Esketamine nasal spray (Spravato®)	Place of Service Office Administration Outpatient Facility Infusion Administration Infusion Center Administration HCPCS: **S0013** per 1 mg

Condition(s) listed in policy *(see criteria for details)*

- Major depressive disorder (MDD), acute suicidal ideation or behavior
- Major depressive disorder (MDD), treatment-resistant depression (TRD)

AHFS therapeutic class: antidepressants, miscellaneous
Mechanism of action: non-competitive N-methyl-D-aspartate (NMDA) receptor antagonist

(1) Special Instructions and Pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for esketamine nasal spray (Spravato®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Major depressive disorder (MDD), treatment-resistant depression (TRD)

1. Patient is at least 18 years of age, **AND**
2. Being used in combination with an oral antidepressant, **AND**
3. Prescribed by or in consultation with a psychiatrist, **AND**
4. Inadequate response to two antidepressants

Covered Doses

Induction (Weeks 1 to 4) & Maintenance (Week 5 and after)		
Week 1 ***Induction***	First dose: up to 56 mg intranasally Second dose: Up to 84 mg intranasally	*Authorize up to one 56 mg dose kit AND one 84 mg dose kit for the first week*
Week 2 – 4 ***Induction***	up to 84 mg intranasally twice per week	*Authorize up to six 84 mg dose kits for the 3-week period*
Week 5 – 8 ***Maintenance***	up to 84 mg intranasally once per week	*Authorize up to four 84 mg dose kits for one month*
Week 9 and after ***Maintenance***	up to 84 mg intranasally every two weeks or once weekly	*Authorize up to four 84 mg dose kits per month*

Coverage period
Initial: 2 months

Reauthorization: 6 months if criteria is met

1. Prescribed by or in consultation with a psychiatrist, and
2. Being used in combination with an oral antidepressant, and
3. Documentation of remission or positive clinical response

ICD-10:
F32, F33

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for esketamine nasal spray (Spravato®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Major depressive disorder (MDD), acute suicidal ideation or behavior

- Diagnosis only

Covered Doses
Up to 84 mg intranasally twice per week
After 4 weeks of treatment, evaluate the therapeutic benefit to determine the need for continued therapy. The use of esketamine, in conjunction with an oral antidepressant, beyond 4 weeks has not been formally evaluated in these patients.

Coverage period
4 weeks

ICD-10: Must contain both
1) F32 or F33, and
2) R45.851

(4) This Medication is NOT medically necessary for the following condition(s):

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information
How supplied:

- Nasal Spray: 28 mg of esketamine per device. Each nasal spray device delivers two sprays containing a total of 28 mg of esketamine.

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Spravato® (esketamine) [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; 7/2020.

(7) Policy Update
Date of last review: 4Q2023
Date of next review: 4Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee