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Department of Origin: Pharmacy	**Date approved:** 12/06/2023
Approved by: Pharmacy and Therapeutics Quality Management Subcommittee	**Effective Date:** 12/06/2023
Pharmacy Clinical Policy: Spravato (esketamine) Prior Authorization	**Replace Effective Policy Dated:** 5/24/2023
Reference #: PC/S007	**Page**: 1 of 4

PURPOSE:
The intent of the Spravato (esketamine) Prior Authorization Pharmacy Clinical Policy is to ensure services are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:
Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

GUIDELINES:
Medical Necessity Criteria - Must satisfy any of the following: I or II

I. Initial use – must satisfy all of the following:

A. Member is aged 18 years or older.

B. Member's current major depressive episode (MDE) meets *DSM* criteria for major depressive disorder (MDD).

C. Member has one of the following: 1 or 2
1. Acute suicidal ideation or behavior; or

2. Member does not have acute suicidal ideation – must satisfy all of the following: a - c
a. Other causes of MDE have been excluded – none of: 1) – 5)
1) Bipolar I disorder; and
2) Schizoaffective disorder; and
3) Substance/medication-induced depressive disorder; and
4) Depressive disorder due to another medical condition; and
5) Personality disorders.
b. Member does not have a current or recent history (ie, within the last 6 months) of moderate or severe substance or alcohol use disorder.
c. Member has demonstrated treatment resistance, during the current MDE, or a similar previous episode, as supported by both of the following: 1) and 2)
1) Member did not experience a *clinically significant response* to adequate psychopharmacologic medication trials during the current MDE as evidenced by the following: i – ii, or iii
i. At least 2 trials involving antidepressants with different mechanisms of action; and
ii. At least 2 trials involving augmentors; or
iii. Member developed severe, treatment-limiting adverse ("side") effects.
2) Member did not experience a *clinically significant response* to an adequate trial of psychotherapy where acceptable modalities include – any of the following: i - iii
i. Individual psychotherapy; or

ii. Intensive outpatient program (IOP); or
iii. Partial hospitalization program (PHP).

F. Spravato will be used in combination with an oral antidepressant.

G. Authorize for up to 3 months.

II. Continuation/maintenance – must satisfy all of the following: A - C

A. The member has had a *clinically significant response* to Spravato.

B. Spravato will continue to be used in combination with an oral antidepressant.

C. Authorize for up to 6 months.

DEFINITIONS:

Adequate psychopharmacologic medication trial:
Medication was taken at its maximum tolerated dose for an appropriate duration (generally weeks to months)

Adequate trial of psychotherapy:
Member received a 10- to 12-week course of evidence-based psychotherapy from a qualified practitioner

Clinically significant response:
50% or greater reduction in objective depression rating scales (see Attachment A)

DSM:
The most current edition of the American Psychiatric Association Diagnostic and Statistical Manual of Mental Health Disorders.

Psychopharmacologic medications:

- Selective serotonin reuptake inhibitors (eg, citalopram, fluoxetine, paroxetine, sertraline, Trintellix [vortioxetine], Viibryd [vilazodone])
- Serotonin norepinephrine reuptake inhibitors (eg, desvenlafaxine, duloxetine, Fetzima [levomilnacipran], venlafaxine)
- Bupropion
- Tricyclic antidepressants (eg, amitriptyline, clomipramine, desipramine, nortriptyline)
- Mirtazapine
- Monoamine oxidase inhibitors (eg, selegiline, tranylcypromine)
- Serotonin modulators (eg, nefazodone, trazodone)
- Augmentation with such as, but not limited to, atypical neuroleptics, “thyroid” such as Cytomel (liothyronine), lithium, anticonvulsants

BACKGROUND:

This clinical policy is based on U.S. Food and Drug Administration (FDA) approved indications, expert consensus opinion and/or available reliable evidence.

Prior Authorization: Yes, per network provider agreement - initial authorization for up to 3 months; continued use authorize for up to 6 months.

Spravato Recommended Dosing Schedule		
Induction Phase	Weeks 1-4: Twice weekly	Day 1: 56mg (2 devices) Subsequent doses: 56mg (2 devices) or 84mg (3 devices)
Maintenance Phase	Weeks 5-8: Once weekly	56mg (2 devices) or 84mg (3 devices)
	Week 9 and after: Every 2 weeks; or Once weekly (the least frequent dosing to maintain response is recommended)	56mg (2 devices) or 84mg (3 devices)

CODING: HCPCS - 2023
S0013 Esketamine, nasal spray, 1mg

RELATED CRITERIA/POLICIES:
Medical Management Process Manual UR015 Use of Medical Policy and Criteria
Medical Policy: MP/C009 Coverage Determination Guidelines
Pharmacy Clinical Policy: PP/T002 Therapeutic Equivalence

REFERENCES:
1. Spravato (esketamine) [package insert]. Titusville, NJ. Janssen Pharmaceuticals, Inc. 2023.
2. Canuso CM, Singh JB, Fedgchin M, et al. Efficacy and Safety of Intranasal Esketamine for the Rapid Reduction of Symptoms of Depression and Suicidality in Patients at Imminent Risk for Suicide: Results of a Double-Blind, Randomized, Placebo-Controlled Study. *Am J Psychiatry*. 2018;175(7):620-630.
3. Daly EJ, Singh JB, Fedgchin M, et al. Efficacy and Safety of Intranasal Esketamine Adjunctive to Oral Antidepressant Therapy in Treatment-Resistant Depression: A Randomized Clinical Trial. *JAMA Psychiatry*. 2018;75(2):139-148.
4. Brown S, Rittenbach K, Cheung S, et al. Current and Common Definitions of Treatment-Resistant Depression: Findings from a Systematic Review and Qualitative Interviews. *Can J Psychiatry.* 2019;64:380.

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Attachment A

Examples of Standardized Depression Rating Scales

- Beck Depression Inventory (BDI)
- Geriatric Depression Scale (GDS)
- Hamilton Depression Rating Scale (HAMD)
- Inventory of Depressive Symptomatology-Systems Review (IDS-SR)
- Montgomery-Asberg Depression Rating Scale (MADRS)
- Personal Health Questionnaire Depression Scale (PHQ-9)
- Quick Inventory of Depressive Symptoms (QIDS)

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PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
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