxine
Brand name:	Effexor IR/XR
Medispan GPI:	5818009010**** MON
Medication class:	Serotonin and Norepinephrine Reuptake Inhibitor
FDA-approved uses:	**Generalized Anxiety Disorder** **Major Depressive Disorder** **Panic Disorder** **Social Anxiety Disorder**

Usual dose range:

Generalized Anxiety Disorder – ER Besylate tabs	**Initial:** 111.5mg per day in patients who have received ≥75 mg/day of another venlafaxine ER product for at least 4 days.	**Maximum:** 225mg/day
Generalized Anxiety Disorder – ER hydrochloride caps	**Initial:** 37.5mg to 75mg per day	**Maximum:** 225mg/day
Major Depressive Disorder – ER Besylate tabs	**Initial:** 111.5mg per day in patients who have received ≥75 mg/day of another venlafaxine ER product for at least 4 days.	**Maximum:** 225mg/day
Major Depressive Disorder – ER hydrochloride caps	**Initial:** 37.5mg to 75mg per day	**Maximum:** 225mg/day
Major Depressive Disorder – Immediate release	**Initial:** 37.5mg to 75mg per day	**Maximum:** 375mg/day
Panic Disorder – ER hydrochloride caps	**Initial:** 37.5mg for 7 days	**Maximum:** 225mg/day
Social Anxiety Disorder – ER hydrochloride caps	**Initial:** 37.5mg for 1 to 2 weeks	**Maximum:** 75mg/day

Duration of Authorization:

Initial:	3 months
Ongoing:	12 months

Estimated Cost: $8138.04/year AWP (150mg XR capsule)

Criteria for use for Indication Generalized Anxiety

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 18 years of age or older.
- Patient has failure following an adequate trial (defined as a minimum of 4 weeks), contraindication, or intolerance to:
    1. At least one generic venlafaxine product
       -AND-
    2. At least one generic SSRI (citalopram (Celexa), escitalopram (Lexapro), fluoxetine (Prozac), fluvoxamine (Luvox), paroxetine (Paxil), sertraline (Zoloft))
       -AND-

3. At least one generic alternative antidepressant (bupropion (Wellbutrin), amitriptyline (Elavil), desipramine (Norpramin), nortriptyline (Pamelor), trazodone (Desyrel, Oleptro), mirtazapine (Remeron), Vilazodone (Viibryd)
   -AND-
4. At least one preferred brand antidepressant (Fetzima, Trintellix)

- In patients who have confirmed failure to generic venlafaxine, and patient is currently stabilized on brand Effexor, therapy can be authorized thru grandfathering criteria. Trial dates of generic venlafaxine trial will be required for review.
- DAW1 is not allowed outside of a confirmed trial of generic venlafaxine.

Criteria for use for Indication Major Depressive Disorder

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 18 years of age or older.
- Patient has failure following an adequate trial (defined as a minimum of 4 weeks), contraindication, or intolerance to:
  - At least one generic venlafaxine product
    -AND-
  - At least one generic SSRI (citalopram (Celexa), escitalopram (Lexapro), fluoxetine (Prozac), fluvoxamine (Luvox), paroxetine (Paxil), sertraline (Zoloft))
    -AND-
  - At least one generic alternative antidepressant (bupropion (Wellbutrin), amitriptyline (Elavil), desipramine (Norpramin), nortriptyline (Pamelor), trazodone (Desyrel, Oleptro), mirtazapine (Remeron), Vilazodone (Viibryd)
    -AND-
  - At least one preferred brand antidepressant (Fetzima, Trintellix)
- In patients who have confirmed failure to generic venlafaxine, and patient is currently stabilized on brand Effexor, therapy can be authorized thru grandfathering criteria. Trial dates of generic venlafaxine trial will be required for review.
- DAW1 is not allowed outside of a confirmed trial of generic venlafaxine

