esketamine (Spravato™)
COMMERCIAL POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: COMM026

Description
Esketamine (Spravato) is an intranasal N-methyl-D-aspartate (NMDA) receptor antagonist. The mechanism by which esketamine (Spravato) exerts its antidepressant effect is unknown.

Length of Authorization
- Treatment resistant depression (TRD)
  - Initial: Six months
  - Renewal: 12 months
- Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior
  - Initial: Four weeks
  - Renewal: Cannot be renewed

Quantity limits

<table>
<tr><th>Product Name</th><th>Indication</th><th>Dosage Form</th><th>Quantity Limit*</th></tr>
<tr><td rowspan="4">esketamine (Spravato)</td><td rowspan="2">Treatment resistant depression (TRD), in conjunction with an oral antidepressant</td><td>56 mg dose kit</td><td rowspan="2">Initial:
• PA #1: 24 devices per 28 days
• PA #2 (maintenance dosing): 12 devices per 28 days* for the remaining five months

Renewal: 12 devices per 28 days*</td></tr>
<tr><td>84 mg dose kit</td></tr>
<tr><td rowspan="2">Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior, in conjunction with an oral antidepressant</td><td>56 mg dose kit</td><td rowspan="2">24 devices per 28 days</td></tr>
<tr><td>84 mg dose kit</td></tr>
</table>

*Allows for 56mg or 84mg at weekly or every other week dosing.

Initial Evaluation

I. **Esketamine (Spravato)** may be considered medically necessary when the following criteria below are met:
   A. Member is between 18 and 64 years of age; **AND**
   B. Medication is prescribed by, or in consultation with, a psychiatrist; **AND**
   C. Member does **not** have a current or prior Diagnostic and Statistical Manual of Mental Disorders (DSM-5) diagnosis of:

1. Concomitant psychotic disorder; **OR**
2. Major depressive disorder (MDD) with psychosis; **OR**
3. Bipolar or related disorders (confirmed by the MINI); **OR**
4. Obsessive compulsive disorder (current episode only); **OR**
5. Intellectual disability; **OR**
6. Personality disorder; **AND**

D. The member does **not** have a contraindication to and has **not** previously failed ketamine; **AND**

E. Documentation of ongoing use of an antidepressant to be used concurrently with esketamine (Spravato); **AND**

F. A diagnosis of **Treatment Resistant Depression (TRD)** when the following are met:
   1. Diagnosis of **Major Depressive Disorder (MDD)** was made following Diagnostic and Statistical Manual of Mental Disorders (DSM-5) diagnostic criteria; **AND**
      i. Member is experiencing a persistent MDD episode, the duration of which must be greater than, or equal to, two years; **OR**
      ii. Member is experiencing recurrent MDD (an interval of at least two consecutive months between separate episodes during which criteria are not met for a major depressive episode); **AND**
   2. Documentation of baseline assessment [e.g. Montgomery-Åsberg Depression Rating Scale (MADRS), Hamilton Rating Scale for Depression (HAM-D), Nine-Item Patient Health Questionnaire (PHQ-9), Sheehan Disability Scale (SDS)]; **AND**
   3. Treatment with **ALL** of the following has been ineffective, contraindicated, or not tolerated in the treatment of the current episode:
      i. Psychotherapy in conjunction with antidepressant treatment [e.g. cognitive-behavioral therapy (CBT), interpersonal psychotherapy (IPT), problem-solving therapy (PST) etc.]; **AND**
      ii. At least four antidepressants from two or more different classes (i.e. SSRI, SNRI, TCA, MAO) at an optimized dose for at least 8 weeks; **AND**
      iii. Augmentation with an atypical antipsychotic (i.e. olanzapine, aripiprazole) or lithium; **AND**
   4. Treatment with electroconvulsive therapy (ECT) **or** repetitive transcranial magnetic stimulation (rTMS) has been ineffective, contraindicated, or not tolerated; **OR**
      i. Member has documentation of contraindication to BOTH; **OR**

G. A diagnosis of **depressive symptoms with major depressive disorder (MDD) with acute suicidal ideation or behavior** when the following are met:
   1. Member has a severe depressive episode (cannot care for self, participate in life, has persistent thoughts of hopelessness, persistent sad, anxious or "empty" mood, thoughts of suicide); **AND**
   2. Provider attests that without esketamine (Spravato), member may require an emergency department (ED) visit or an inpatient psychiatric hospitalization in the next 24-48 hours.

