

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

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- 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.

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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)

Nondiscrimination & Language Access Policy

Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity. We do not exclude people or treat them differently because of race, color, national origin, age, disability, sex, sexual orientation, or gender identity.

We will:

Provide free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provide free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact us at the phone number shown on the inside cover of this contract, your id card, or aspirushealthplan.com.

If you believe that we have failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity, you can file a grievance with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1062
Minneapolis, MN 55440
Phone: 1.866.631.5404 (TTY: 711)
Fax: 763.847.4010
Email: customerservice@aspirushealthplan.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Nondiscrimination Grievance Coordinator is available to help you.

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)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1.866.631.5404 (TTY: 711).

Arabic: تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلی رقم الهاتف 1.866.631.5404 (رقم هاتف الصم والبك : 711)

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German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.866.631.5404 (TTY: 711).

Hindi: _यान द_ : य_द आप िहंदी बोलते ह_ तो आपके िलए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_। 1.866.631.5404 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 711).

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Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.866.631.5404 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (TTY: 711)

Traditional Chinese: 注意: 如果您使用繁體中文, 您可以免費獲得語言援助服務。請致電 1.866.631.5404 (TTY: 711)。

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.866.631.5404 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 711).

Lao: ໄປດຊາຍ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.866.631.5404 (TTY: 711).