Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Spravato® (esketamine)

Effective: August 11, 2026

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

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 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

Food and Drug Administration (FDA) Approved Indications:

Spravato (esketamine) nasal spray 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.

Spravato is only available through a REMS (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:

Initial Criteria for Treatment-Resistant Depression

1. The member is 18 years of age and older

AND

2. Documented diagnosis of Major Depressive Disorder

AND

3. Documentation that in the current depressive episode member had not responded adequately to at least two antidepressants (each from a different pharmacologic class) at an adequate therapeutic dose used for at least 6 weeks

AND

4. Documentation that member had inadequate response to at least **ONE or contraindication to ALL** of these antidepressant augmentation strategies
    a) Second-generation antipsychotic
    b) Lithium
    c) A second antidepressant from a different class
    d) Thyroid hormone

AND

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

AND

6. Attestation from the provider that the Member does not have a current or recent history of moderate or severe substance or alcohol use disorder

Reauthorization Criteria for Treatment-Resistant Depression (TRD)

1. Documentation of improvement or sustained improvement from baseline in depressive symptoms documented by standardized rating scales is provided

Criteria for 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. Documented diagnosis of Major Depressive Disorder

AND

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

AND

4. Documentation that Spravato will be used concomitantly with an oral antidepressant (e.g., buspirone, duloxetine, escitalopram, sertraline, or venlafaxine). Oral antidepressant therapy can be newly initiated or an optimized oral antidepressant.

AND

5. Medical records documenting current acute suicidal ideation, intent, or behavior related to depressive symptoms or major depressive disorder

Limitations

- Initial approval for Treatment-Resistant Depression is limited to 12 weeks (3 months). Reauthorization for continuation of treatment is limited to 12 months.
- Approval for management of depressive symptoms with acute suicidal ideation or behavior is limited to 4 weeks.
- 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.
- Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception but will be considered on an individual basis for prior authorization.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0013	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:

1. Food and Drug Administration (FDA). Drugs@FDA. URL: accessdata.fda.gov/scripts/cder/drugsatfda. Available from Internet. Accessed 2019a March 1.
2. Food and Drug Administration. FDA approves new nasal spray medication for treatment-resistant depression; available only at a certified doctor's office or clinic. 2019c March. URL: fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632761.htm. Available from Internet. Accessed 2019 April 1.
3. Food and Drug Administration. FDA drug safety communication: suicidality in children and adolescents being treated with

antidepressant medications. 2019e. URL: fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm161679. htm. Available from Internet. Accessed 2019 March 10.
4. Gadad BS, Jha MK, Czysz A et al. Peripheral biomarkers of major depression and antidepressant treatment response: Current knowledge and future outlooks. J Affect Disord. 2018; 233:3-14.
5. Gartlehner G, Gaynes BN, Amick HR et al. Comparative benefits and harms of antidepressant, psychological, complementary, and exercise treatments for major depression: an evidence report for a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2016; 164(5):331-41.
6. Gautam S, Jain A, Gautam M et al. Clinical practice guidelines for the management of depression. Indian J Psychiatry. 2017; 59(Suppl 1):S34-S50.
7. Gelenberg AJ, Freeman MP, Markowitz JC et al. Practice guideline for the treatment of patients with major depressive disorder, 3rd edition. 2010 October. URL: psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf. Available from Internet. Accessed 2019 January 25.
8. Gonda X, Petschner P, Eszlari N et al. Genetic variants in major depressive disorder: From pathophysiology to therapy. Pharmacol Ther. 2019; 194:22-43.
9. Haigh EAP, Bogucki OE, Sigmon ST et al. Depression among older adults: A 20-year update on five common myths and misconceptions. Am J Geriatr Psychiatry. 2018; 26(1):107-22.
10. Henssler J, Bschor T, Baethge C. Combining antidepressants in acute treatment of depression: a meta-analysis of 38 studies including 4511 patients. Can J Psychiatry. 2016; 61(1):29-43.
11. Henssler J, Kurschus M, Franklin J et al. Long-term acute-phase treatment with antidepressants, 8 weeks and beyond: a systematic review and meta-analysis of randomized, placebo-controlled trials. J Clin Psychiatry. 2018; 79(1).
12. Ijaz S, Davies P, Williams CJ et al. Psychological therapies for treatment-resistant depression in adults. Cochrane Database Syst Rev. 2018; 5:CD010558.
13. Institute for Clinical and Economic Review (ICER). Overview of the ICER value assessment framework and update for 2017-2019. 2017. URL: http://icer-review.org/wp- content/uploads/2017/06/ICER-value-assessment-framework-Updated-050818.pdf. Available from Internet. Accessed 2019 April 1.
14. Singh JB, Fedgchin M, Daly E et al. Intravenous esketamine in adult treatment-resistant depression: a double-blind, double-randomization, placebo-controlled study. Biol Psychiatry. 2016; 80(6):424-31.
15. Spravato (esketamine) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; July 2024.

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)

August 13, 2024: 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, updated MATogether and RITogether fax numbers to 617-673-0939
- May 17, 2023: Annual review, no change, effective July 1, 2023
- August 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024
- August 2024: Annual review, no change, effective August 13, 2024
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template
- August 12, 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.
- January 2026: Administrative update: Added J Code J0013 and removed S0013 from guideline effective 1/1/26.
- August 11, 2026: No changes.

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.