II. Esketamine (Spravato) is considered not medically necessary when criteria above are not met and/or when used for treatment resistant depression in members 65 years of age or older.

III. Esketamine (Spravato) is considered investigational when used for all other conditions, including but not limited to:
   A. Pain management
   B. Anesthesia

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. Initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. Documentation of improvement from baseline assessment (e.g., PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, HAM-D) by 50% or more, indicating clinical benefit for treatment resistant depression; **OR**
   A. Documentation attesting member is in remission (MADRS total score ≤12, HRSD or HAM-D score less than 10, PHQ-9 score less than 5 or SDS score of less than 6 at day 28,); **AND**
IV. Documentation of ongoing use of an oral antidepressant; **AND**
V. Provider attests that member is utilizing the least frequent dosing to maintain disease response and/or remission

Supporting Evidence

I. Clinical trials showing statistical significance in clinical outcomes had a population aged between 18-64 years of age. TRANSFORM-3 evaluated patients 65 years and older and outcomes were found to be not statistically significant. There are current ongoing clinical trials to further evaluate this population.
II. TRANSFORM-1 evaluated a similar population to pivotal trial TRANSFORM-2 but found a lack of statistical significance in clinical outcomes in patients aged 18-64 years.
III. Considering the severity and complexity of the disease state and the safety profile of esketamine (Spravato), this therapy needs to be prescribed by, or in consultation with, a psychiatrist.
IV. Patients with DSM-5 diagnosis of concomitant psychotic disorder, MDD with psychosis, bipolar or related disorders, obsessive compulsive disorder (OCD), and personality disorder were excluded from the esketamine (Spravato) landmark studies (NCT02418585 and NCT02493868) and are not currently being studied for treatment with esketamine (Spravato). The known adverse events include dissociative or perceptual changes (including distortion of time, space, and illusions) and derealization and depersonalization (61% to 75% of SPRAVATO-treated patients developed dissociative or perceptual changes based on the Clinician Administered Dissociative Symptoms Scale). There is no safety and efficacy clinical trial data to support the use of esketamine (Spravato) in this patient population. Considering the symptomology of the

disease states, known adverse events and unknown long-term safety profile, it is unknown how esketamine (Spravato) would affect this patient population.

V. There is no clinical trial data to show efficacy of esketamine (Spravato) in patients who have not responded to ketamine infusions that have been used in treatment of MDD off label. There is no clinical trial safety data to support the use of esketamine (Spravato) if ketamine has been contraindicated or not tolerated. Participants who have previously demonstrated nonresponse of depressive symptoms to ketamine were excluded from the clinical trial.

VI. Clinical trials were conducted as dual therapy in conjunction with oral antidepressants and esketamine (Spravato) is indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults and depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior.

VII. Esketamine (Spravato) is indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults. In clinical trials, TRD was defined as a DSM-5 diagnosis of major depressive disorder (MDD) [recurrent or single-episode (duration ≥2 years) without psychotic features or recurrent MDD (an interval of at least two consecutive months between separate episodes during which criteria are not met for a major depressive episode);] in patients who have not responded adequately to at least two different antidepressants of adequate dose and duration in the current depressive episode.

VIII. There are no current American Psychiatric Association (APA) guidelines specific to TRD. In the 2019 APA guidelines for treatment of depression in the general adult population, initial treatment of MDD was recommended to include a second-generation oral antidepressant and psychotherapy, either as monotherapy or in combination with each other.

- Recommended psychotherapies include:
  - Behavioral therapy
  - Cognitive-behavioral therapy (CBT) evaluates, challenges, and modifies dysfunctional thoughts that maintain depression. Behavioral strategies are also used to increase pleasant activities to treat anhedonia.
  - Interpersonal psychotherapy (IPT) is a structured and brief intervention addressing social issues that maintain depression.
  - Problem-solving therapy (PST) teaches to define personal problems, develop multiple solutions, identify the best one and implement it, then assess its effectiveness.
  - Supportive therapy
- Meta-analyses that compare the effectiveness of CBT, IPT, and PST indicate no large differences in effectiveness between these treatments.

