Spravato™ (esketamine hydrochloride) Nasal Spray

Policy Origination date: August 1, 2019     Number: MG.MM.PH.196

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Length of Authorization
Coverage will be provided: Initial: 3 months, Continuation: 6 months

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 (A or B):

  A. Major depressive disorder (treatment-resistant)

  - Patient has a diagnosis of moderate to severe major depressive disorder; AND
  
  - 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
  
  - Patient has had an inadequate response (≤ 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
  
  - Patient will be using Spravato in conjunction with an oral antidepressant.
B. Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior

- 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
- 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
- Patient will be using Spravato in conjunction with an oral antidepressant.

II. RENEWAL CRITERIA

Coverage can be renewed based upon the following criteria:

- 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
- 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:

<table>
<thead>
<tr>
<th>Phase</th>
<th>Weeks 5-8: Once weekly</th>
<th>Week 9 and after: every 2 weeks OR once weekly*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Induction Phase</td>
<td></td>
<td>56 mg (2 devices) or 84 mg (3 devices)</td>
</tr>
<tr>
<td>Maintenance Phase</td>
<td></td>
<td>56 mg (2 devices) or 84 mg (3 devices)</td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>S0013</td>
<td>Esketamine, nasal spray, 1 mg</td>
</tr>
<tr>
<td>J3499</td>
<td>Unclassified drugs (when specified as Spravato)</td>
</tr>
</tbody>
</table>

Applicable NDC’s
Spravato™ (esketamine hydrochloride)

Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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</thead>
<tbody>
<tr>
<td>F33.0-F33.9</td>
<td>Major depressive disorder, recurrent</td>
</tr>
<tr>
<td>R45.851</td>
<td>Suicidal ideations</td>
</tr>
</tbody>
</table>

Revision History:

- 7/7/2021: Updated Procedure codes
- 08/13/2020: 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