
Non-Injectable Drugs

Page updated: August 2020

This section includes information about billing for non-injectable drug services.

NDC Billing Requirement

The Federal Deficit Reduction Act of 2005 (DRA) requires collection of rebates from drug manufacturers for physician-administered drugs. This policy may affect the billing of non-injectable drugs. Before submitting claims for non-injectable drugs, providers should review important NDC billing instructions in the *Physician-Administered Drugs – NDC* section of this manual.

Treatment Policy for the Management of Chronic Hepatitis C

This policy was developed by the Department of Health Care Services (DHCS) based on a review of the medical literature, the most recent guidelines and reports published by:

- American Association for the Study of Liver Diseases (AASLD)
- Infectious Diseases Society of America (IDSA)
- European Association for the Study of the Liver (EASL)
- California Technology Assessment Forum (CTAF)
- Institute for Clinical and Economic Review (ICER)
- World Health Organization (WHO)
- federal Department of Veterans Affairs (VA)
- and recommendations from experts in the management of hepatitis C virus

The treatment of hepatitis C virus is rapidly evolving. Accordingly, this policy may be revised as new information becomes available.

Treatment Considerations and Choice of Regimen for Hepatitis C Virus Infected Patients

Please refer to AASLD guidelines (hcvguidelines.org) for treatment regimens and durations.

Identifying Treatment Candidates

Disease Prognosis and Severity – Any of the following clinical states identify candidates for treatment:

- Evidence of Stage 2 or greater hepatic fibrosis/cirrhosis including one of the following:
 - Liver biopsy confirming a METAVIR score F2 or greater
 - Transient elastography (Fibroscan®) score greater than or equal to 7.5 kPa
 - FibroSure® score of greater than or equal to 0.48
 - APRI score greater than 0.7
 - FIB-4 greater than 0.35
- Evidence of extra-hepatic manifestation of hepatitis C virus, such as type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g., vasculitis), or kidney disease (e.g., proteinuria, nephrotic syndrome or membranoproliferative glomerulonephritis)
- Patients with hepatocellular carcinoma with a life expectancy of greater than 12 months
- Pre- and post-liver transplant, or other solid organ transplant
- HIV-1 co-infection
- Hepatitis B co-infection
- Other coexistent liver disease (e.g., nonalcoholic steatohepatitis)
- Type 2 diabetes mellitus (insulin resistant)
- Porphyria cutanea tarda
- Debilitating fatigue impacting quality of life (e.g., secondary to extra-hepatic manifestations and/or liver disease)
- Men who have sex with men with high-risk sexual practices
- Active injection drug users
- Patients on long-term hemodialysis
- Women of childbearing age who wish to get pregnant
- HCV-infected health care workers who perform exposure-prone procedures

Patient Readiness and Adherence

1. Patients shall be evaluated for readiness to initiate treatment.
2. Patients selected for treatment shall be able and willing to strictly adhere to treatment protocols prescribed by their provider.
3. Caution shall be exercised with patients who have a history of treatment failure with prior hepatitis C treatment due to non-adherence with treatment regimen and appointments. Patients shall be educated regarding potential risks and benefits of hepatitis C virus therapy, as well as the potential for resistance and failed therapy if medication is not taken as prescribed.

Age Requirements

Treatment candidate must be 18 years of age or older.

Quantity Limits

Prescription of hepatitis C therapy will be dispensed in quantities up to 28 days at a time.

Criteria for Reauthorization/Continuation of Therapy

1. Initial authorization criteria have been met, and
2. Evidence of lack of adherence may result in denial of treatment reauthorization.
3. Missed medical appointments related to the hepatitis C virus may result in denial of treatment authorization.

Laboratory Testing

1. Documentation of baseline hepatitis C virus-RNA level
2. Documentation of hepatitis C virus Genotype
3. Laboratory testing should be consistent with current AASLD/IDSA guidelines.