Criteria for use for Indication Panic Disorder

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 18 years of age or older.
- Patient has failure following an adequate trial (defined as a minimum of 4 weeks), contraindication, or intolerance to:
  - At least one generic venlafaxine product
    -AND-
  - At least one generic SSRI (citalopram (Celexa), escitalopram (Lexapro), fluoxetine (Prozac), fluvoxamine (Luvox), paroxetine (Paxil), sertraline (Zoloft))
    -AND-
  - At least one generic alternative antidepressant (bupropion (Wellbutrin), amitriptyline (Elavil), desipramine (Norpramin), nortriptyline (Pamelor), trazodone (Desyrel, Oleptro), mirtazapine (Remeron), Vilazodone (Viibryd)
    -AND-
  - At least one preferred brand antidepressant (Fetzima, Trintellix)

- In patients who have confirmed failure to generic venlafaxine, and patient is currently stabilized on brand Effexor, therapy can be authorized thru grandfathering criteria. Trial dates of generic venlafaxine trial will be required for review.
- DAW1 is not allowed outside of a confirmed trial of generic venlafaxine

Criteria for use for Indication Social Anxiety Disorder

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 18 years of age or older.
- Patient has failure following an adequate trial (defined as a minimum of 4 weeks), contraindication, or intolerance to:
    - At least one generic venlafaxine product
      -AND-
    - At least one generic SSRI (citalopram (Celexa), escitalopram (Lexapro), fluoxetine (Prozac), fluvoxamine (Luvox), paroxetine (Paxil), sertraline (Zoloft))
      -AND-
    - At least one generic alternative antidepressant (bupropion (Wellbutrin), amitriptyline (Elavil), desipramine (Norpramin), nortriptyline (Pamelor), trazodone (Desyrel, Oleptro), mirtazapine (Remeron), Vilazodone (Viibryd)
      -AND-
    - At least one preferred brand antidepressant (Fetzima, Trintellix)
- In patients who have confirmed failure to generic venlafaxine, and patient is currently stabilized on brand Effexor, therapy can be authorized thru grandfathering criteria. Trial dates of generic venlafaxine trial will be required for review.
- DAW1 is not allowed outside of a confirmed trial of generic venlafaxine

Criteria continuation of therapy

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- Updated chart notes or other clinical documentation confirming efficacy and tolerability of the requested treatment will be required for all renewal reviews. Submitted clinical documentation must be from an encounter after the start date of the current approval.
- Patient demonstrates adequate compliance as defined as an MPR >80%.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Use of MAOIs (concurrently or within 14 days of discontinuing either bupropion or the MAOI)
- Initiation of bupropion in a patient receiving linezolid or IV methylene blue.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patients under the age of 18, safety and effectiveness have not been established in pediatric patients

Special Considerations:

- May cause CNS depression, which may impair physical or mental abilities; patients must be cautioned about performing tasks that require mental alertness (eg, operating machinery or driving).
- Use caution in patients with recent history of MI, unstable heart disease, cerebrovascular conditions, or hyperthyroidism.

- Use caution in patients with a previous seizure disorder; discontinue in any patient who develops seizures.

References:

15. Effexor XR (venlafaxine) [prescribing information]. Philadelphia, PA: Wyeth Pharmaceuticals Inc; August 2022.
16. American Psychiatric Association (APA). Practice guideline for the treatment of patients with major depressive disorder. 3rd ed. http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf. Published October 2010. Accessed March 27, 2019.

MedOne P&T Committee approval: Date: 9-7-22

Adopted: 9-7-22
Revised:
Updates:

Effective Date (most recent revisions): 11-7-22

**Revisions are effective the first of the month following a 45 day notification and comment period.*

UM PROGRAM CRITERIA REVISED	
Fetzima (Levomilnacipran)	
Program Type: ☒ Prior Authorization ☒ Quantity Limit ☒ Step Therapy	
Fetzima (Levomilnacipran)	1. Updated continuation criteria 2. Added generic vilazodone to alternative antidepressant list

Prior Authorization Approval Criteria

Fetzima (Levomilnacipran)

Generic name: Levomilnacipran
Brand name: Fetzima
Medispan GPI: 5818005010**** MONY
Medication class: Serotonin and Norepinephrine Reuptake Inhibitors
FDA-approved uses: **Major Depressive Disorder**

Usual dose range:

Major Depressive Disorder	Initial: 20mg/day	Maximum: 120mg/day

Duration of Authorization:
Initial: 3 months
Ongoing: 12 months

Estimated Cost: $6638.74/year AWP

Criteria for use for Major Depressive Disorder

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Grandfather criteria allowed as defined as patient is new to the plan and currently stabilized on Fetzima (as evidenced by coverage effective date of less than or equal to 120 days)

- Please see policy and procedure *"14 – Grandfather Status Authorization"* for additional information.

