Spravato® (Esketamine)

Guideline Number: MPG393.03
Approval Date: February 14, 2024

➲ Terms and Conditions

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Related Medicare Advantage Reimbursement Policy

- Discarded Drugs and Biologicals Policy, Professional

Related Medicare Advantage Coverage Summary

- Medications/Drugs (Outpatient/Part B)

Policy Summary

➲ See Purpose

Overview

SPRAVATO® is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults.

Guidelines

Drugs and biologicals must be determined to meet the statutory definition under the statute 1861(t) (1) Drugs and Biologicals.

This guideline provides billing and coding guidance for the drug SPRAVATO® (esketamine) when administered at healthcare sites enrolled in the Food and Drug Administration (FDA) risk evaluation and mitigation strategies (REMS) program. Consistent with Title XVIII of the Social Security Act, Section 1861(t)(2)(B) the term “medically accepted indication”, with respect to the use of a drug, includes any use which has been approved by the FDA for the drug, and includes another use of the drug if such use is supported by one or more citations which are included (or approved for inclusion) in one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, the United States Pharmacopoeia-Drug Information, and other authoritative compendia as identified by the Secretary.

Prescribing medications for indications that are not approved by the FDA or are not supported in one of the compendia listed above may lead to revocation from the Medicare program consistent with CFR, Title 42, Chapter IV, Subchapter B, Part 424, Section 424.535.

Coding Guidelines

Notice: It is not appropriate to bill Medicare for services that are not covered as if they are covered. When billing for non-covered services, use the appropriate modifier.

Diagnosis code selection is based on the FDA approved label indication treatment of treatment-resistant depression (TRD) in adults. At this time, no other use of the drug is supported by one or more CMS approved compendium.

FDA label for SPRAVATO® (esketamine) nasal spray, CIII: Warning: Sedation; dissociation; abuse and misuse; and suicidal thoughts and behaviors. Refer to full prescribing information for complete boxed warning.

- Risk for sedation and dissociation after administration. Monitor patients for at least two hours after administration.

- Potential for abuse and misuse. Consider the risks and benefits of prescribing SPRAVATO® prior to using in patients at higher risk of abuse. Monitor patients for signs and symptoms of abuse and misuse.
- SPRAVATO® is only available through a restricted program called the SPRAVATO® REMS.
- Increased risk of suicidal thoughts and behaviors in pediatric and young adult patients taking antidepressants. Closely monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors. SPRAVATO® is not approved for use in pediatric patients.

Limitations of Use

SPRAVATO® is not approved as an anesthetic agent. The safety and effectiveness of SPRAVATO® as an anesthetic agent have not been established.

Frequency of administration exceeding the FDA label may be subject to medical review.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
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
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

Diagnosis Code	Description
F32.0	Major depressive disorder, single episode, mild
F32.1	Major depressive disorder, single episode, moderate
F32.2	Major depressive disorder, single episode, severe without psychotic features
F32.3	Major depressive disorder, single episode, severe with psychotic features (Effective 12/21/2023)
F32.4	Major depressive disorder, single episode, in partial remission
F32.5	Major depressive disorder, single episode, in full remission
F32.89	Other specified depressive episodes
F33.0	Major depressive disorder, recurrent, mild
F33.1	Major depressive disorder, recurrent, moderate
F33.2	Major depressive disorder, recurrent severe without psychotic features
F33.3	Major depressive disorder, recurrent, severe with psychotic symptoms
F33.40	Major depressive disorder, recurrent, in remission, unspecified
F33.41	Major depressive disorder, recurrent, in partial remission
F33.42	Major depressive disorder, recurrent, in full remission
F33.8	Other recurrent depressive disorders
F33.9	Major depressive disorder, recurrent, unspecified

References

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
N/A	A59250 Billing and Coding: Esketamine	First Coast	FL, PR, VI	FL, PR, VI
N/A	A59249 Billing and Coding: Esketamine	Novitas	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX

CMS Benefit Policy Manual

Chapter 15; § 50 Drugs and Biologicals

CMS Claims Processing Manual

Chapter 17; § 10 Payment Rules for Drugs and Biologicals

Others

Code of Federal Regulations, Title 42, Chapter IV, Subchapter B, Part 424, Section 424.535 Revocation of enrollment in the Medicare Program
Social Security Act, Title XVIII, Section 1833(e)
Social Security Act, Title XVIII, Section 1861(t)(2)(A) Drugs
Social Security Act, Title XVIII, Section 1861(t)(2)(B) Medically Accepted Indication
Spravato® Prescribing Information
SPRAVATO™ (esketamine) nasal spray, CIII Date: December 21, 2023, CGS Website

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
02/14/2024	**Related Policies** • Removed reference link to the UnitedHealthcare Medicare Advantage Reimbursement Policy titled *National Drug Code (NDC) Requirement Policy, Professional and Facility* **Applicable Codes** • Removed HCPCS code J3490 • Added ICD-10 diagnosis code F32.3 **Supporting Information** • Updated *References* section to reflect the most current information • Archived previous policy version MPG393.02

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support

coverage. Please utilize the links in the References section above to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.