



# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Spravato Clinical Edit
<b>First Implementation Date:</b>	August 17, 2020
<b>Proposed Date:</b>	March 18, 2021
<b>Prepared for:</b>	MO HealthNet
<b>Prepared by:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** Ensure appropriate utilization and control of Spravato® (esketamine) nasal spray

**Why Issue Selected:** Spravato® (esketamine) nasal spray was FDA approved in March 2019, for treatment-resistant depression (TRD) in adults in conjunction with an oral antidepressant. In July 2020, Spravato received a second approved indication for the treatment of depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior. Sixteen million patients in the United States are diagnosed with MDD, and 30%-40% of these patients fail to respond to multiple first line antidepressant medications and/or psychotherapy. TRD is defined as MDD unresponsive to at least two antidepressants (monotherapy) of adequate dose and duration (usually at least 4 to 6 weeks) including current episode. TRD is a serious, life-threatening condition with increased rates of suicide, hospitalization, and impairment in daily functioning. Spravato is the first approved agent for depression with a novel mechanism of action (NMDA-receptor antagonist) in decades and stands out from currently available antidepressant therapies in that it can exert an antidepressant effect within 24 hours of administration. The FDA has required a REMS program due to the risk of serious adverse outcomes from sedation, dissociation, and abuse/misuse of Spravato. Under the REMS program, administration must occur in registered healthcare settings where the patient is monitored for 2 hours after administration and pharmacies, practitioners, or healthcare settings that dispense the drug are specially certified and ensure that Spravato is not dispensed directly to a patient. Due to the high cost, possible adverse events, and specific approved indications, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Spravato.

**Program-Specific Information:**

Date Range FFS 1-1-2020 to 12-31-2020			
Drug	Claims	Spend	Avg Spend per Claim
SPRAVATO 56 MG DOSE PACK	66	\$42,224.47	\$639.76
SPRAVATO 84 MG DOSE PACK	127	\$125,607.61	\$989.03

**Type of Criteria:**  Increased risk of ADE  Preferred Drug List  
 Appropriate Indications  Clinical Edit

**Data Sources:**  Only Administrative Databases  Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Spravato® (esketamine)
- Age range: All appropriate MO HealthNet participants aged 18 years or older

## Approval Criteria

- Participant is aged 18 years or older **AND**
- **For documented diagnosis of major depressive disorder with current suicidal ideation with intent:**
  - **Documentation of concurrent antidepressant therapy AND**
  - **Prescriber attests that:**
    - **An accessible treatment center certified in the Spravato Risk Evaluation and Mitigation Strategies (REMS) program has been identified AND**
    - **Dosing schedule has been reviewed with the participant AND**
    - **The participant understands and is committed to dosing schedule and requirements (e.g., office visits, transportation)**
- For treatment resistant depression:
  - Documented diagnosis of major depressive disorder **AND**
  - Diagnosis confirmed by baseline depression assessment using any validated rating scale **AND**
  - Prescribed by or in consultation with a psychiatrist, psychiatric mental health nurse practitioner (PMHNP), psychiatric physician assistant, or other specialist in the treated disease state **AND**
  - Documented therapeutic trial (duration of ≥ 6 weeks each at generally accepted doses) with inadequate response (defined as < 50% reduction in symptom severity using any validated depression rating scale) of ≥ 2 antidepressants from different classes in the current depressive episode, unless contraindicated or clinically significant adverse effects are experienced **AND**
  - Documented therapeutic trial (duration of ≥ 6 weeks) of antidepressant augmentation therapy in the current depressive episode with ≥ 1 of the following, unless contraindicated, or clinically significant adverse effects are experienced **or participant is at high risk for suicidality:**
    - Atypical antipsychotic **OR**
    - Lithium **OR**
    - Antidepressant from a different class used in the previous therapeutic trials **OR**
    - Electroconvulsive therapy **OR**
    - Transcranial Magnetic Stimulation (TMS) **AND**
  - Documentation of concurrent antidepressant therapy **AND**
  - Prescriber attests that:
    - An accessible treatment center certified in the Spravato Risk Evaluation and Mitigation Strategies (REMS) program has been identified **AND**
    - Dosing schedule has been reviewed with the participant **AND**
    - The participant understands and is committed to dosing schedule and requirements (e.g., office visits, transportation)
- Renewal Criteria:
  - Initial approval of prior authorization is 4 weeks
  - Renewal of prior authorization may be up to 6 months, with subsequent authorizations of up to 12 months, following documentation of the following:
    - All initial approval criteria continue to be met **AND**
    - Prescriber attestation of participant compliance with doses and appointments **AND**
    - Attestation or documentation of improvement in diagnosis as evidenced by improvement in the same validated rating scale used for baseline depression assessment

## Denial Criteria

- Therapy will be denied if all approval criteria are not met

*SmartPA Clinical Proposal Form*

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- Documented history of aneurysmal vascular disease (thoracic and abdominal aorta, intracranial and peripheral arterial vessels), arteriovenous malformation, or intracerebral hemorrhage in the past 2 years
- Participant is currently pregnant

## Required Documentation

Laboratory Results:  
MedWatch Form:


Progress Notes:  
Other:

X
X

## Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)  
Rule Type: CE

## Default Approval Period

4 weeks

## References

- SPRAVATO® (esketamine) nasal spray, [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; July 2020.
- IPD Analytics. New Drug Approval: Spravato (esketamine) nasal spray. March 2019.
- IPD Analytics. Rx Insights: Health Outcomes and Pharmacoeconomic Evaluation. Spravato (esketamine) Review - ICER Public Advisory Council. June 2019.
- IPD Analytics. Rx Brief: Behavioral Health. Spravato (Esketamine) Nasal Spray Receives FDA Approval for Depressive Symptoms in Adults with Major Depressive Disorder with Acute Suicidal Ideation. September 2020.
- IPD Analytics. Behavioral Health: Depression. Accessed February 12, 2021.