

**Spravato (esketamine)
Effective January 1, 2020**

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|------------------------------|---|---------------------|---|
| Plan | <input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange | Program Type | <input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy |
| Benefit | <input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX) | | |
| Specialty Limitations | N/A | | |
| Contact Information | Specialty Medications | | |
| | All Plans | Phone: 866-814-5506 | Fax: 866-249-6155 |
| | Non-Specialty Medications | | |
| | MassHealth | Phone: 877-433-7643 | Fax: 866-255-7569 |
| | Commercial | Phone: 800-294-5979 | Fax: 888-836-0730 |
| | Exchange | Phone: 855-582-2022 | Fax: 855-245-2134 |
| | Medical Specialty Medications (NLX) | | |
| | All Plans | Phone: 844-345-2803 | Fax: 844-851-0882 |
| Exceptions | N/A | | |

Overview

Esketamine (S-enantiomer of racemic ketamine) is a nonselective, noncompetitive N-methyl-D-aspartate (NMDA) receptor antagonist FDA approved for treatment of treatment-resistant depression (TRD) in adults, in conjunction with an oral antidepressant. 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

1. Authorization may be granted for members who are currently receiving treatment with Spravato, excluding when the product is obtained as samples or via manufacturer’s patient assistance program
OR
2. Authorization may be granted for members who meet all the following criteria and documentation has been submitted:
 - a. The member is at least 18 years of age
 - b. The member is diagnosed with treatment-resistant severe Major Depressive Disorder (MDD)
 - c. 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.
 - d. The prescriber attests that Spravato will be administered under the direct supervision of a healthcare provider.
 - e. The member will be using Spravato in combination with an oral antidepressant
 - f. The member has had an inadequate response or adverse reaction to one SSRI and one other antidepressant that is not an SSRI



- g. The member has had an inadequate response or adverse reaction to one of the following antidepressant augmentation strategies:
 - Second-generation antipsychotic
 - Lithium
 - A second antidepressant from a different class
 - Thyroid hormone

OR

- h. The member has a contraindication to all augmentation strategies

Continuation of Therapy

Reauthorizations may be granted when documentation of improvement in member's depressive symptoms has been submitted.

Limitations

1. Initial approvals will be granted for 3 months
2. Reauthorizations will be granted for 12 months

References

1. Spravato (esketamine) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc; May 2019
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

11/20/19 – Reviewed at P&T

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