

Medical Policy:

Spravato (esketamine hydrochloride) Nasal Spray

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.196	January 3, 2024	August 1, 2019

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Length of Authorization

Coverage will be provided: Initial: 3 months, Continuation: 6 months

Max Units (per dose and over time) [Medical Benefit]:

Treatment Resistant Depression

- Induction (weeks 1 to 4): 84 mg twice weekly (56 mg Day 1)
- Maintenance (weeks 5 to 8): 84 mg weekly

Major Depressive Disorder (MDD)

- 2 kits (84 mg kit) weekly

Guideline

I. INITIAL APPROVAL CRITERIA

Coverage is provided in the following conditions:

- Patient is 18 years of age or older; **AND** meets criteria for one of the following diagnoses 1 or 2):
1. **Major depressive disorder (treatment-resistant)**
 - A. Patient has a diagnosis of moderate to severe major depressive disorder; **AND**
 - B. Patient’s baseline depression symptoms must be measured and documented with an appropriate rating scale (such as PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, or HAM-D) as a tool for monitoring response to therapy; **AND**
 - C. Patient has had an inadequate response ($\leq 50\%$ improvement in depression symptoms or scores) to the maximum tolerated dose of at least **TWO** antidepressant therapies (e.g., selective serotonin reuptake inhibitors [SSRIs], serotonin-norepinephrine reuptake inhibitors [SNRIs], tricyclic antidepressants [TCAs], bupropion, mirtazapine, etc.) for at least 6 weeks during the current major depressive episode (MDE) (**Document medication, dose, and duration**); **AND**
 - D. Patient will be using Spravato in conjunction with an oral antidepressant.

 2. **Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior**
 - A. The prescriber represents that, in the absence of the requested drug, within the next 24 to 48 hours the member will require confinement in an acute care psychiatric institution; **AND**
 - B. Member has a depressive episode so acute and so severe that the member is not able to participate in self-care (e.g., washing, eating), is unable to participate at all in their usual daily activities (e.g., work), and has persistent thoughts of hopelessness and helplessness as well as anhedonia; **AND**
 - C. Patient will be using Spravato in conjunction with an oral antidepressant.

II. RENEWAL CRITERIA

Coverage can be renewed based upon the following criteria:

1. Patient has had at least a 50% reduction in symptoms of depression compared to baseline using a standard rating scale that reliably measures depressive symptoms; **AND**
2. Patient will continue Spravato in conjunction with an oral antidepressant.

Dosing/Administration

Spravato is administered intranasally twice weekly for 4 weeks, then once weekly for four weeks, then weekly or every other week thereafter.

The recommended dosing schedule is as follows:

TRD-Induction Phase	Weeks 1-4: Twice weekly	Day 1: 56 mg (2 devices) Subsequent doses: 56 mg or 84 mg (3 devices)
TRD-Maintenance Phase	Weeks 5-8: Once weekly	56 mg (2 devices) or 84 mg (3 devices)
	Week 9 and after: every 2 weeks OR once weekly*	56 mg (2 devices) or 84 mg (3 devices)

MDD	Twice per week for 4 weeks	84mg (3 devices), dose may be reduced to 56mg (2 devices based on tolerability)
MDD	After 4 weeks reevaluate to determine need for continued treatment	

**Dosing frequency should be individualized to the least frequent dosing to maintain remission/response*

Limitations/Exclusions

Spravato is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

Other Exclusions:

1. Patient has aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels) or arteriovenous malformation.
2. Patient has intracerebral hemorrhage.

Applicable Procedure Codes

Code	Description
S0013	Esketamine, nasal spray, 1 mg

Applicable NDCs

Code	Description
50458-0028--00	Unit-dose carton containing 28 mg nasal spray device
50458-0028--02	Unit-dose carton containing 28 mg (56 mg dose) nasal spray device
50458-0028--03	Unit-dose carton containing 28 mg (84 mg dose) nasal spray device

ICD-10 Diagnoses

Code	Description
F33.0-F33.9	Major depressive disorder, recurrent
R45.851	Suicidal ideations

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/3/2024	Annual Review: Added Max units, updated dosing chart
EmblemHealth & ConnectiCare	4/27/2023	Annual Review: no criteria changes
EmblemHealth & ConnectiCare	1/12/2023	Transfer to New Template

EmblemHealth & ConnectiCare	7/7/2021	Updated Procedure codes
EmblemHealth & ConnectiCare	8/13/2020	Added new indication: Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior. Added criteria for new indication. Added diagnosis code R45.851 suicidal ideations.

References

1. Spravato [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; March 2019.