Populations Unlikely to Benefit from Hepatitis C Virus Treatment

According to AASLD/IDSA hepatitis C virus Guidelines, “patients with limited life expectancy for whom hepatitis C virus therapy would not improve symptoms or prognosis do not require treatment. Chronic hepatitis C is associated with a wide range of comorbid conditions. Little evidence exists to support initiation of hepatitis C virus treatment in patients with limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions. For these patients, the benefits of hepatitis C virus treatment are unlikely to be realized, and palliative care strategies should take precedence.” In patients with a life expectancy less than 12 months, treatment is not recommended.

Retreatment

Retreatment will be considered where there is evidence that such retreatment will improve patient outcomes. Please refer to AASLD guidelines for recommended retreatment regimens (hcvguidelines.org).

Criteria for Coverage of Investigational Services (Title 22 § 51303)

Investigational services are not covered except when it is clearly documented that all of the following apply:

- Conventional therapy will not adequately treat the intended patient's condition;
- Conventional therapy will not prevent progressive disability or premature death;
- The provider of the proposed service has a record of safety and success with it equivalent or superior to that of other providers of the investigational service;
- The investigational service is the lowest cost item or service that meets the patient's medical needs and is less costly than all conventional alternatives;
- The service is not being performed as a part of a research study protocol;
- There is a reasonable expectation that the investigational service will significantly prolong the intended patient's life or will maintain or restore a range of physical and social function suited to activities of daily living;
- All investigational services require prior authorization. Payment will not be authorized for investigational services that do not meet the above criteria or for associated inpatient care when a patient needs to be in the hospital primarily because she/he is receiving such non-approved investigational services.

Unlabeled Use of Medication

Authorization for unlabeled use of drugs shall not be granted unless the requested unlabeled use represents reasonable and current prescribing practices. The determination of reasonable and current prescribing practices shall be based on:

- Reference to current medical literature.
- Consultation with provider organizations, academic and professional specialists.

Ganciclovir Long-Acting Implant

The ganciclovir, 4.5 mg, long-acting implant is billed with HCPCS code J7310 for the treatment of cytomegalovirus (CMV) retinitis in patients with AIDS.

The insertion of the implant should be performed by a board-certified ophthalmologist who is trained in this procedure. Each ganciclovir long-acting implant contains a minimum of 4.5 mg of ganciclovir and is designed to slowly release ganciclovir into the vitreous cavity over a period of five to eight months. The implants are usually replaced electively at seven to eight months. However, the implant may be replaced earlier if the depletion of ganciclovir from the implant occurs, as evidenced by progression of retinitis.

Billing

The ganciclovir long-acting implant is reimbursable when billed in conjunction with ICD-10-CM diagnosis codes B25.8, B25.9 (cytomegaloviral disease) or codes H30.001 through H31.099 (chorioretinal inflammation and other disorders of choroid). The implantation procedure is billed using CPT® code 67027 (implantation of intravitreal drug delivery system [e.g., ganciclovir implant], includes concomitant removal of vitreous) and is reimbursable to the ophthalmologic surgeon who performs the insertion or to the surgeon's employer, such as an eye clinic or hospital outpatient department. One ganciclovir long-acting implant is reimbursed per patient in any six-month period. Additional implants may be reimbursed if documented medical justification accompanies the claim such as, but not limited to, one of the following:

- The patient requires an implant in both eyes.
- The implant becomes depleted of ganciclovir and needs to be replaced.
- It is time for elective replacement of the implant.
- The patient has developed an infection and/or complication.

Patients with a ganciclovir long-lasting implant in one eye may still require systemic coverage with either ganciclovir or foscarnet to protect the contralateral, uninvolved eye. Ganciclovir administered intravenously will not be approved for longer than 30 days following the insertion of a ganciclovir implant unless documentation of medical justification is entered in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19) of the claim or on an attachment. Patients with bilateral retinal disease and a ganciclovir long-lasting implant in both eyes may not require oral or intravenous therapy unless there is evidence of previous pulmonary, gastrointestinal or other systemic CMV disease.

Azithromycin for Chlamydia

Physicians, nurse practitioners or nurse midwives may be reimbursed for azithromycin when provided for the treatment of chlamydial infections of the cervix or urethra.

Required codes

Required ICD-10-CM codes are as follows:

- Chlamydial infection of lower genitourinary tract A56.01, A56.09

Billing

HCPCS code Q0144 (azithromycin dihydrate, oral, capsules/powder, 1 gram)

For the diagnoses above, providers may be reimbursed for a maximum of 1 gram of azithromycin per patient and date of service.

Albuterol

Claims for albuterol inhalation solution (HCPCS code J7611) billed in excess of 30 mg require documentation of continued airflow obstruction.

Granisetron (Oral Tablets)

Granisetron hydrochloride is indicated for the prevention of:

- Nausea and vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose cisplatin
- Nausea and vomiting associated with radiation, including total body irradiation and fractionated abdominal radiation

Dosing

The recommended adult dosage of oral granisetron hydrochloride is 2 mg once daily or 1 mg twice daily. In the 2 mg once-daily regimen, the 2 mg dose is given up to 1 hour before chemotherapy. In the 1 mg twice-daily regimen, the first 1 mg dose is given up to 1 hour before chemotherapy, and the second dose is given 12 hours after the first. Either regimen is administered only on the day(s) chemotherapy is given.

Billing

HCPCS code Q0166 (granisetron hydrochloride, 1 mg, oral)

Histrelin Implant

HCPCS code J9225 (histrelin implant, 50 mg, Vantas[®]), for the treatment of males 30 years of age or older with prostate cancer, is reimbursable when billed with ICD-10-CM diagnosis code C61. Coverage is limited to one in 12 months.

HCPCS code J9226 (histrelin implant, 50 mg, Supprelin LA[®]), is used for the treatment of precocious puberty in children aged 2 through 15 years. Claims may be reimbursed when billed in conjunction with ICD-10-CM diagnosis code E30.1 or E30.8. Coverage is limited to one in 12 months.

Dornase Alfa

HCPCS code J7639 (dornase alfa, 1 mg, inhalation solution, FDA-approved final product, noncompounded, administered through DME, unit dose form, per mg) must be billed with ICD-10-CM codes E84.0 through E84.9. Maximum dosage is 2 mg.

Testosterone Pellet

HCPCS code S0189 (testosterone pellet, 75 mg), is used for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone. Code S0189 is restricted to males only.

Required Codes

Claims for code S0189 must be billed in conjunction with ICD-10-CM diagnosis codes E29.1, E29.8 or E29.9.

Dosage

Maximum dosage is 450 mg every 90 days.

Formoterol Fumarate

For HCPCS code J7606 (formoterol fumarate, inhalation solution, 20 mcg), when billing for a quantity greater than two (40 mcg), providers must document that either the recipient's weight requires a higher dose or that there is a continued airway obstruction.

Capsaicin Patch

The capsaicin patch is reimbursable for treatment of post-herpetic neuralgia for recipients 18 years of age and older.

Required Codes

ICD-10-CM diagnosis codes B02.21 through B02.23

Billing

HCPCS code J7336 (capsaicin 8% patch, per square centimeter)

Lidocaine and Tetracaine Patch

Claims for HCPCS code C9285 (lidocaine 70 mg/tetracaine 70 mg, per patch) billed in excess of 2 patches per day require an approved *Treatment Authorization Request* (TAR) for reimbursement.

Mannitol

Claims for HCPCS code J7665 (mannitol, administered through an inhaler, 5 mg) billed in excess of 635 mg (127 units) require authorization.

Goserelin

Goserelin is reimbursable for the treatment of endometriosis, advanced carcinoma of the prostate and for the palliative use in women with advanced breast cancer.

Dosage

The maximum dosage is 10.8 mg every 28 days.

Billing

HCPCS code J9202 (goserelin acetate implant, per 3.6 mg)

Ciprofloxacin Otic Solution

Ciprofloxacin is a quinolone antimicrobial. Quinolones rapidly inhibit DNA synthesis by promoting cleavage of bacterial DNA in the DNA-enzyme complexes of DNA gyrase and type IV topoisomerase, resulting in rapid bacterial death.