IX. Standard practice for treatment resistant depression, supported by the American Psychiatric Association (APA), include:

- Use of monotherapy antidepressants
- Trial of more than one antidepressant
- Augmentation with additional antidepressant therapy
- Augmentation with other therapies including antipsychotics or lithium.

X. The National Institute for Health and Care Excellence (NICE) guideline for treatment of depression defines treatment resistant depression (TRD) as ‘people with major depressive

disorder who fail to respond to two different oral antidepressants'. Within the recommended treatment pathway, treatment options for TRD include:

- Oral antidepressants
- Augmentation with lithium or an antipsychotic treatment, or combined with another oral antidepressant
- Electroconvulsive therapy (ECT)

XI. Electroconvulsive therapy (ECT) has the highest rates of response and remission of any form of antidepressant treatment, with 70%–90% of those treated showing improvement. According to APA, ECT should be considered for patients with severe major depressive disorder that is not responsive to psychotherapeutic and/or pharmacological interventions, particularly those with significant functional impairment who have not responded to numerous medication trials. Contraindications to ECT according to FDA labeling includes:

- Severe and unstable cardiovascular conditions (e.g., recent myocardial infarction, unstable angina, congestive heart failure, critical aortic stenosis, uncontrolled hypertension/hypotension)
- Cerebrovascular conditions (e.g., aneurysm, arteriovenous malformation)
- Increased intracranial pressure
- Space-occupying cerebral lesions (e.g., tumors)
- Recent hemorrhagic or ischemic stroke
- Severe and unstable pulmonary conditions (e.g., chronic obstructive pulmonary disease, asthma, pneumonia)

XII. Transcranial magnetic stimulation (TMS) uses a specifically designed magnetic coil that is placed in contact with the head to generate rapidly alternating magnetic-resonance imaging-strength magnetic fields and produce electrical stimulation of superficial cortical neurons. Based on the results of a multisite randomized sham-controlled clinical trial of high-frequency TMS over the left dorsolateral prefrontal cortex, TMS was cleared by the FDA in 2008 for use in individuals with major depressive disorder who have not had a satisfactory response to at least one antidepressant trial in the current episode of illness. Clinical guidelines recommend reserving use of rTMS to patients who have failed at least three antidepressant therapies. Contraindications to rTMS according to FDA labeling includes metallic objects and implanted stimulator devices in or near the head.

XIII. Brain stimulation therapies, including ECT and rTMS, require multiple sessions per week for up to 6-12 weeks to be effective. Ability to coordinate work and childcare schedules, as well as access to care should be taken into consideration when determining if these therapies are appropriate for a patient.

XIV. For the treatment of depressive symptoms with major depressive disorder (MDD) with acute suicidal ideation or behavior, esketamine (Spravato) was studied in 456 patients in two phase III, double-blind, randomized, multicenter studies (ASPIRE I and ASPIRE II). Esketamine was compared to placebo with standard-of-care (SOC).

- The first dose of study drug was administered in an emergency department or in an inpatient psychiatric unit. Patients were to remain hospitalized for a recommended 5 days (14 days in 7 countries in European Union based on health authority request during the clinical trial approval). Shorter or longer periods of hospitalization were permitted, if clinically necessary, per local standard practice.

- The primary outcome: Change in the Montgomery-Asberg Depression Rating Scale (MADRS) total score from baseline (day 1, pre-dose) to 24 hours post–first dose
    - ASPIRE I: esketamine + SOC (mean [SD]: –16.4 [11.95]) and placebo + SOC (–12.8 [10.73]), with significantly greater improvement with esketamine (least-squares mean difference [SE]: –3.8 [1.39]; 95% CI, −6.56 to −1.09; 2-sided P = 0.006)
    - ASPIRE II: esketamine + SOC (mean [SD]: –15.7 [11.56]) and the placebo + SOC (–12.4 [10.43]), with significantly greater improvement in depressive symptoms with esketamine ([SE]: –3.9 [1.39], 95% CI: -6.60, -1.11; 2-sided p=0.006).
- The secondary: Change in the Clinical Global Impression - Severity of Suicidality - Revised (CGI-SS-R) score from baseline to 24 hours after the first dose
    - ASPIRE I and ASPIRE II: Both treatment groups demonstrated improvements in severity of suicidality scores; however, the treatment difference was not significant (P=0.379)
    - The efficacy of esketamine (Spravato) regarding suicidality has not been established in the clinical trial.