- Must be 18 years of age or older.
- Patient has failure following an adequate trial (defined as a minimum of 4 weeks), contraindication, or intolerance to:
  - At least one generic SSRI
    - citalopram (Celexa)
    - escitalopram (Lexapro)
    - fluoxetine (Prozac)
    - fluvoxamine (Luvox)
    - paroxetine (Paxil)
    - sertraline (Zoloft)

  -AND-
  - At least one generic SNRI
    - desvenlafaxine (Pristiq, Khedezla)
    - duloxetine (Cymbalta)
    - venlafaxine (Effexor)

  -AND-
  - At least one generic antidepressant from another class
    - Dopamine/Norepinephrine-reuptake inhibitor (DNRI)
      - Bupropion (Wellbutrin)
    - Tricyclic Antidepressants
      - amitriptyline (Elavil)
      - desipramine (Norpramin)
      - nortriptyline (Pamelor)
    - 5-TH2 Receptor Antagonists
      - trazodone (Desyrel, Oleptro)
    - Noradrenergic Antagonist
      - mirtazapine (Remeron)
    - 5-HT_{1A} Receptor Agonist
      - Vilazodone (Viibryd)

Criteria continuation of therapy

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- Updated chart notes or other clinical documentation confirming efficacy and tolerability of the requested treatment will be required for all renewal reviews. Submitted clinical documentation must be from an encounter after the start date of the current approval.
- Patient demonstrates adequate compliance as defined as an MPR >80%.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Use of MAOIs intended to treat psychiatric disorders (concurrently, within 7 days of discontinuing levomilnacipran, or within 2 weeks of discontinuing the MAOI)
- Initiation of levomilnacipran in a patient receiving linezolid or methylene blue IV.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patients under the age of 18, safety and effectiveness have not been established in pediatric patients

Special Considerations:

- In patients with moderately impaired renal function (CrCl 30-59mL/min) – Maintenance dosage should not exceed 80 mg once daily.
- In patients with severely impaired renal function (CrCl 12-29mL/min) – Maintenance dosage should not exceed 40 mg once daily.
- In patients with ESRD – Fetzima is not recommended.
- Beers Criteria: Use caution or avoid use as potentially inappropriate in older adults
- When discontinuing antidepressant treatment that has lasted for >3 weeks, gradually taper the dose (eg, over 2 to 4 weeks) to minimize withdrawal symptoms and detect reemerging symptoms. Reasons for a slower taper (eg, over 4 weeks) include use of a drug with a half-life <24 hours (eg, paroxetine, venlafaxine), prior history of antidepressant withdrawal symptoms, or high doses of antidepressants. If intolerable withdrawal symptoms occur, resume the previously prescribed dose and/or decrease dose at a more gradual rate. Select patients (eg, those with a history of discontinuation syndrome) on long-term treatment (>6 months) may benefit from tapering over >3 months. Evidence supporting ideal taper rates is limited.
- Antidepressants increase the risk of suicidal thinking and behavior in children, adolescents, and young adults (18 to 24 years of age) with MDD and other psychiatric disorders; consider risk prior to prescribing. Short-term studies did not show an increased risk in patients older than 24 years and showed a decreased risk in patients 65 years and older. Closely monitor for clinical worsening, suicidality, or unusual changes in behavior, particularly during the first few months of therapy or during periods of dosage adjustments (increases or decreases); instruct the patient's family or caregiver to closely observe the patient and communicate condition with the health care provider. Dispense a Medication Guide concerning the use of antidepressants in children and teenagers with each prescription. Levomilnacipran is not FDA-approved for use in children
- The possibility of a suicide attempt is inherent in major depression and may persist until remission occurs. Observe patients treated with antidepressants for clinical worsening and suicidality, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases. Worsening depression and severe abrupt suicidality that are not part of the presenting symptoms may require discontinuation or modification of drug therapy. Use caution in high-risk patients during initiation of therapy.
- Write prescriptions for the smallest quantity consistent with good patient care. Alert the patient's family or caregiver to monitor patients for the emergence of suicidality and associated behaviors, such as aggressiveness, anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, and mania; instruct patients to notify their health care provider if any of these symptoms or worsening depression occurs
- Potentially life-threatening serotonin syndrome has occurred with serotonergic agents (eg, selective serotonin reuptake inhibitors [SSRIs], selective norepinephrine reuptake inhibitors [SNRIs]), particularly when used in combination with other serotonergic agents (eg, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, buspirone, St. John's wort, tryptophan) or agents that impair metabolism of serotonin (eg, MAOIs intended to treat psychiatric disorders, other MAOIs [ie, linezolid and methylene blue IV]). Monitor patients closely for signs of serotonin syndrome, such as mental status changes (eg, agitation, hallucinations, delirium, coma), autonomic instability (eg, tachycardia, labile blood pressure, diaphoresis), neuromuscular changes (eg, tremor, rigidity, myoclonus), GI symptoms (eg, nausea, vomiting, diarrhea), and/or seizures. Discontinue treatment (and any concomitant serotonergic agent) immediately if signs/symptoms arise.

