SmartPA Criteria Proposal

Drug/Drug Class: Spravato Clinical Edit
First Implementation Date: August 17, 2020
Revised Date: July 21, 2022
Prepared for: MO HealthNet
Prepared by: MO HealthNet/Conduent
Criteria Status: ☒ Existing 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:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Claims</th>
<th>Spend</th>
<th>Avg Spend per Claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPRAVATO 56 MG DOSE PACK</td>
<td>102</td>
<td>$63,494.48</td>
<td>$622.49</td>
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<tr>
<td>SPRAVATO 84 MG DOSE PACK</td>
<td>196</td>
<td>$222,998.00</td>
<td>$1,137.74</td>
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</tbody>
</table>

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

Data Sources: ☒ Databases + Prescriber-Supplied
☐ Only Administrative Databases

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

### Required Documentation

<table>
<thead>
<tr>
<th>Laboratory Results:</th>
<th>Progress Notes:</th>
<th>MedWatch Form:</th>
<th>Other:</th>
</tr>
</thead>
</table>

### Disposition of Edit

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

### Default Approval Period

4 weeks

### References