XV. Suicidal ideation is defined as thoughts of serving as the agent of one's own death and may vary in seriousness depending on the specificity of suicide plans and the degree of suicidal intent.

- Suicidal intent is the subjective expectation and desire for a self-destructive act to end in death.
- Lethality of suicidal behavior is the objective danger to life associated with a suicide method or action. Lethality is distinct from and may not always coincide with an individual's expectation of what is medically dangerous.

XVI. Symptoms for MDD, according to Anxiety and Depression Association of America (ADAA), are persistent sad, anxious or "empty" mood, feelings of hopelessness, pessimism, feelings of guilt, worthlessness, helplessness, loss of interest or pleasure in hobbies and activities, including sex, decreased energy, fatigue, feeling "slowed down", difficulty concentrating, remembering, making decisions, insomnia, early-morning awakening, or oversleeping, low appetite and weight loss or overeating and weight gain, thoughts of death or suicide, suicide attempts, restlessness, irritability, and persistent physical symptoms that do not respond to treatment, such as headaches, digestive disorders and pain for which no other cause can be diagnosed.

XVII. In ASPIRE I and ASPIRE II clinical trial the safety and efficacy of esketamine (Spravato) has been evaluated in the treatment of patients for whom acute psychiatric hospitalization (within 24 to 48 hours) is clinically warranted due to their imminent risk of suicide.

XVIII. The MADRS is a clinician-rated scale designed to measure depression severity and to detect changes due to antidepressant treatment. The scale consists of 10 items (to evaluates apparent sadness, reported sadness, inner tension, sleep, appetite, concentration, lassitude, inability to feel [interest level], pessimistic thoughts, and suicidal thoughts), each of which is scored from 0 (item not present or normal) to 6 (severe or continuous presence of the symptoms), summed for a total possible score range of 0-60. Higher scores represent a more severe condition. Negative change in score indicates improvement. MADRS measures severity of depression in individuals 18 years and older. Each item is rated on a 7-point scale. The scale is an adaptation of the Hamilton Depression Rating Scale and has a greater sensitivity to change over time. The scale can be completed in 20 to 30 minutes.

XIX. The Patient Health Questionnaire (PHQ) is a self-report measure designed to screen depressive symptoms. It takes one to five minutes to complete and roughly the same amount of time for a clinician to review the responses. The PHQ-9 is available in multiple languages. The diagnostic validity of the PHQ has recently been established in 2 studies involving 3,000 patients in 8 primary care clinics and 3,000 patients in 7 obstetrics-gynecology clinics. At 9 items, the PHQ depression scale (which we call the PHQ-9) is half the length of many other depression measures, has comparable sensitivity and specificity, and consists of the actual 9 criteria upon which the diagnosis of DSM-IV depressive disorders is based.

XX. The Hamilton Rating Scale for Depression, abbreviated HDRS, HRSD, or HAM-D, measures depression in individuals before, during, and after treatment. The scale is administered by a health care professional and contains 21 items, but is scored based on the first 17 items, which are measured either on 5-point or 3-point scales. It takes 15 to 20 minutes to complete and score. Results of a meta-analysis over a period of 49 years suggest that HRSD provides a reliable assessment of depression.

XXI. The SDS is a brief, 5-item self-report tool that assesses functional impairment in work/school, social life, and family life. Total score ranges from 0-30 (0 unimpaired, 30 highly impaired) and segments [work/school (0-10), social life (0-10), family life/home responsibilities (0-10] get scored. Scores of ≥5 on any of the 3 scales, with high scores associated with significant functional impairment, and sensitivity is 83% and specificity 69%.

XXII. Remission for MADRS is defined with a total score ≤12, HRSD or HAM-D score less than 10, PHQ-9 score less than 5 or SDS score of less than 6 at day 28.

