Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	NA	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Spravato (esketamine) nasal spray

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial approval: 3 months Maintenance approval: 12 months

Medications	Quantity Limit
Spravato (esketamine) nasal spray 56 mg Dose Kit, 84 mg Dose Kit	4 kits per 28 days*

*Initiation of therapy for Spravato (esketamine): May approve up to 4 additional kits in the first month (28 days) of treatment.

APPROVAL CRITERIA

Initial requests for Spravato (esketamine) nasal spray may be approved if the following criteria are met (Daly 2018):

I. Individual is 18 years of age or older; **AND**
II. Individual has been diagnosed with moderate to severe major depressive disorder; **AND**
III. Individual has had an inadequate response to the maximum tolerated dose of two antidepressant therapies during the current major depressive episode (MDE) as defined by less than 50% reduction in symptom severity using a standard rating scale that reliably measures depressive symptoms; **AND**
IV. Individual will use Spravato in addition to antidepressant therapy.

Continuation of Spravato (esketamine) nasal spray may be approved if the following criteria are met:

I. Individual 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**
II. Individual will use Spravato in addition to antidepressant therapy.

Requests for Spravato (esketamine) nasal spray may not be approved for the following criteria:

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	NA	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

I. Individual has aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels) or arteriovenous malformation; **OR**
II. Individual has intracerebral hemorrhage.

Note: Spravato has a black box warning for sedation and dissociation, potential for misuse and abuse, and increased risk of suicidal thoughts and behaviors. Spravato is not approved for use in pediatric patients.

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: http://www.clinicalpharmacology.com. Updated periodically.
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4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. 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;175:620-630.
6. 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;75:139-148.
7. Spravato [package insert]. Titusville, NJ: Janssen Pharmaceutical Companies; 2019.