Indications

Ciprofloxacin otic solution is a quinolone antimicrobial indicated for the treatment of acute otitis externa due to susceptible isolates of *Pseudomonas aeruginosa* or *Staphylococcus aureus*.

Authorization

An approved TAR is required for reimbursement. The TAR must state that the patient has otitis externus due to susceptible isolates of *Pseudomonas aeruginosa* or *Staphylococcus aureus*.

Dosage

Contents of one single-use container should be instilled into the affected ear twice daily (approximately 12 hours apart) for seven days.

Required Code

ICD-10-CM diagnosis code H60.20

Billing

HCPCS code J7342 (installation, ciprofloxacin otic suspension, 6 mg)

Buprenorphine Implant

Buprenorphine implant is a partial opioid agonist for subdermal administration. Each implant is 26 mm in length and 2.5 mm in diameter and contains 74.2 mg of buprenorphine (equivalent to 80 mg of buprenorphine hydrochloride) and ethylene vinyl acetate (EVA).

Indications

Buprenorphine implant is reimbursable for the maintenance treatment of moderate or severe opioid dependence in patients who have already started buprenorphine therapy with dose titration and stabilization for ≥ 7 days.

Buprenorphine implant is used as part of a comprehensive treatment program including psychosocial counseling, support and regular, frequent office visits to continually evaluate and monitor the patient's progress.

Comprehensive treatment program best-practice guidelines are described in, but are not limited to, the following references:

- *Federal Guidelines for Opioid Treatment Programs* by the Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services, 2015;
- *ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use* by the American Society of Medicine, 2015;
- *Practice Guideline for the Treatment of Patients with Substance Use Disorders, Second Edition* by the American Psychiatric Association (APA), 2010;
- *Model Policy on Data 2000 and Treatment of Opioid Addiction in the Medical* by the Federation of State Medical Boards, 2013.

A prescribing physician, nurse practitioner or physician assistant must hold a current state medical practitioner license number, a regular U.S. Drug Enforcement Agency (DEA) controlled substance registration number and a special SAMHSA waiver DEA identification number. Prescription use is limited under the Drug Addiction Treatment Act of 2000 (Public Law 106-310, Title XXXV, Sections 3501 and 3502) and the Comprehensive Addiction and Recovery Act of 2016 (Public Law 114-198, Title III, Section 303).

Due to the risk of migration, protrusion, expulsion and nerve damage associated with the insertion and removal of the implant, buprenorphine implant is only available through a restricted distribution program called the Probuphine[®] REMS Program. Healthcare providers who prescribe, insert and remove buprenorphine implant must be certified with the Probuphine[®] REMS Program.

Age

16 years and older

Dosage

After induction, titration and stabilization with a buprenorphine transmucosal formulation for ≥ 7 days, the recommended dose of four buprenorphine implants is inserted sub-dermally into the inner side of an upper arm. The implants release up to six months of buprenorphine treatment until removal by the end of the sixth month. A subsequent dose may be administered in the contralateral arm, but buprenorphine implants should not be used beyond a single insertion per arm.

Authorization

An approved TAR is required for reimbursement.

The TAR must include clinical documentation that demonstrates medical necessity for maintenance treatment of moderate or severe opioid use disorder as defined in the DSM-V by the presence of ≥ 4 symptom criteria for opioid use disorder within a 12-month period:

- The diagnosis has been confirmed by a comprehensive assessment including but not limited to a medical history and physical examination, objective clinical scales that measure symptoms of withdrawal, psychosocial and functional impairment, laboratory testing data, etc.
- The service is part of a comprehensive treatment program including psychosocial treatment and regular, frequent office visits to continually evaluate and monitor the patient's progress.
- The patient has voluntarily demonstrated the motivation and ability to participate in maintenance treatment for opioid use disorder.
- The patient is currently on a dose of 8 to 24 mg per day of a buprenorphine transmucosal formulation for seven or more days.
- The treating practitioner's completed order/treatment plan/procedure note for buprenorphine implant, including the practitioner's current CA medical license, regular DEA registration control number and special SAHMSA waiver DEA identification number.

