Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Spravato® (esketamine)

Effective: April 8, 2025

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

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

Food and Drug Administration (FDA) Approved Indications:

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

- Treatment-resistant depression in adults
- Depressive symptoms in adults with major depressive disorder with acute suicidal ideation or behavior.

Spravato is only available through a Risk Evaluation Mitigation Strategies program. Spravato must be administered under direct supervision of a healthcare provider. Spravato is a Schedule III controlled substance.

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. The Member is 18 years of age or older

AND

2. The Member has a confirmed diagnosis of severe major depressive disorder (single or recurrent episode), documented by standardized rating scales that reliably measure depressive symptoms (e.g., Beck Depression Scale [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS], or Quick Inventory of Depressive Symptomatology [QIDS, also known as QIDS-SR-16]).

AND

3. The Member must meet both of the following:
   - A. The Member has experienced inadequate response during the current depressive episode with at least two antidepressants from at least two different classes (different mechanisms of action) at the maximally tolerated labeled dose, each used for a minimum of at least 6 weeks. See antidepressant classes below:
     - I. Aminoketone (Wellbutrin/SR/XL [bupropion])
     - II. Monoamine oxidase inhibitors (MAOIs) (e.g., Marplan, Nardil, Parnate, phenelzine, tranylcypromine)
     - III. Noradrenaline and specific serotoninergic antidepressants (NASSAs) (e.g., amoxapine, maprotiline, mirtazapine/ODT, Oleptro ER, Remeron/Solutab, trazodone)
     - IV. Selective serotonin reuptake inhibitors (SSRIs) (e.g., Celexa, citalopram, escitalopram, fluoxetine, fluvoxamine, Lexapro, Luvox/CR, paroxetine, Paxil/CR, Pexeva, Prozac/Weekly, sertraline, Zoloft)
     - V. Serotonin-norepinephrine reuptake inhibitors (SNRIs) (e.g., Cymbalta, desvenlafaxine/ER, duloxetine, Effexor/XR, Fetzima, Irenka, Khedezla, Pristiq, venlafaxine/ER)
     - VI. Tricyclic antidepressants (TCAs) (e.g., amitriptyline, desipramine, doxepin, Elavil, imipramine, Norpramin, nortriptyline, Pamelor, Surmontil, Tofranil, trimipramine)

   AND

   - B. The Member has experienced an inadequate response with an adequate trial of augmentation therapy OR cognitive

behavioral therapy during the current depressive episode. Augmentation therapy is defined as:

I. Two antidepressants with different mechanisms of action used concomitantly
II. An antidepressant and a second-generation antipsychotic used concomitantly
III. An antidepressant and lithium used concomitantly
IV. An antidepressant and thyroid hormone used concomitantly
V. An antidepressant and buspirone used concomitantly

AND

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

Reauthorization Criteria

1. Initial authorization criteria as noted above have been met

AND

2. Documentation of improvement or sustained improvement from baseline in depressive symptoms documented by standardized rating scales is provided (e.g., Beck Depression Scale [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS], or Quick Inventory of Depressive Symptomatology [QIDS, also known as QIDS-SR-16]).

Depressive Symptoms in Adults with Major Depressive Disorder with Acute Suicidal Ideation or Behavior

1. The Member is 18 years of age and older

AND

2. The Member has a confirmed diagnosis of severe major depressive disorder (single or recurrent episode), documented by standardized rating scales that reliably measure depressive symptoms (e.g., Beck Depression Scale [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS], or Quick Inventory of Depressive Symptomatology [QIDS, also known as QIDS-SR-16]).

AND

3. 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

4. The Member has current suicidal ideation with intent defined as **at least one (1)** of the following:
    a. The Member has thoughts, even momentarily, of self-harm with at last some intent or awareness that they may die as a result, or member thinks about suicide
    b. The Member intends to act on thoughts of killing themselves

AND

5. Documentation of **one (1)** of the following:
    a. Medical records documenting current acute suicidal ideation, intent, or behavior related to depressive symptoms of major depressive disorder is provided
    b. The prescriber represents that in the absence of treatment with the requested drug within the next 24 to 48 hours, the member will require confinement in an acute care psychiatric institution.

AND

6. Documentation that Spravato will be used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline, venlafaxine).

Limitations

- Initial approval of Spravato for Treatment-Resistant Depression will be authorized for 3 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.
- The Plan does not cover Spravato for any indications other than those listed on this Medical Necessity Guidelines. Spravato is not considered medically necessary for anesthesia, pain, or migraine headaches.

Codes

The following code(s) require prior authorization:

HCPCS Codes	Description
S0013	Esketamine, nasal spray, 1 mg
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:

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Approval And Revision History

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

Subsequent endorsement date(s) and changes made:

- May 17, 2023: Reviewed by the Medical Policy Approval Committee (MPAC)
- Administrative update: April 2023 added Medical Benefit Drugs to title, updated MATogether and RITogether fax numbers to 617-673-0939
- May 17, 2023: No changes (effective 7/1/23)
- August 8, 2023: Added the following Limitation “Members new to the Plan stable on Spravato should be reviewed against Reauthorization Criteria.” Administrative update to Codes section to align with consolidated reimbursement of HCPCS codes across Commercial business lines (effective 11/1/23).
- August 13, 2024: No changes
- April 8, 2025: Updated criteria to align with expanded indication on Spravato for treatment resistant depression in adults as monotherapy or in conjunction with an oral antidepressant by removing the criteria requiring use in conjunction with an antidepressant.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is 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.