Spravato Prior Authorization Guideline

Guideline Name	Spravato (esketamine) Nasal Spray
Formulary	• Medicaid - Arizona SP (AZM, AZMCMDP, AZMREF, AZMDDD)

Guideline Note:

Effective Date:	6/22/2020

1 . Criteria

Product Name: Spravato Nasal Spray	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Member has a confirmed diagnosis of major depressive disorder as defined by the DSM-V criteria and is treatment resistant.

AND

2 - Member is 18 years of age or older.

AND

3 - Spravato is prescribed by or in consultation with a psychiatric provider.

AND

4 - One of the following:

4.1 Member does not have an active substance use disorder (SUD)

OR

4.2 Both of the following:

- Member has an active substance use disorder
- Member is currently receiving treatment

AND

5 - One of the following:

5.1 Member has experienced an inadequate response during the current depressive episode with each of the following therapies:

5.1.1 Two antidepressants from at least two different classes (must include one of each AHCCCS preferred agents: SSRI, SNRI, or bupropion) having different mechanisms of action at the maximally tolerated labeled dose, each used for at least 4-6 weeks

AND

5.1.2 At least two augmentation therapies below for at least 4 weeks:

- SSRI or SNRI, and a second-generation antipsychotic used concomitantly (aripiprazole, quetiapine, risperidone, olanzapine)
- SSRI or SNRI, and lithium used concomitantly
- SSRI or SNRI, and liothyronine (T3) used concomitantly
- SSRI or SNRI, and mirtazapine
- SSRI and bupropion and buspirone

OR

5.2 Member has active suicidal ideation and urgent symptom control is necessary

AND

6 - Esketamine is used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline, venlafaxine)

AND

7 - Esketamine is administered under the direct supervision of a healthcare provider

AND

8 - Provider is certified in the Spravato REMS program

AND

9 - Member must be monitored by a health care provider for at least 2 hours after administration.

Notes	Quantity Limit: For induction phase (weeks 1-4): 24 devices/month, For maintenance phase: 12 devices/month

Product Name: Spravato Nasal Spray	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Provider attests that the member has documented improvement or sustained improvement in depressive symptoms from baseline.

AND

2 - Member use of esketamine is in combination with an oral antidepressant. **AND** **3** - Member administers esketamine under the direct supervision of a healthcare provider **AND** **4** - Provider is certified in the Spravato REMS Program **AND** **5** - Member must continue to be monitored by a health care provider certified by the Spravato REMS Program for at least 2 hours after administration.	
Notes	Quantity Limit: For induction phase (weeks 1-4): 24 devices/month, For maintenance phase: 12 devices/month

2 . Background

Benefit/Coverage/Program Information

Quantity Limits and Exclusions:

- Maximum dose of Spravao is 84 mg intranasally twice per week during the induction phase, (weeks 1-4); 84 mg intranasally once per week during the maintenance phase, weeks 5-8. During week 9 and thereafter, administer 56mg or 84mg every two weeks or once weekly.
- Spravato is available as a nasal spray containing 28 mg of esketamine per device. Each nasal spray device delivers two sprays containing a total of 28 mg esketamine.
- Esketamine will be considered experimental and investigational for all other indications.

Spravato REMS Program:
Spravato is available only through a restricted program called the SPRAVATO REMS. Important requirements of the SPRAVATO REMS include the following:

- Pharmacies must be certified in the REMS and must only dispense Spravato to healthcare providers and settings that are certified for the REMS Program and to the provider's address that is listed on the provider's certification. Further information, including a list of certified pharmacies is available at www.SPRAVATOrems.com or 1-855- 382-6022.
- SPRAVATO as part of the REMS Program, must be dispensed to a certified Health Care Setting operating under a DEA number for the overall management and storage elements related to a controlled substance. When a healthcare setting is registered, they must designate an authorized representative to be responsible for ensuring compliance with all REMS requirements.
- Each provider who prescribes and oversees SPRAVATO administration must have a DEA number.
- A provider can enroll his/her own DEA # as a Healthcare setting as long as the location/address of the physician's DEA registration is the same as the Healthcare Setting where SPRAVATO will be administered.
- Healthcare practitioners must be certified in the program and ensure that Spravato is: 1) Only dispensed in healthcare settings to patients who are enrolled in the Spravato REMS Program. 2) Administered by patients under the direct observation of a healthcare provider and that patients are monitored by a healthcare provider for at least 2 hours after administration of Spravato.

3 . Revision History

Date	Notes
	Update criteria