SmartPA Criteria Proposal

Drug/Drug Class:	Spravato® (esketamine) Clinical Edit
First Implementation Date:	TBD
Proposed Date:	March 19, 2020
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☐Revision of Existing Criteria ☒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. Major depressive disorder (MDD) is the leading cause of disability worldwide. 2016 data from the National Institute of Mental Health indicated 16.2 million adults in the US have had at least one MDD episode. Approximately 1/3 do not respond to currently available treatments. 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.

Program-Specific Information:

Date Range FFS 1-1-2019 to 12-31-2019			
Drug	**Claims**	**Spend**	**Cost per pack**
SPRAVATO 56 MG DOSE PACK	85	$65,531.45	$618.92 WAC
SPRAVATO 84 MG DOSE PACK	89	$91,548.93	$928.38 WAC

Type of Criteria:
- ☒ **Increased risk of ADE**
- ☒ **Appropriate Indications**
- ☐ **Preferred Drug List**
- ☒ **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**
- Documented diagnosis of major depressive disorder in the past 2 years **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, 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 no approval crieria are met
- 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:		Progress Notes:	X
MedWatch Form:		Other:	X

Disposition of Edit

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

Default Approval Period

4 weeks

References

- Kim MD, J. Potter PhD, A. NDA 211243 Esketamine Treatment of Treatment-Resistant Depression (TRD). https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PsychopharmacologicDrugsAdvisoryCommittee/UCM631429.pdf. Accessed 2/27/2020.
- IPD Analytics Rx Insights_FDA Advisory Committee_Esketamine_02 2019.pdf
- Spravato™ (esketamine nasal spray) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; May 2019.
- IPD Analytics. New Drug Approval: Spravato (esketamine) nasal spray. March 2019.
- IPD Analytics. Rx Insights: Spravato (esketamine) Review - ICER Public Advisory Council. May 2019.