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

Effective: November 16, 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 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® (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:

1. The member is 18 years of age and older

AND

2. Documented diagnosis of severe Major Depressive Disorder

AND

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

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

AND

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

AND

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

LIMITATIONS

1. Approvals are limited to 12 weeks (3 months). Reauthorization for continuation of treatment is limited to 12 months and may be granted if there is documentation of improvement or sustained improvement from baseline in depressive symptoms documented by standardized rating scales.
2. 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.
3. 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

None

REFERENCES

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APPROVAL HISTORY

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

Subsequent endorsement date(s) and changes made:

1. January 14, 2020: Administrative update, separated Tufts Health RITogether from the Medical Necessity Guideline.
2. July 14, 2020: Administrative update, added language regarding samples to the limitations section of the MNG.
3. November 10, 2020: Administrative update, added the FDA indication for depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior to the background section of the MNG.

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