Reference number(s)
4213-A

STANDARD MEDICARE PART B MANAGEMENT

SPRAVATO (esketamine) nasal spray

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Spravato is indicated, in conjunction with an oral antidepressant, for the treatment of:
A. Treatment-resistant depression (TRD) in adults
B. Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior

Limitations of Use:
The effectiveness of Spravato in preventing suicide or in reducing suicidal ideation or behavior has not been demonstrated. Use of Spravato does not preclude the need for hospitalization if clinically warranted, even if patients experience improvement after an initial dose of Spravato.

Spravato is not approved as an anesthetic agent. The safety and effectiveness of Spravato as an anesthetic agent have not been established.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
A. For initial requests:
   1. Pretreatment depression severity score(s) from standardized rating scale(s) that reliably measure depressive symptoms (e.g., Beck Depression Inventory [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS], etc.)
   2. Medical records documenting inadequate response with antidepressants for the current depressive episode (if applicable)
B. For continuation of therapy:
   Current depression severity score(s) from standardized rating scale(s) that reliably measure depressive symptoms (if applicable)

III. CRITERIA FOR INITIAL APPROVAL

A. **Treatment-resistant depression (TRD)/Major Depressive Disorder (MDD) with acute suicidal ideation or behavior**
Authorization of 1 month may be granted for treatment of TRD or MDD with acute suicidal ideation or behavior when all of the following criteria are met:
1. Member has a confirmed diagnosis of severe major depressive disorder (single or recurrent episode), documented by standardized rating scales that reliably measure depressive symptoms (e.g., Beck Depression Inventory [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS]).
2. The requested medication will be prescribed by or in consultation with a psychiatrist.
3. The requested drug will be administered under the direct supervision of a healthcare provider.
4. The requested drug will be used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline, venlafaxine).
5. Member meets either of the following criteria:
    i. Member has experienced an inadequate response during the current depressive episode with two antidepressants (e.g., selective serotonin reuptake inhibitor [SSRI], serotonin-norepinephrine reuptake inhibitor [SNRI], tricyclic antidepressant [TCA], bupropion, mirtazapine).
    ii. Member has current suicidal ideation with intent defined as both of the following:
        a. Member has thoughts, even momentarily, of self-harm with at least some intent or awareness that they may die as a result, or member thinks about suicide.
        b. Member intends to act on thoughts of killing themselves.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

A. Treatment-resistant depression (TRD)
Authorization for 12 months may be granted when all of the following criteria are met:
1. The member is currently receiving therapy with Spravato
2. Spravato is being used to treat treatment-resistant depression
3. The member is receiving benefit from therapy. Benefit is defined as:
    i. An improvement or sustained improvement from baseline in depressive symptoms documented by standardized rating scales that reliably measure depressive symptoms (e.g., Beck Depression Inventory [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS]).

B. Major depressive disorder (MDD) with acute suicidal ideation or behavior
1. If the member has not received 1 full month of therapy, then authorization for up to 1 month to complete a treatment course may be granted when all the following criteria are met:
    i. The member is currently receiving therapy with Spravato
    ii. Spravato is being used to treat major depressive disorder with acute suicidal ideation or behavior
    iii. The member is receiving benefit from therapy. Benefit is defined as:
        a. An improvement or sustained improvement from baseline in depressive symptoms documented by standardized rating scales that reliably measure depressive symptoms (e.g., Beck Depression Inventory [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS]).

2. If the member has completed one full month of therapy, then member must meet all initial criteria for approval. The use of Spravato beyond 4 weeks has not been systematically evaluated in the treatment of depressive symptoms in members with MDD with acute suicidal ideation or behavior.

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Spravato.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Spravato are covered.

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VII. REFERENCES

1. Spravato [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; July 2020.