XXIII. Data from SUSTAIN-2, a phase 3, open-label, long term (up to one year) clinical trial to evaluate long-term safety and efficacy of esketamine nasal spray plus oral antidepressant therapy, showed that reduction in dosing frequency from weekly to every-other-week regimens was achieved in 38.1% of patients. This indicates that for a considerable majority of patients, dose reduction to every-other-week regimens may not be clinically appropriate. Provider evaluation of the member's likelihood to maintain clinical stability or remission of depressive symptoms on weekly vs. every-other-week dosing can be reliably trusted with minimal risk for overutilization.

Investigational or Not Medically Necessary Uses

I. Pain management
   A. Not FDA approved. Safety and efficacy for use of esketamine (Spravato) for pain management or anesthesia has not been established.

Appendix

<table>
<tr><th></th><th>QL</th><th colspan="2">Dosing Schedule</th><th>Cumulative Spravato Doses/Devices</th></tr>
<tr><td rowspan="5">Induction Phase: Week 1 - 4</td><td rowspan="5">24 devices/28 days*</td><td rowspan="2">Week 1 (twice weekly dosing)</td><td>Day 1, dose 1</td><td>56 mg (2 devices)</td></tr>
<tr><td>Second dose</td><td>56 mg (4 devices) or 84 mg (5 devices)</td></tr>
<tr><td colspan="2">Week 2 (twice weekly dosing)</td><td>56 mg (8 devices) or 84 mg (11 devices)</td></tr>
<tr><td colspan="2">Week 3 (twice weekly dosing)</td><td>56 mg (12 devices) or 84 mg (17 devices)</td></tr>
<tr><td colspan="2">Week 4 (twice weekly dosing)</td><td>56 mg (16 devices) or 84 mg (23 devices)</td></tr>
<tr><td></td><td></td><td colspan="2">Week 5 (once a week dosing)</td><td>56 mg (2 devices) or 84 mg (3 devices)</td></tr>
</table>

Maintenance Phase: Week 5 - 8	12 devices/28 days	Week 6 (once a week dosing)	56 mg (4 devices) or 84 mg (6 devices)
		Week 7 (once a week dosing)	56 mg (6 devices) or 84 mg (9 devices)
		Week 8 (once a week dosing)	56 mg (8 devices) or 84 mg (12 devices)
Maintenance: Week 9 and after	12 devices/28 days	Week 9 - ∞ (every two weeks dosing or once weekly dosing)	56 mg (4-8 devices/28) or 84 mg (6 – 12 devices/28)

*Max allowance: 24 devices/28 days: This includes the 2 devices from the 56mg dose done on day one. Although we technically expect patients to use a maximum of 23 devices, a maximum of 24 devices in the first month would allow all weeks to pay below the max dose loaded.

I. Table 1: Quantity limits on per week level for the treatment of treatment resistant depression (TRD)

II. Table 2: Antidepressant Example (*please note list below is not comprehensive*)

Selective Serotonin Reuptake Inhibitors (SSRI)	
• Paroxetine (Paxil) • Fluvoxamine (Luvox) • Escitalopram (Lexapro)	• Sertraline (Zoloft) • Fluoxetine (Prozac) • Citalopram (Celexa)
Serotonin and Norepinephrine Reuptake Inhibitors (SNRI)	
• Duloxetine (Cymbalta) • Venlafaxine (Effexor) • Desvenlafaxine (Pristiq)	• Milnacipran (Savella) • Levomilnacipran (Fetzima)
Tricyclic antidepressant (TCA)	
• Amitriptyline (Elavil) • Clomipramine (Anafranil) • Nortriptyline (Pamelor)	
Other	
• Bupropion (Wellbutrin) • Mirtazapine (Remeron)	• Vilazodone (Viibryd) • Vortioxetine (Trintellix) • Nefazodone (Serzone)

III. Table 3: Quantity limits for the treatment of depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior

Week	**Cumulative Spravato Doses/Devices**
Week 1 (twice weekly)	84mg (6 devices)
Week 2 (twice weekly)	56mg (4 devices) or 84mg (12 devices)
Week 3 (twice weekly)	56mg (8 devices) or 84mg (18 devices)
Week 4 (twice weekly)	56mg (10 devices) or 84mg (24 devices)

IV. Table 4: Medical billing units

Stage:	**Total Units Approved:**	**Length of Approval:**
Initial	7056	6 months
Continuation/Renewal	12096	12 months

