Humana. CareSource™

PHARMACY POLICY STATEMENT
Kentucky Medicaid

DRUG NAME	Spravato (esketamine)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy or Medical
SITE OF SERVICE ALLOWED	Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product)
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Spravato (esketamine) is a **non-preferred** product and will only be considered for coverage under the **medical or pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with the following disease state and meet the individual criteria as stated.

TREATMENT RESISTANT DEPRESSION

For **initial** authorization:

1. Member has diagnosis of treatment resistant depression; AND
2. Member is 18 years old or older; AND
3. Medication must be used in conjunction with an oral antidepressant (e.g., citalopram, escitalopram, fluoxetine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, nortriptyline, bupropion, trazodone); AND
4. Member has had a 30-day trial and failure of **at least two** of the following:
   a) Selective Serotonin Reuptake Inhibitor;
   b) Selective Norepinephrine Reuptake Inhibitor;
   c) Tricyclic Antidepressant;
   d) Monoamine Oxidase Inhibitor;
   e) Bupropion;
   f) Mirtazapine;
   g) Trazodone; AND
5. Documentation of the member's baseline depression status using an appropriate rating scale (e.g., PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, HAM-D).
6. **Dosage allowed:** Weeks 1-4: Maximum of 8 kits per month for 56 mg device and 7 kits per month for 84 mg device; Weeks 5-8: Maximum of 4 kits per month.

If member meets all the requirements listed above, the medication will be approved for 2 months.

For **reauthorization**:
1. Documented maintenance of clinical improvement in depression symptoms as measured by improvement from baseline score on an appropriate rating scale.
2. **Dosage allowed:** Dose: 4 kits per 28 days.

Note: Healthcare site, dispensing pharmacy, and patient must all be enrolled in the Spravato REMS program.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 1 year.

CareSource considers Spravato (esketamine) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
05/23/2019	New policy for Spravato created.

References:
1. Spravato [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; May, 2019.
2. A Randomized, Double-blind, Multicenter, Active-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Flexible Doses of Intranasal Esketamine Plus an Oral Antidepressant in Adult Subjects With Treatment-resistant Depression (TRANSFORM-2). Janssen Research & Development. NCT0241858. April 2019. Available at: https://clinicaltrials.gov/ct2/show/NCT02418585?term=02418585&rank=1.
3. An Open-label Long-term Extension Safety Study of Intranasal Esketamine in Treatment-resistant Depression (SUSTAIN-3). Janssen Research & Development. NCT02493868. May 2019. Available at: https://clinicaltrials.gov/ct2/show/NCT02493868?term=02493868&rank=1.
4. Gelenberg A., Freeman M., Markowitz J., et. al. Practice guideline for the treatment of patients with major depressive disorder. Am J Psychiatry. May 2010. Available at: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf.

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