References:

17. Fetzima (levomilnacipran) [prescribing information]. Irvine, CA: Allergan USA Inc; December 2017.
18. American Psychiatric Association (APA). Practice guideline for the treatment of patients with major depressive disorder. 3rd ed. http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf. Published October 2010. Accessed September 21, 2018.
19. Bauer M, Severus E, Köhler S, Whybrow PC, Angst J, Möller HJ; WFSBP Task Force on Treatment Guidelines for Unipolar Depressive Disorders. World Federation of Societies of Biological Psychiatry (WFSBP) guidelines for biological treatment of unipolar depressive disorders. Part 2: maintenance treatment of major depressive disorder-update 2015. World J Biol Psychiatry. 2015;16(2):76-95.[PubMed 25677972]10.3109/15622975.2014.1001786
20. Hirsch M, Birnbaum RJ. Discontinuing antidepressant medications in adults. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed March 26, 2019.
21. Shelton RC. Steps following attainment of remission: discontinuation of antidepressant therapy. Prim Care Companion J Clin Psychiatry. 2001;3(4):168-174.[PubMed 15014601]

MedOne P&T Committee approval: Date: 1-1-17

Adopted: 1-1-17
Revised: 9-17-21

	9-6-22
Updates:	
9-17-21	Updated initial auth from 3 months to 12 months
9-6-22	• Updated continuation criteria • Added generic vilazodone to alternative antidepressant list
Effective Date (most recent revisions):	11-7-22

**Revisions are effective the first of the month following a 45 day notification and comment period.*

UM PROGRAM CRITERIA REVISED			
Trintellix (vortioxetine)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Trintellix (vortioxetine)	1. Updated continuation criteria 2. Added generic vilazodone to alternative antidepressant list		

Prior Authorization Approval Criteria

Trintellix (vortioxetine)

Generic name:	Vortioxetine	
Brand name:	Trintellix	
Medispan GPI:	5812009310****	MONY
Medication class:	Selective Serotonin Reuptake Inhibitors	
FDA-approved uses:	**Major Depressive Disorder**	
Usual dose range:		
Major Depressive Disorder	Initial: 5 to 10mg/day	Maximum: 20mg/day
Duration of Authorization:		
Initial:	3 months	
Ongoing:	12 months	
Estimated Cost:	$6484.47/year AWP	

Criteria for use for Major Depressive Disorder

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Grandfather criteria allowed as defined as patient is new to the plan and currently stabilized on Trintellix (as evidenced by coverage effective date of less than or equal to 120 days)
    - Please see policy and procedure *"14 – Grandfather Status Authorization"* for additional information.
- Must be 18 years of age or older.
- Patient has failure following an adequate trial (defined as a minimum of 4 weeks), contraindication, or intolerance to:
    - At least one generic SSRI
        - citalopram (Celexa)

        - escitalopram (Lexapro)
        - fluoxetine (Prozac)
        - fluvoxamine (Luvox)
        - paroxetine (Paxil)
        - sertraline (Zoloft)

