CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines
Medical Benefit Drugs

Spravato® (esketamine)

Effective: February 1, 2025

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
☒ CarePartners of Connecticut Medicare Advantage PPO plans, Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Over sixteen million patients in the United States are diagnosed with major depression, with 30–40% of these patients failing to respond to multiple first line antidepressant medications and/or psychotherapy.

Spravato nasal spray is indicated for treatment-resistant depression (TRD) in adults and, in conjunction with an oral antidepressant, for the treatment of depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior.

Spravato is a Non-competitive N-methyl-D-aspartate (NMDA) receptor antagonist. Spravato must be administered under the direct supervision of a healthcare provider. A treatment session consists of nasal administration of Spravato and post-administration observation under supervision. Spravato is for nasal use only. The nasal spray device delivers a total of 28 mg of esketamine. To prevent loss of medication, do not prime the device before use. Use 2 devices (for a 56 mg dose) or 3 devices (for an 84 mg dose), with a 5-minute rest between use of each device.

Spravato approval was based on 2 identical phase 3 trials (ASPIRE I and II) that compared the efficacy and safety of esketamine, an N-methyl-D-aspartate (NMDA) receptor antagonist, to placebo in 449 adults with moderate to severe MDD who had active suicidal ideation and intent. Patients were randomized to receive esketamine nasal spray 84mg twice weekly for 4 weeks or placebo in addition to standard of care (initial hospitalization and a newly initiated and/or optimized antidepressant regimen). The primary end point was the change from baseline in Montgomery-Asberg Depression Rating Scale (MADRS) total score 24 hours after the first dose.

Results from both studies showed that esketamine nasal spray plus standard of care was found to be statistically superior on the primary end point compared with placebo plus standard of care (mean difference in MADRS total score: 3.8 points in ASPIRE I and 3.9 points in ASPIRE II). In both studies, the treatment difference between esketamine nasal spray and placebo was observed as early as 4 hours with continued improvement for both groups through day 25; the difference between both groups generally remained but did not appear to increase over time.

Additionally, 41% and 43% of patients treated with esketamine nasal spray plus standard of care achieved clinical remission of depression (minimal or no symptoms) in ASPIRE I and II, respectively, compared with 34% and 27% for placebo plus standard of care by the end of the double-blind period, respectively.

Spravato is available exclusively through a Risk Evaluation and Mitigation Strategy (REMS) program, including administration under the direct supervision of a healthcare provider and post administration observation for 2 hours due to the risk of sedation and dissociation.

Food and Drug Administration (FDA) Approved Indications:

Spravato (esketamine) is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for the treatment of:

- Treatment-resistant depression (TRD) in adults
  Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Spravato when **ALL** of the following criteria are met:

Treatment-Resistant Depression

Initial Authorization Criteria:

1. Documented diagnosis of treatment-resistant depression

AND

2. Documentation Spravato will be used in conjunction with an oral antidepressant

AND

3. The Member is 18 years of age or older

AND

4. The prescriber is a mental health specialist (e.g., psychiatrist, nurse practitioner prescriber with a specialty in behavioral health, or a psychiatric nurse mental health clinical specialist)

Reauthorization Criteria:

1. Documented diagnosis of treatment-resistant depression

AND

2. Documentation Spravato will be used in conjunction with an oral antidepressant

AND

3. The Member is 18 years of age or older

AND

4. The prescriber is a mental health specialist (e.g., psychiatrist, nurse practitioner prescriber with a specialty in behavioral health, or a psychiatric nurse mental health clinical specialist)

AND

5. There is documented improvement or sustained improvement from baseline in depressive symptoms since initiating Spravato treatment.

Major Depressive Disorder with acute suicidal ideation or behavior

1. Documented diagnosis of severe major depressive disorder

AND

2. Documentation of current suicidal ideation

AND

3. Documentation Spravato will be used in conjunction with an oral antidepressant

AND

4. The Member is 18 years of age or older

AND

5. The prescriber is a mental health specialist (e.g., psychiatrist, nurse practitioner prescriber with a specialty in behavioral health, or a psychiatric nurse mental health clinical specialist)

Limitations

- Initial approval of Spravato for Treatment Resistant Depression (TRD) will be authorized for 3 (three) months. Reauthorization of Spravato will be provided in 12-month intervals.
- Approval of Spravato for the management of depressive symptoms associated with acute suicidal ideation or behavior will be provided in 4-month intervals.
- Members new to the plan stable on Spravato should be reviewed against Reauthorization Criteria.
- Any indications other than FDA-approved indications are considered experimental or investigational and will not be approved by the Plan.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
S0013	Esketamine, nasal spray, 1 mg – Does not include service
G2082	Drug + service for up to 56mg: Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified healthcare provider and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation.
G2083	Drug + service for doses greater than 56mg (84mg): Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified healthcare provider and provision of greater than 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation.

References:

1. Spravato (esketamine). Titusville, NJ: Janssen Pharmaceuticals, Inc.; October 2023.
2. Practice Guideline for the Treatment of Patients with Major Depressive Disorder. American Psychiatric Association (2010). Accessed October 2024. https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf.

Approval And Revision History

May 17, 2023: Reviewed by the Medical Policy Approval Committee (MPAC).

June 13, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T).

Subsequent endorsement date(s) and changes made:

- Originally approved September 13, 2022, by P&T and September 21, 2022 by MPAC committees effective January 1, 2023.
- Administrative update: April 2023 added Medical Benefit Drugs to title and CPCT logo update.
- May 17, 2023: Annual review, no change, effective July 1, 2023.
- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- November 12, 2024: Minor wording changes. Removed “Documentation the Member will receive Spravato treatment with monitoring at a healthcare facility certified by the Spravato REMS program”. Added provider specialty requirements. Clarified duration of approval and review process for Members new to the plan stable on the medication (eff 2/1/2025).
- December 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 2/1/25).

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.