Pharmacy Medical Necessity Guidelines: Spravato™ (esketamine) Nasal Spray

Effective: October 19, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	MED	Department to Review	PRECERT /MM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
MM: 888.415.9055
PRECERT: 617.972.9409

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Spravato™ (esketamine) nasal spray is indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults and depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior

Spravato™ (esketamine) is only available through a restricted program called the SPRAVATO REMS. This drug must be administered under direct supervision of a healthcare provider. Spravato™ (esketamine) is a Schedule III controlled substance.

COVERAGE GUIDELINES

The plan may authorize coverage of Spravato™ (esketamine) when **ALL** of the following criteria are met:

Initial Criteria

1. The member is 18 years of age and older

2. Documented diagnosis of severe Major Depressive Disorder

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

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

5. Documentation that Spravato™ (esketamine) will be used concomitantly with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline, venlafaxine)

6. The prescriber is a mental health specialist (e.g. psychiatrist, nurse prescriber with a specialty in behavioral health)

7. 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

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

LIMITATIONS

- Approvals are limited to 12 weeks (3 months). Reauthorization for continuation of treatment is limited to 12 months.
- Tufts Health Plan does not cover Spravato™ (esketamine) for any indications other than those listed on this Medical Necessity Guidelines. Spravato™ (esketamine) is not considered medically necessary for anesthesia, pain, or migraine headaches.

CODES

The following HCPCS/CPT code(s) are:

Code	Description
S0013	Esketamine, nasal spray, 1 mg

REFERENCES

1. Food and Drug Administration (FDA). Drugs@FDA. URL: http://www.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: https://www.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: https://www.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: https://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 prescribing information. Titusville, NJ: Janssen Pharmaceuticals, Inc.; July 2020.

APPROVAL HISTORY

August 13, 2019: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. January 14, 2020: Administrative update, removed Tufts Health Together and Tufts Health RITogether from the Medical Necessity Guideline.
2. October 13, 2020: Added supplemental indication to overview, to include Spravato's indication including depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior. Moved Reauthorization criteria is moved up into the body for the criteria and removed from the limitations section. No change to existing criteria.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be 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 the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy 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 Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services