-AND-

- At least one generic SNRI
    - desvenlafaxine (Pristiq, Khedezla)
    - duloxetine (Cymbalta)
    - venlafaxine (Effexor)

-AND-

- At least one generic antidepressant from another class
    - Dopamine/Norepinephrine-reuptake inhibitor (DNRI)
        - Bupropion (Wellbutrin)
    - Tricyclic Antidepressants
        - amitriptyline (Elavil)
        - desipramine (Norpramin)
        - nortriptyline (Pamelor)
    - 5-TH2 Receptor Antagonists
        - trazodone (Desyrel, Oleptro)
    - Noradrenergic Antagonist
        - mirtazapine (Remeron)
    - 5-HT_{1A} Receptor Agonist
        - Vilazodone (Viibryd)

Criteria continuation of therapy

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- Updated chart notes or other clinical documentation confirming efficacy and tolerability of the requested treatment will be required for all renewal reviews. Submitted clinical documentation must be from an encounter after the start date of the current approval.
- Patient demonstrates adequate compliance as defined as an MPR >80%.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Use of MAOIs intended to treat psychiatric disorders (concurrently or within 21 days of discontinuing vortioxetine or within 14 days of discontinuing the MAOI)
- Initiation of vortioxetine in a patient receiving linezolid or methylene blue IV.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patients under the age of 18, safety and effectiveness have not been established in pediatric patients

Special Considerations:

- No dosage adjustments are necessary in patients with renal or hepatic function impairment.
- The half-life of vortioxetine is significantly greater than 24 hours, decreasing the risk of withdrawal symptoms. Although few withdrawal symptoms due to abrupt discontinuation of vortioxetine have been described, it is recommended that patients receiving 15 or 20 mg/day be tapered to 10 mg/day for 1 week before full discontinuation. Patients with a prior history of antidepressant withdrawal symptoms or on a high dose may require a slower taper (eg, over 4 weeks). If intolerable withdrawal symptoms occur, resume the previously prescribed dose and/or decrease dose at a more gradual rate. Select patients (eg, those with a history of

discontinuation syndrome) on long-term treatment (>6 months) may benefit from tapering over >3 months. Evidence supporting ideal taper rates is limited.

- Consider risk prior to prescribing. Short-term studies did not show an increased risk in patients >24 years of age and showed a decreased risk in patients ≥65 years of age. Instruct the patient's family or caregiver to closely observe the patient and communicate condition with health care provider, particularly during the first few months of therapy or during periods of dose adjustments. A medication guide concerning the use of antidepressants should be dispensed with each prescription.
- The possibility of a suicide attempt is inherent in major depression and may persist until remission occurs. Worsening depression and severe abrupt suicidality that are not part of the presenting symptoms may require discontinuation or modification of drug therapy. Use caution in high-risk patients during initiation of therapy.
- Prescriptions should be written for the smallest quantity consistent with good patient care. The patient's family or caregiver should be alerted to monitor patients for the emergence of suicidality and associated behaviors such as anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia, hypomania, and mania; patients should be instructed to notify their healthcare provider if any of these symptoms or worsening depression occurs.
- Potentially life-threatening serotonin syndrome has occurred with serotonergic antidepressants (eg, selective serotonin reuptake inhibitors [SSRIs], serotonin-norepinephrine reuptake inhibitors [SNRIs]), particularly when used in combination with other serotonergic agents (eg, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, buspirone, St. John's wort, tryptophan) or agents that impair metabolism of serotonin (eg, MAOIs intended to treat psychiatric disorders, other MAOIs [ie, linezolid, methylene blue IV]). Monitor patients closely for signs of serotonin syndrome, such as mental status changes (eg, agitation, hallucinations, delirium, coma); autonomic instability (eg, tachycardia, labile blood pressure, diaphoresis); neuromuscular changes (eg, tremor, rigidity, myoclonus); GI symptoms (eg, nausea, vomiting, diarrhea); and/or seizures. Discontinue treatment (and any concomitant serotonergic agent) immediately if signs/symptoms arise.

References:

1. Trintellix (vortioxetine) [prescribing information]. Deerfield, IL: Lundbeck; January 2021.
2. Hirsch M, Birnbaum RJ. Discontinuing antidepressant medications in adults. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed May 27, 2020a.
3. Shelton RC. Steps following attainment of remission: discontinuation of antidepressant therapy. Prim Care Companion J Clin Psychiatry. 2001;3(4):168-174.[PubMed 15014601]
4. Bauer M, Severus E, Köhler S, Whybrow PC, Angst J, Möller HJ; WFSBP Task Force on Treatment Guidelines for Unipolar Depressive Disorders. World Federation of Societies of Biological Psychiatry (WFSBP) guidelines for biological treatment of unipolar depressive disorders. Part 2: maintenance treatment of major depressive disorder-update 2015. World J Biol Psychiatry. 2015;16(2):76-95.[PubMed 25677972]10.3109/15622975.2014.1001786

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Adopted:	1-1-17
Revised:	9-17-21
	12-7-21
	9-6-22

Updates:

9-17-21	1. Updated initial auth from 3 months to 12 months
12-7-21	1. Corrected max dose from 10mg to 20mg.
	2. Clarification for Update on 9-17-21 – Authorization period was updated to initial approval for 3 months, and renewal approval for 12 months; previously indefinite.
9-6-22	1. Updated continuation criteria
	2. Added generic vilazodone to alternative antidepressant list

Effective Date (most recent revisions): 11-7-22

**Revisions are effective the first of the month following a 45 day notification and comment period.*

UM PROGRAM CRITERIA REVISED			
Viibryd (vilazodone)			
Program Type:	☒ Prior Authorization	☒ Quantity Limit	☒ Step Therapy
Viibryd (vilazodone)	1. Updated continuation criteria 2. Updated to MON formulation only 3. Update fail first to include trial of generic vilazodone and preferred brand product prior to authorization of brand Viibryd 4. Included modified grandfather requirements for brand use		

Prior Authorization Approval Criteria

Viibryd (vilazodone)

Generic name: Vilazodone
Brand name: Viibryd
Medispan GPI: 5812008810**** MON
Medication class: Selective Serotonin Reuptake Inhibitors
FDA-approved uses: **Major Depressive Disorder**

Usual dose range:
Major Depressive Disorder Initial: 10 to 40mg/day Maximum: 40mg/day

Duration of Authorization:
Initial: 3 months
Ongoing: 12 months

Estimated Cost: $4602.65/year AWP

Criteria for use for Major Depressive Disorder

- Submitted clinical documentation and prescription claims records must be consistent and non-contradictory to the treatment plan.
- Must be 18 years of age or older.
- Patient has failure, contraindication, or intolerance to:
    - Generic vilazodone

  -AND-
    - At least one generic SSRI
        - citalopram (Celexa)
        - escitalopram (Lexapro)
        - fluoxetine (Prozac)
        - fluvoxamine (Luvox)
        - paroxetine (Paxil)
        - sertraline (Zoloft)

  -AND-
    - At least one generic SNRI
        - desvenlafaxine (Pristiq, Khedezla)
        - duloxetine (Cymbalta)
        - venlafaxine (Effexor)
- AND-

    - At least one preferred brand antidepressant (Fetzima, Trintellix)
- In patients who have confirmed failure to generic vilazodone, and patient is currently stabilized on brand Viibryd, therapy can be authorized thru grandfathering criteria. Trial dates of generic vilazodone trial will be required for review.
- DAW1 is not allowed outside of a confirmed trial of generic vilazodone.

Criteria continuation of therapy

- Patient is tolerating and responding to medication and there continues to be a medical need for the medication.
- Updated chart notes or other clinical documentation confirming efficacy and tolerability of the requested treatment will be required for all renewal reviews. Submitted clinical documentation must be from an encounter after the start date of the current approval.
- Patient demonstrates adequate compliance as defined as an MPR >80%.

Contraindications:

- History of hypersensitivity to any of the product ingredients.
- Use of MAOIs intended to treat psychiatric disorders (concurrently or within 14 days of discontinuing vilazodone or within 14 days of discontinuing the MAOI)
- Initiation of vilazodone in a patient receiving linezolid or methylene blue IV.