	Quantity Limit	**Dosing Schedule**		**Cumulative Spravato Doses/ Devices**	**Billing Units**
			Day 1, dose 1	56 mg (2 devices)	

Induction Phase: Week 1 - 4	24 devices/28 days*	Week 1 (twice weekly dosing)	Second dose	56 mg (4 devices) or 84 mg (5 devices)	2016 units (to allow for 56mg and 84mg)
		Week 2 (twice weekly dosing)		56 mg (8 devices) or 84 mg (11 devices)	
		Week 3 (twice weekly dosing)		56 mg (12 devices) or 84 mg (17 devices)	
		Week 4 (twice weekly dosing)		56 mg (16 devices) or 84 mg (23 devices)	
Maintenance Phase: Week 5 - 8	12 devices/28 days	Week 5 (once a week dosing)		56 mg (2 devices) or 84 mg (3 devices)	1008 units (to allow for 56mg or 84mg units)
		Week 6 (once a week dosing)		56 mg (4 devices) or 84 mg (6 devices)	
		Week 7 (once a week dosing)		56 mg (6 devices) or 84 mg (9 devices)	
		Week 8 (once a week dosing)		56 mg (8 devices) or 84 mg (12 devices)	
Maintenance: Week 9 and after	12 devices/28 days	Week 9 - ∞ (every two weeks dosing or once weekly dosing)		56 mg (4-8 devices/28) or 84 mg (6 – 12 devices/28)	1008 units (to allow for 56mg or 84mg units)
Units: 1:1 conversion (1 unit = 1mg)					

For further guidance, please reference Spravato's billing guide at: https://www.spravatohcp.com/sites/www.spravatohcp-v1.com/files/spravato_access_reimbursement_guideline.pdf?v=14878

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Policy Implementation/Update:

Action and Summary of Changes	Date
Extended initial duration approval timeframe from two months to six months	08/2023
Added medical billing unit conversion	06/2023
Updated QL table/PAC instructions, appendix tables, and references	04/2023
• Removed requirement of augmentation with an additional antidepressant • Updated renewal requirement for weekly dosing to require provider attestation that member is using least frequent dosing possible to maintain symptom control/remission • Updated quantity limit to 12 devices per month to align with allowance of weekly administration; noted quantity exceptions will not be allowed in the maintenance phase • Updated supporting evidence	05/2022

• Added new indication of depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior and appropriate criteria • Updated criteria for TRD to reflect that prior treatment failures must be associated with the current depressive episode and changed the number of prior antidepressants to four from two different classes	10/2020
• Added major depressive disorder (MDD) symptoms, including suicidal ideation in patients who are at imminent risk for suicide as an investigational indication • Added criteria: o Documentation of improvement from baseline assessment by 50% or more, indicating clinical benefit for treatment resistant depression or documentation attesting member is in remission (MADRS total score ≤12, HRSD or HAM-D score less than 10, PHQ-9 score less than 5 or SDS score of less than 6 at day 28,); o The member does not have a contraindication to and has not previously failed ketamine o Treatment has been ineffective, contraindicated, or not tolerated with psychotherapy in conjunction with antidepressant treatment [e.g. cognitive-behavioral therapy (CBT), interpersonal psychotherapy (IPT), problem-solving therapy (PST) etc.] and ECT (Electroconvulsive therapy) or repetitive transcranial magnetic stimulation (rTMS) unless all are contraindicated has been ineffective, contraindicated, or not tolerated o Diagnoses of major depressive disorder (MDD) was made following Diagnostic and Statistical Manual of Mental Disorders (DSM-5) diagnostic criteria and member is experiencing a persistent MDD episode (duration greater than or equal to two years) or member is experiencing recurrent MDD (an interval of at least two consecutive months between separate episodes during which criteria are not met for a major depressive episode) o Member doesn't have a current or prior Diagnostic and Statistical Manual of Mental Disorders (DSM-5) diagnosis of concomitant psychotic disorder or major depressive disorder (MDD) with psychosis or bipolar or related disorders (confirmed by the MINI) or obsessive-compulsive disorder (current episode only) or intellectual disability or personality disorder o Medication is prescribed by, or in consultation with a psychiatrist • Updated quantity limit to better align with dosing regimen	03/2020
Policy effective	05/2019
Policy created	03/2019