Esketamine nasal spray (Spravato®)

<u>Place of Service</u> 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 <u>sent for clinical review</u> and receive authorization <u>prior to drug administration or claim payment</u>.

# 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

## 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)

PHP Medi-Cal

esketamine nasal spray (Spravato®)

Week 1	First dose: up to 56 mg	Authorize up to
Induction	intranasally	one 56 mg dose kit
	Second dose: Up to 84 mg	AND
	intranasally	one 84 mg dose kit
		for the first week
Week 2 – 4	up to 84 mg intranasally	Authorize up to six 84 mg dose kits
Induction	twice per week	for the 3-week period
Week 5 – 8	up to 84 mg intranasally	Authorize up to four 84 mg dose kits
Maintenance	once per week	for one month
Week 9 and after	up to 84 mg intranasally every	Authorize up to four 84 mg dose kits
Maintenance	two weeks or once weekly	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) <u>DO NOT</u> require Prior Authorization/Preservice All requests for esketamine nasal spray (Spravato®) must be <u>sent for clinical review</u> and receive authorization <u>prior to drug administration or claim payment</u>.

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

<u>Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code §</u> 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<sup>®</sup>. Available by subscription at <u>http://www.lexi.com</u>
- DrugDex<sup>®</sup>. Available by subscription at <u>http://www.micromedexsolutions.com/home/dispatch</u>
- Spravato<sup>®</sup> (esketamine) [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; 7/2020.

# (7) Policy Update

Date of last review: 4Q2023 Date of next review: 4Q2024

PHP Medi-Cal

esketamine nasal spray (Spravato®)

Effective: 04/03/2024

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