Reference number(s)
2889-A

SPECIALTY GUIDELINE 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 Indication
Spravato is indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults.

Limitations of Use: 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 are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. For initial requests:
   1. Pretreatment depression severity score(s) from standardized rating scale(s) that reliably measure depressive symptoms (e.g., Beck Depression Scale [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS], etc.)
   2. Medical records documenting inadequate response with antidepressant and augmentation agents 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

III. EXCLUSION

Coverage will not be provided for members with current or recent history (i.e., within the last 6 months) of moderate or severe substance or alcohol use disorder.

IV. CRITERIA FOR INITIAL APPROVAL

Treatment-resistant depression (TRD)
Authorization of 1 month may be granted for treatment of TRD when all of the following criteria are met:

A. 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 Scale [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS]).

B. Diagnosis is verified by a psychiatrist.
C. Member is 18 years of age or older.
D. Requested drug will be administered under the direct supervision of a healthcare provider.
E. Member will be monitored by a health care provider for at least 2 hours after administration.
F. Member meets either of the following criteria:
    1. Member must meet both of the following:
        i. Member has experienced 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) from at least two different classes (different mechanisms of action) at the maximally tolerated labeled dose, each used for at least 8 weeks;
            - Aminoketone (Wellbutrin/SR/XL [bupropion])
            - Monoamine oxidase inhibitors (MAOIs) (e.g., Marplan, Nardil, Parnate, phenelzine, tranylcypromine)
            - Noradrenaline and specific serotoninergic antidepressants (NASSAs) (e.g., amoxapine, maprotiline, mirtazapine/ODT, Oleptro ER, Remeron/Solutab, trazodone)
            - Selective serotonin reuptake inhibitors (SSRIs) (e.g., Celexa, citalopram, escitalopram, fluoxetine, fluvoxamine, Lexapro, Luvox/CR, paroxetine, Paxil/CR, Pexeva, Prozac/Weekly, sertraline, Zoloft)
            - Serotonin-norepinephrine reuptake inhibitors (SNRIs) (e.g., Cymbalta, desvenlafaxine/ER, duloxetine, Effexor/XR, Fetzima, Irenka, Khedezla, Pristiq, venlafaxine/ER)
            - Tricyclic antidepressants (TCAs) (e.g., amitriptyline, desipramine, doxepin, Elavil, imipramine, Norpramin, nortriptyline, Pamelor, Surmontil, Tofranil, trimipramine)
        ii. Member has experienced an inadequate response with an adequate trial of augmentation therapy OR cognitive behavioral therapy during the current depressive episode
            - Augmentation therapy is defined as:
                - Two antidepressants with different mechanisms of action used concomitantly
                - An antidepressant and a second-generation antipsychotic used concomitantly
                - An antidepressant and lithium used concomitantly
                - An antidepressant and thyroid hormone used concomitantly
                - An antidepressant and buspirone used concomitantly
    2. Member has profound depression and persistent suicidal ideation defined as all of the following:
        i. The prescriber represents that, in the absence of the requested drug, within the next 24 to 48 hours the member will require confinement in an acute care psychiatric institution.
        ii. Member has a depressive episode so acute and so severe that the member is not able to participate in self-care (e.g., washing, eating) and is unable to participate at all in their usual daily activities (e.g., work). Member has persistent thoughts of hopelessness and helplessness as well as anhedonia.
        iii. Member has thoughts of dying and/or self-harm for at least some part of each and every day.
G. Requested drug will be used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline, venlafaxine).

V. CONTINUATION OF THERAPY

Treatment-resistant depression (TRD)
Authorization of 3 months may be granted for the continuation of treatment of TRD when there is improvement or sustained improvement from baseline in depressive symptoms documented by standardized rating scales that reliably measure depressive symptoms (e.g., Beck Depression Scale [BDI], Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS]).

VI. REFERENCES

1. Spravato [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; May 2019.