Not approved if:

- Patient does not meet any of the above criteria.
- Patient has a contraindication to treatment.
- Patients under the age of 18, safety and effectiveness have not been established in pediatric patients

Special Considerations:

- No dosage adjustments are necessary in patients with renal or hepatic function impairment.
- The half-life of vortioxetine is significantly greater than 24 hours, decreasing the risk of withdrawal symptoms. Although few withdrawal symptoms due to abrupt discontinuation of vortioxetine have been described, it is recommended that patients receiving 15 or 20 mg/day be tapered to 10 mg/day for 1 week before full discontinuation. Patients with a prior history of antidepressant withdrawal symptoms or on a high dose may require a slower taper (eg, over 4 weeks). If intolerable withdrawal symptoms occur, resume the previously prescribed dose and/or decrease dose at a more gradual rate. Select patients (eg, those with a history of discontinuation syndrome) on long-term treatment (>6 months) may benefit from tapering over >3 months. Evidence supporting ideal taper rates is limited.
- Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients; consider risk prior to prescribing. Short-term studies did not show an increased risk in patients >24 years of age and showed a decreased risk in patients ≥65 years of age. Closely monitor patients for clinical worsening, suicidality, or unusual changes in behavior, particularly during the initial 1 to 2 months of therapy or during periods of dosage adjustments (increases or decreases); the patient's family or caregiver should be instructed to closely observe the patient and communicate condition with health care provider. A medication guide concerning the use of antidepressants should be dispensed with each prescription. Vilazodone is not approved for use in pediatric patients.
- The possibility of a suicide attempt is inherent in major depression and may persist until remission occurs. Worsening depression and severe abrupt suicidality that are not part of the presenting symptoms may require discontinuation or modification of drug therapy. Use caution in high-risk patients during initiation of therapy.
- Prescriptions should be written for the smallest quantity consistent with good patient care. The patient's family or caregiver should be alerted to monitor patients for the emergence of suicidality and associated behaviors such as anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, and mania; patients should be instructed to notify their health care provider if any of these symptoms or worsening depression or psychosis occur

- Potentially life-threatening serotonin syndrome has occurred with serotonergic agents (eg, selective serotonin reuptake inhibitors [SSRIs], serotonin norepinephrine reuptake inhibitors [SNRIs]), particularly when used in combination with other serotonergic agents (eg, triptans, tricyclic antidepressants [TCAs], fentanyl, lithium, tramadol, buspirone, St. John's wort, tryptophan) or agents that impair metabolism of serotonin (eg, MAOIs, including linezolid and IV methylene blue). Monitor patients closely for signs of serotonin syndrome such as mental status changes (eg, agitation, hallucinations, delirium, coma); autonomic instability (eg, tachycardia, labile blood pressure, diaphoresis); neuromuscular changes (eg, tremor, rigidity, myoclonus); GI symptoms (eg, nausea, vomiting, diarrhea); and/or seizures. Discontinue treatment (and any concomitant serotonergic agent) immediately if signs/symptoms arise.

References:

5. Viibryd (vilazodone) [prescribing information]. Irvine, CA: Allergan USA Inc; January 2020.
6. Hirsch M, Birnbaum RJ. Discontinuing antidepressant medications in adults. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed May 27, 2020a.
7. Shelton RC. Steps following attainment of remission: discontinuation of antidepressant therapy. Prim Care Companion J Clin Psychiatry. 2001;3(4):168-174.[PubMed 15014601]
8. Bauer M, Severus E, Köhler S, Whybrow PC, Angst J, Möller HJ; WFSBP Task Force on Treatment Guidelines for Unipolar Depressive Disorders. World Federation of Societies of Biological Psychiatry (WFSBP) guidelines for biological treatment of unipolar depressive disorders. Part 2: maintenance treatment of major depressive disorder-update 2015. World J Biol Psychiatry. 2015;16(2):76-95.[PubMed 25677972]10.3109/15622975.2014.1001786

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9-6-22

Updates:

9-17-21 Updated initial auth from 3 months to 12 months

9-6-22
- Updated continuation criteria
- Updated to MON formulation only
- Update fail first to include trial of generic vilazodone and preferred brand product prior to authorization of brand Viibryd
- Included modified grandfather requirements for brand use

Effective Date (most recent revisions): 11-7-22

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