Mass General Brigham
Health Plan

Spravato (esketamine)
Effective 01/01/2026

Plan	☐ MassHealth UPPL ☒ Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
Spravato (esketamine) (S-enantiomer of racemic ketamine) is a noncompetitive N-methyl-D-aspartate (NMDA) receptor antagonist indicated for the treatment of:

- Treatment-resistant depression (TRD) in adults, as monotherapy or in conjunction with an oral antidepressant
- Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior in conjunction with an oral antidepressant

Limitations:
The effectiveness of Spravato in preventing suicide or in reducing suicidal ideation or behavior has not been demonstrated. Use of Spravato does not preclude the need for hospitalization if clinically warranted, even if the patient experiences improvement after an initial dose of Spravato. Additionally, Spravato is not approved as an anesthetic agent. The safety and effectiveness of Spravato as an anesthetic agent have not been established.

Spravato does have a boxed warning concerning the risk of sedation, dissociation, respiratory depression, abuse and misuse, and suicidal thoughts and behaviors. Spravato is only available through a Risk Evaluation and Mitigation Strategy (REMS) program. Spravato must be administered under the direct supervision of a healthcare provider and patients must be monitored by a healthcare provider for at least two hours after administering the drug.

Coverage Guidelines
Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance program
OR
Authorization may be granted when all of the following criteria are met:

Major Depressive Disorder (MDD) with Acute Suicidal Ideation or Behavior

1. Member 18 years of age or older
2. Member is diagnosed with major depressive disorder (MDD) with suicidal ideation or behavior

3. Prescriber is a mental health specialist (e.g. psychiatrist or nurse prescriber with a specialty in behavioral health) or consultation notes from a mental health specialist are provided.
4. Prescriber attests that Spravato will be administered under the direct supervision of a healthcare provider.
5. Member will be using Spravato in combination with an oral antidepressant

Treatment-Resistant Depression (TRD)

1. Member is 18 years of age or older
2. Member is diagnosed with treatment-resistant depression (TRD)
3. Prescriber is a mental health specialist (e.g. psychiatrist or nurse prescriber with a specialty in behavioral health) or consultation notes from a mental health specialist are provided.
4. Prescriber attests that Spravato will be administered under the direct supervision of a healthcare provider.
5. Member has had an inadequate response or adverse reaction to one SSRI and one other antidepressant that is not an SSRI
6. Member meets ONE of the following:
    a. Member has had an inadequate response or adverse reaction to one of the following antidepressant augmentation strategies:
        i. Second-generation antipsychotic
        ii. Lithium
        iii. A second antidepressant from a different class
        iv. Thyroid hormone
    b. The member has a contraindication to all augmentation strategies

<u>Continuation of Therapy</u>

Requests for reauthorization criteria will be approved when the following diagnosis-specific criteria are met:

1. **TRD:** Documentation is provided demonstrating improvement in the member's depressive symptoms
2. **MDD with Acute Suicidal Ideation or Behavior:** Member meets initial criteria

Limitations

1. For a diagnosis of TRD:
    - Initial approvals will be granted for 3 months
    - Reauthorizations will be granted for 12 months
2. For treatment of MDD with acute suicidal ideation or behavior, a 1-month authorization will be granted *

* The recommended dosage of SPRAVATO for the treatment of depressive symptoms in adults with MDD with acute suicidal ideation or behavior is 84 mg twice per week for 4 weeks. Dosage may be reduced to 56 mg twice per week based on tolerability. After 4 weeks of treatment with SPRAVATO, evidence of therapeutic benefit should be evaluated to determine need for continued treatment. The use of SPRAVATO, in conjunction with an oral antidepressant, beyond 4 weeks has not been systematically evaluated in the treatment of depressive symptoms in patients with MDD with acute suicidal ideation or behavior.

References

1. Daly EJ, Singh JB, Fedgchin M, et al. Efficacy and Safety of Intranasal Esketamine Adjunctive to Oral Antidepressant Therapy in Treatment-Resistant Depression: A Randomized Clinical Trial. JAMA Psychiatry 2018; 75:139
2. Hasin DS, Sarvet AL, Meyers JL, et al. Epidemiology of Adult DSM-5 Major Depressive Disorder and Its Specifiers in the United States. JAMA Psychiatry 2018; 75:336
3. Ijaz S, Davies P, Williams CJ, et al. Psychological therapies for treatment-resistant depression in adults. Cochrane Database Syst Rev 2018; 5:CD010558
4. McLachlan G. Treatment resistant depression: what are the options? BMJ 2018; 363:k5354
5. Nelson JC, Baumann P, Delucchi K, et al. A systematic review and meta-analysis of lithium augmentation of tricyclic and second generation antidepressants in major depression. J Affect Disord 2014; 168:269
6. Papadimitropoulou K, Vossen C, Karabis A, et al. Comparative efficacy and tolerability of pharmacological and somatic interventions in adult patients with treatment-resistant depression: a systematic review and network meta-analysis. Curr Med Res Opin 2017; 33:701
7. Papakostas GI, Fava M, Thase ME. Treatment of SSRI-resistant depression: a meta-analysis comparing within- versus across-class switches. Biol Psychiatry 2008; 63:699
8. Spravato (esketamine) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc; January 2025.

Review History

11/20/2019 – Reviewed at P&T

09/16/2020 – Reviewed and updated Sept P&T Mtg; added MDD indication with suicidal ideation or behavior plus limitations; added started and stabilized statement for treatment resistant depression; references updated. Effective 12/01/2020.

11/16/2022 – Reviewed for Nov P&T. Separated out MH vs Comm/Exch. No clinical changes.

02/12/2025 – Reviewed and updated for February P&T. Updated criteria for TRD to no longer require concomitant use with an antidepressant to reflect update package labeling. Updated policy to indicate that Spravato is now a dual benefit drug. Effective 05/01/2025.

10/08/2025 – Reviewed at October P&T. Updated policy to indicate that it no longer applies to the medical benefit. Effective 01/01/2026.