Mass General Brigham
Health Plan

Spravato (esketamine)
Effective 12/01/2020

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview

Esketamine (S-enantiomer of racemic ketamine) is a nonselective, noncompetitive N-methyl-D-aspartate (NMDA) receptor antagonist. Esketamine is FDA approved for the treatment-resistant depression (TRD) or major depressive disorder (MDD) with acute suicidal ideation or behavior in conjunction with an oral antidepressant in adults. The mechanism by which it exerts its antidepressant effect is unknown . Spravato is only available through a restricted program: SPRAVATO REMS and must be administered under the direct supervision of a healthcare provider.

Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with Spravato for the treatment of treatment-resistant depression, excluding when the product is obtained as samples or via manufacturer's patient assistance program

OR

Authorization may be granted for members who meet all the following criteria and documentation has been submitted:

1. The member is at least 18 years of age
2. The member is diagnosed with treatment-resistant depression (TRD) OR major depressive disorder (MDD) with suicidal ideation or behavior
3. The 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. The prescriber attests that Spravato will be administered under the direct supervision of a healthcare provider.
5. The member will be using Spravato in combination with an oral antidepressant
6. The member has had an inadequate response or adverse reaction to one SSRI and one other antidepressant that is not an SSRI
7. The member has had an inadequate response or adverse reaction to one of the following antidepressant augmentation strategies:
    a. Second-generation antipsychotic

b. Lithium
c. A second antidepressant from a different class
d. Thyroid hormone
e. OR

8. The member has a contraindication to all augmentation strategies

Continuation of Therapy

For TRD: Reauthorizations may be granted when documentation of improvement in member's depressive symptoms has been submitted.
For MDD with acute suicidal ideation or behavior: Reauthorizations may be granted if 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. Spravato (esketamine) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc; August 2020
2. 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
3. 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
4. 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
5. McLachlan G. Treatment resistant depression: what are the options? BMJ 2018; 363:k5354
6. Ijaz S, Davies P, Williams CJ, et al. Psychological therapies for treatment-resistant depression in adults. Cochrane Database Syst Rev 2018; 5:CD010558
7. 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
8. 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

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.