EFFECTIVE DATE: 12|01|2019
POLICY LAST UPDATED: 01|21|2020

OVERVIEW

Spravato™ (esketamine) is indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults.

This policy is applicable to BlueCHiP for Medicare products only. For Commercial Products, see related policy section.

MEDICAL CRITERIA

Initial Evaluation

Spravato™ (esketamine) will be approved when ALL of the following are met:

1) The patient is 18 years of age or older

AND

2) Both of the following:
   a) The patient has a diagnosis of Treatment-Resistant Depression

   AND

   b) ONE of the following:
      i) The patient has tried and had an inadequate response to medication augmentation (i.e. dual combination treatment- with a second drug or psychotherapy

      OR

      ii) The patient has tried and had an inadequate response to electroconvulsive therapy (ECT)

AND

3) The prescriber is a specialist (e.g. psychiatrist) or the prescriber has consulted with a specialist

AND

4) The patient is currently being treated and will continue treatment with an oral antidepressant

AND

5) ONE of the following:
   a) The patient does not have a substance use disorder

   OR

   b) The patient is being treated for substance use disorder and is NOT at risk for relapse

AND

6) The baseline depression rating scale results are provided (e.g. MADRS)

AND

7) Medication will be administered in a setting equipped to monitor patient vital signs and provide supportive care as needed

AND

8) The patient does NOT have any FDA labeled contraindications to the requested agent

AND

9) The requested dose is within FDA labeled dosing for the requested indication

Length of Approval: 6 months

Renewal Evaluation
Spravato™ (esketamine) will be approved when ALL of the following are met:
1) The patient has been previously approved for the requested agent through the Prime Therapeutics Medical Drug Review process

AND

2) The patient has had clinical benefit with the requested agent as demonstrated by 50% improvement from baseline in depression rating scale (e.g. MADRS) (submit documentation)

AND

3) The prescriber is a specialist (e.g. psychiatrist) or the prescriber has consulted with a specialist

AND

4) The patient is currently being treated with an oral antidepressant

AND

5) The patient does NOT have any FDA labeled contraindications to the requested agent

AND

6) The requested dose within FDA labeled dosing for the requested indication

Length of Approval: 12 months

PRIOR AUTHORIZATION
Prior authorization is required for BlueCHiP for Medicare.

POLICY STATEMENT
BlueCHiP for Medicare
Spravato™ (esketamine) is medically necessary when the criteria above have been met.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable physician administered drug benefits/coverage.

BACKGROUND
Clinical Rationale
Treatment-resistant depression (TRD) refers to a major depressive episode with an inadequate response to therapy of adequate dosing and duration. The failure of two or more trials of antidepressant monotherapies are commonly considered TRD, but the number of trials has not been standardized. Some TRD drug trials include patients with failure of only one or more trials. Overall, approximately one in three patients with depression are considered 'treatment resistant'.

Spravato™ was approved on a short-term and a long-term study. The short-term study was a randomized, placebo-controlled, double-blind, multicenter, 4-week study in patients aged 18 to <65 years old. Patients met the DSM-5 criteria for major depressive order, and in the current depressive episode, had not responded adequately to at least two different antidepressants of adequate dose and duration. Patients were randomized to either twice weekly doses of Spravato™ (flexible at 56 or 84 mg) or placebo. Both groups were given concomitant treatment with a newly-initiated oral antidepressant. The primary efficacy measure was the change in baseline in the Montgomery-Asberg Depression Rating Scale (MADRS). The MADRS is scored from 0 to 60, with the higher MADRS scores indicating more severe depression. Scoring is usually broken down with 0 and 6 indicating no depression, 7-19 mild depression, 20-34 moderate depression, and over 34 severe depression.3 The Spravato™ arm had a mean baseline score of 37.0, while the control arm had a score of 37.3. The Spravato™ plus antidepressant arm demonstrated statistically superiority in the primary efficacy measure over the placebo plus antidepressant arm. Spravato caused a decrease in score of 19.8, versus a decrease of 15.8 for placebo.

The long-term study was a randomized, double-blind, parallel group, multicenter maintenance of effect study in adults 18 to <65 years of age who were known responders to Spravato™. After at least 16 weeks of

treatment with Spravato™ and an oral antidepressant, stable patients were randomized to continue the Spravato™ and antidepressant or to be switched to a placebo spray and antidepressant. The primary endpoint was time to relapse, where relapse was defined as a MADRS score of ≥ 22 for 2 consecutive weeks or hospitalization for depression. Patients who continued Spravato with an antidepressant experienced a statistically significantly longer time of relapse than did placebo patients.

Safety

Spravato™ is available only through a restricted program under a REMS because of the risks of serious adverse outcomes from sedation, dissociation, and abuse and misuse. Spravato™ is contraindicated in aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels) or arteriovenous malformation, intracerebral hemorrhage, and hypersensitivity to esketamine, ketamine, or any of the excipients.

CODING

BlueCHiP for Medicare

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 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation (new code effective 1/1/20)

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 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation (new code effective 1/1/20)

Note: As of 1/1/20, for both BlueCHiP for Medicare and Commercial Products, claims should not be filed with an unlisted code such as J3490 and the NDC number. To ensure correct claims processing, claims should be filed with one of the codes listed above.

RELATED POLICIES

Prior Authorization of Drugs

PUBLISHED

Provider Update, March 2020
Provider Update, October 2019

REFERENCES

1) Spravato Prescribing Information. March 2019.
2) "Esketamine for Treatment-Resistant Major Depressive Disorder. Effectiveness and Value. Draft Background and Scope." ICER, 2018. Accessed March 2019. Available at: https://icer-review.org/wp-content/uploads/2018/10/TRD-Draft-Scope-FOR-PUBLICATION-10.31.pdf
3) Canadian Partnership for Stroke Recovery. Montgomery Asberg Depression Rating Scale (MADRS). https://www.strokengine.ca/en/indepth/madrs_indepth/ Accessed 3/19/19.

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