Spravato™ (esketamine hydrochloride) Nasal Spray

Medical Guideline Disclaimer

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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

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.
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>Induction Phase</th>
<th>Weeks 1-4: Twice weekly</th>
<th>Day 1: 56 mg (2 devices)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance Phase</td>
<td>Weeks 5-8: Once weekly</td>
<td>56 mg (2 devices) or 84 mg (3 devices)</td>
</tr>
<tr>
<td>Maintenance Phase</td>
<td>Week 9 and after: every 2 weeks OR once weekly*</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

| J3490 | Unclassified drugs (when specified as Spravato) |

Applicable NDC’s

| 50458-0028--xx | Unit-dose carton containing two/three 28 mg nasal spray devices |

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>
</tbody>
</table>

Revision History: N/A

References