blue california

esketamine (Spravato)

Commercial Medical Benefit Drug Policy

<u>Place of Service</u>
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: ANTIDEPRESSANTS
Mechanism of Action: Non-competitive N-methyl-D-aspartate (NMDA) receptor antagonist
<u>HCPCS:</u>
J0013:Esketamine, nasal spray, 1 mg
<u>How Supplied:</u>
Nasal Spray: 28 mg of esketamine per device. Each nasal spray device delivers two sprays containing a total of 28 mg of esketamine.

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

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

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

<u>Major depressive disorder (MDD), treatment-resistant depression (TRD)</u>
Meets medical necessity if all the following are met:
<u>Initial</u>

1. Age is consistent with the FDA-approved indication(18 years of age and older)
2. Prescribed by or in consultation with a psychiatrist
3. Meets ONE of the following:
    a. ***Through 4/30/2026:*** Inadequate response to two antidepressants
    b. ***Effective 5/1/2026 and after:***
        i. Meets one (1) of the following: (a or b)

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   a. Inadequate response to two medications from different classes of antidepressants
   b. Intolerance or contraindication to all classes of antidepressants
4. Baseline score from one of the following clinical assessment tools for depression: (a, b, c, or d)
   a. Montgomery-Ashberg Depression Rating Scale (MADRS)
   b. Hamilton Rating Scale for Depression (HAMD17)
   c. Quick Inventory of Depressive Symptomatology (QIDS-C16)
   d. Patient Health Questionnaire (PHQ-9)

Reauthorization
1. Prescribed by or in consultation with a psychiatrist
2. One of the following: (a, b, or c)
   a. ***Through 4/30/2026:*** Documentation of positive clinical response
   b. Documentation of positive clinical response as demonstrated by an improvement from baseline score
   c. Documentation of remission defined by one of the following: (i, ii, iii, or iv)
      i. MADRS score is12 or less
      ii. HAMD17 score is 7 or less
      iii. QIDS-C16 is 5 or less
      iv. PHQ-9 is less than 5

Covered Doses:

Induction (Weeks 1 to 4) & Maintenance (Week 5 and after)	
Weeks 1 - 4 *Induction*	56 mg or 84 mg administered twice per week
Week 5 – 8 *Maintenance*	56 mg or 84 mg administered once weekly
Week 9 and after *Maintenance*	56 mg or 84 mg intranasally every two weeks or once weekly

Coverage Period:
Initial: 2 months
Reauthorization: 6 months

ICD-10:
F32.0, F32.1, F32.2, F32.3, F32.4, F32.5, F32.81, F32.89, F32.9, F32.A, F33.0, F33.1, F33.2, F33.3, F33.40, F33.41, F33.42, F33.8, F33.9

The following condition(s) DO NOT require Prior Authorization/Preservice if ALL its parameters are met, otherwise Prior Authorization/Preservice is required.

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

Covered Doses:
84 mg intranasally twice per week for 4 weeks total
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.

ICD-10: Must contain both
1. F32.0, F32.1, F32.2, F32.3, F32.4, F32.5, F32.81, F32.89, F32.9, F32.A, F33.0, F33.1, F33.2, F33.3, F33.40, F33.41, F33.42, F33.8, or F33.9
2. R45.851

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Spravato (esketamine) [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; 4/2025.

Review History

Date of Last Annual Review: 1Q2026
Changes from previous policy version:
- Treatment-Resistant Depression:
  - ***Effective 4/1/2026 and after***, will require prior use of two antidepressants from different classes (Rationale: Spravato prescribing information).
  - ***Effective 4/1/2026 and after***, will require documentation of positive clinical response as demonstrated by an improvement from baseline score (Rationale: Spravato prescribing information).

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee