Pharmacy Drug Policy & Procedure

Policy Name:	Spravato (esketamine)	Policy #:	2697P

Purpose of the Policy

The purpose of this policy is to establish criteria for coverage of Spravato. Health Alliance Drug Policies are developed and reviewed annually in compliance with the Mental Health Parity and Addiction Equity Act (MHPAEA) of 2008. MHPAEA requires group health plans and health insurance issuers to ensure that financial requirements (such as co-pays, deductibles) and treatment limitations (prior authorization, step-therapy) applicable to mental health or substance use disorder (MH/SUD) benefits are no more restrictive than the predominant requirements or limitations applied to substantially all medical/surgical benefits.

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Spravato under the specialty medical benefit when the following criteria have been met.

Criteria

1. Coverage Criteria for Treatment-Resistant Unipolar Depression

1.1 Diagnosis of treatment-resistant unipolar depression

1.2 Prescribed by a psychiatrist (mental health specialist) that will administer Spravato in a Spravato Risk Evaluation and Mitigation Strategy (REMS) certified healthcare setting

1.3 Documented trial and failure of at least 3 months on one preferred SSRI (citalopram, escitalopram, fluvoxamine, fluoxetine, paroxetine, paroxetine controlled-release, sertraline)

1.4 Documented trial and failure of at least 3 months on one preferred SNRI (duloxetine, venlafaxine, venlafaxine extended-release)

1.5 Documented failure of at least 3 months on one additional antidepressant in any of the following drug classes

- Selective Serotonin Reuptake Inhibitors (SSRIs)
- Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs)
- Tricyclic Antidepressants
- Monoamine Oxidase Inhibitors (MAOIs)
- Dopamine/Norepinephrine Reuptake Inhibitor (bupropion)
- Serotonin Reuptake Inhibitor/Antagonist (trazodone, nefazodone)
- Alpha-2 Antagonist (mirtazapine)

1.6 Documentation that at least one of the member's prior failed antidepressants was augmented with one of the following:

- Bupropion
- Buspirone
- Mirtazapine
- Atypical antipsychotics
- Liothyronine
- Lithium

1.7 Documentation and/or claims history confirming the patient has filled at least 150 days' worth of any antidepressant medication within the previous 180 days.
1.8 Documentation that the member will be using an antidepressant in conjunction with Spravato
1.9 Review of chart notes documenting diagnosis and confirming that patient has met all of the above requirements for treatment with Spravato by both a pharmacist and medical director

2. Coverage Criteria for Major Depressive Disorder with Suicidality

2.1 Diagnosis of major depressive disorder with suicidality
2.2 Documentation that the member has experienced suicidal ideation or behavior within the previous 30 days
2.3 Prescribed by a psychiatrist (mental health specialist) that will administer Spravato in a Spravato Risk Evaluation and Mitigation Strategy (REMS) certified healthcare setting
2.4 Review of chart notes documenting diagnosis and confirming that patient has met all of the above requirements for treatment with Spravato by both a pharmacist and medical director

3. Exclusion Criteria

3.1 Severe allergic reaction to esketamine, ketamine, or any component of the formulation
3.2 Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation
3.3 History of intracerebral hemorrhage

4. Approval Period

4.1 Initial Approval: 12 months
4.2 Subsequent Approvals: 12 months

CPT Codes	
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56mg of esketamine nasal self-administration, includes 2 hours post-administration observation.
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56mg of esketamine nasal self-administration, includes 2 hours post-administration observation.

HCPCS Codes	
S0013	Esketamine, nasal spray, 1 mg

References

1. Fu DJ, Ionescu DF, Li X, et al. Esketamine Nasal Spray for Rapid Reduction of Major Depressive Disorder Symptoms in Patients Who Have Active Suicidal Ideation With Intent: Double-Blind, Randomized Study (ASPIRE I). J Clin Psychiatry. 2020 May 12;81(3):19m13191.
2. Spravato (esketamine) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc; July 2020.
3. Wajs E, Aluisio L, Holder R, et al. Esketamine Nasal Spray Plus Oral Antidepressant in Patients With Treatment-Resistant Depression: Assessment of Long-Term Safety in a Phase 3, Open-Label Study (SUSTAIN-2). J Clin Psychiatry. 2020 Apr 28;81(3):19m12891.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.