denotes change in current criteria
denotes new criteria

Spravato

SPRAVATO™ *is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults or depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior.*

Prior authorization requests for Spravato may be approved if the following criteria are met:

1) Diagnosis of treatment resistant depression (TRD) or depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior by an M.D./D.O. identified psychiatrist ~~by an identified psychiatrist;~~ **AND**
2) Prescribed by a M.D./D.O. psychiatrist; **AND**
3) The prescriber/treatment facility, pharmacy and patient are enrolled in the SPRAVATO REMS program; **AND**
4) Patient is within the age range as recommended by the FDA label; **AND**
5) Progress notes are required as documentation of the patient's diagnosis of treatment-resistant Major Depressive Disorder and must include screening to rule out Bipolar Disorder as well as all previous therapies failed; **AND**
6) The patient's baseline depression symptoms must be measured and documented using an objective clinical rating scale such as (but not limited to) the PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, or HAM-D; **AND**
7) Patient has failed to achieve a satisfactory response after attempting a minimum of THREE separate therapeutic trials* for 12 weeks each. These trials* must include antidepressants from at least two (2) different therapeutic drug classes as well as at least one trial* using augmentation therapy; **AND**
8) All medications for the above trials* must be taken compliantly for at least ~~**8 weeks**~~ 12 weeks within the past three years based on pharmacy claims data (if claims data is not available, a medication fill history report must be obtained from the dispensing pharmacy and is required to be submitted); **AND**
9) Spravato must be used in combination with an oral antidepressant; **AND**
10) Patient is not concurrently being prescribed or utilizing ketamine.

***All trials must be within an FDA approved therapeutic dose range. Agents must be prescribed at/titrated up to the maximum dose.**

Initial approvals will be for 30 days. Further approvals may be granted for 6 months after all of the continuation of therapy criteria has been met.

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CONTINUATION OF THERAPY CRITERIA (only applicable for treatment resistant depression)

1) Patient's claims history must indicate compliant (compliance being defined as having no longer than a 10-day gap between when a prescription may be refilled and actually is refilled) concurrent use of an oral antidepressant; **AND**
2) Patient must show demonstrable improvement over baseline as measured by the same scale used for the initial approval.

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Tryvio- (aprocitentan)

TRYVIO (aprocitentan) *is* an endothelin receptor antagonist indicated for the treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adult patients who are not adequately controlled on other drugs. Lowering blood pressure reduces the risk of fatal and non-fatal cardiovascular events, primarily strokes and myocardial infarctions.

CRITERIA FOR APPROVAL:

1. Patient has a diagnosis of hypertension; **AND**
2. Patient is within the age range as recommended by the FDA label; **AND**
3. Prescribed by, or in consultation with, a cardiologist or nephrologist; **AND**
4. The prescriber and pharmacy must be enrolled in the TRYVIO REMS program; **AND**
5. Patient must have uncontrolled blood pressure (systolic blood pressure [SBP] ≥140 mmHg) despite the compliant concurrent use of agents at maximally tolerated doses from each of the following classes:

    a. angiotensin-converting enzyme [ACE] inhibitors or angiotensin receptor blockers [ARB],
    b. long-acting dihydropyridine calcium channel-blockers,
    c. long-acting thiazide like diuretics and/or loop diuretics,
    d. mineralocorticoid receptor antagonist (spironolactone or eplerenone), **AND**

6. Causes of secondary hypertension (such as obstructive sleep apnea [OSA], primary aldosteronism, and renal artery stenosis) have been ruled out; **AND**
7. Patients who are taking a medication that can exacerbate hypertension should discontinue the medication (or have been evaluated for a dose reduction); **AND**
8. Patient does not have moderate to severe hepatic impairment or elevated aminotransferases (>3 × ULN); **AND**
9. Tryvio is not prescribed concurrently with other endothelin receptor antagonists; **AND**
10. **FOR FEMALE PATIENTS:** Documentation has been submitted that the patient is not pregnant and has been counseled that they must not become pregnant while taking this medication and for at least 1 month after treatment has been stopped.

Initial approvals will be for 90 days. Further approvals may be granted for 1 year after all the continuation of therapy criteria has been met.

CONTINUATION OF THERAPY CRITERIA:

1) Patient in not pregnant; **AND**

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2) Demonstrate continued documented compliance; **AND**
3) Documentation of positive clinical response to therapy must be provided (such as achieving and maintaining goal blood pressure for patient

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Patient-Provider Agreement – Hepatitis C

I, _____, have been counseled by my healthcare provider on the following:

- ~~☐~~ The importance of not drinking alcohol or using illicit drugs during and after my treatment for Hepatitis C to minimize reinfection and liver damage. ~~and that I may be required to submit to a drug screen at the discretion of my healthcare provider.~~
- ☐ How to avoid being re-infected with Hepatitis C during and after my treatment.
- ☐ If the patient has been diagnosed with a Substance Use Disorder, the prescriber has counseled/recommended/encouraged the patient to enroll in a treatment program.
- ☐ (**Male**) The importance of using a barrier method of birth control and encouraging my partner to also use birth control.
- ☐ (**Female**) The importance of using two forms of birth control (one of which must be a barrier method) while being treated. I agree to have pregnancy tests as ordered by my healthcare provider. I also understand that I must tell my healthcare provider if I do become pregnant.
- ☐ I agree to complete the entire course of treatment, as well as all associated laboratory tests during and after treatment, as ordered by my healthcare provider.
- ☐ **I agree to IMMEDIATELY notify my prescriber if for any reason I feel that I should stop my treatment. I understand that failure to complete my full course of therapy solely due to actions on my part may result in loss of future coverage through Medicaid.**

X _____ _____
Patient Signature Date

- - - - - - - - - - - - - - - -

- **(Prescriber)** I understand that an SVR12 is requested to verify treatment success and that failure to provide these results to Medicaid may result in disqualification of my patient from future coverage.

X _____ _____
Prescriber Signature Date

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Albenza (albendazole) and Emverm (mebendazole)

Previous Criteria:

~~1. Requests to treat an indication of *Enterobius vermicularis* (pin-worm) shall require documentation indicating failure of a recent treatment course of Pin-Ex (pyrantel pamoate). This treatment course shall consist of no fewer than 2 doses taken within 2 weeks of each other.~~

~~1. Prior authorization requests for indications other than pinworm may be approved for FDA approved or common off-label indications. Diagnoses must accompany all requests; unrecognized off-label requests may require supporting literature references.~~

Albenza (albendazole):

Albenza (albendazole) may be approved for FDA approved indications or common off-label indications. Diagnoses must accompany all requests; unrecognized off-label requests may require supporting literature references.

Emverm (mebendazole):

1. Emverm may be approved for an FDA approved diagnosis for the treatment of patients with gastrointestinal infections caused by any of the following:

    A. Ancylostoma duodenale or Necator americanus (hookworms); **OR**

    B. Treatment of Ascaris lumbricoides (roundworm).

    C. Treatment of Enterobius vermicularis (pinworm); **OR**

    D. Treatment of Trichuris trichiura (whipworm); **OR**

2. For the treatment of Ancylostoma duodenale or Necator americanus (hookworms), Ascaris lumbricoides (roundworm) or Enterobius vermicularis (pinworms), a clinically significant, patient-specific reason why a more cost-effective anthelmintic therapy, such as albendazole, cannot be used must be provided.