Required Codes

One of the following ICD-10-CM diagnosis codes is required for reimbursement:

F11.20 (opioid dependence, uncomplicated)

F11.21 (opioid dependence, in remission)

F11.24 (opioid dependence with opioid-induced mood disorder)

F11.250 (opioid dependence with opioid-induced psychotic disorder with delusions)

F11.251 (opioid dependence with opioid-induced psychotic disorder with hallucinations)

F11.259 (opioid dependence with opioid-induced psychotic disorder, unspecified)

F11.281 (opioid dependence with opioid-induced sexual dysfunction)

F11.282 (opioid dependence with opioid-induced sleep disorder)

F11.288 (opioid dependence with other opioid-induced disorder)

F11.29 (opioid dependence with unspecified opioid-induced disorder)

Billing

HCPCS code J0570 (buprenorphine implant, 74.2 mg)

One (1) unit of J0570 = a single 74.2 mg-buprenorphine implant

Rolapitant

Rolapitant is a substance P/neurokinin 1 (NK1) receptor antagonist indicated in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.

Dosage

The recommended dosage is 180 mg rolapitant administered approximately one to two hours prior to the start of chemotherapy in patients 18 years of age and older. Administer dosage in combination with dexamethasone and a 5-hydroxytryptamine₃ (5-HT₃) receptor antagonist.

Required Code

ICD-10-CM diagnosis code R11.2

Billing

HCPCS code J8670 (rolapitant, oral, 1 mg)

Aminolevulinic Acid 10% Gel

Aminolevulinic acid 10% gel, is a porphyrin precursor, used in combination with photodynamic therapy using BF-RhodoLED lamp. Photoactivation following topical application of Ameluz[®] occurs when aminolevulinic acid (prodrug) is metabolized to protoporphyrin IX (PpIX), a photoactive compound which accumulates in the skin. When exposed to red light of a suitable wavelength and energy, PpIX is activated resulting in an excited state of porphyrin molecules. In the presence of oxygen, reactive oxygen species are formed which causes damage to cellular components, and eventually destroys the cells.

Indication

Aminolevulinic acid 10% gel is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp for patients 18 years of age and older.

Dosage

Administer Ameluz only by a health care provider.

- Ameluz is for topical use only
- Photodynamic therapy with Ameluz involves preparation of lesions, application of the product, occlusion and illumination with BF-RhodoLED.
- Retreat lesions that have not completely resolved 3 months after the initial treatment
- See BF-RhodoLED user manual for detailed lamp safety and operating instructions

Authorization

A TAR is required for reimbursement.

Required Codes

ICD-10-CM diagnosis code L57.0

Billing

HCPCS code J7345 (aminolevulinic acid HCl for topical administration, 10% gel, 10 mg)

«Cinacalcet tablets (Sensipar®)

Sensipar is an oral calcimimetic medication that lowers the levels of parathyroid hormone (PTH), phosphorous and calcium in patients undergoing kidney dialysis or in patients with parathyroid cancer. The calcium-sensing receptor on the surface of the chief cell of the parathyroid gland is the principal regulator of PTH synthesis and secretion. Cinacalcet, the active ingredient in Sensipar, directly lowers PTH levels by increasing the sensitivity of the calcium-sensing receptor to activation by extracellular calcium. The reduction in PTH is associated with a concomitant decrease in serum calcium levels.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

TAR Criteria

Sensipar will be considered medically necessary when the following criteria are met:

- Must be used for FDA approved indications and dosages
- Patient must be 18 years of age or older
- Patient must have a diagnosis of one of the following
 1. Secondary hyperparathyroidism (HPT) with chronic kidney disease (CKD) and is on dialysis
 - Current lab results show intact parathyroid hormone (iPTH) and serum calcium levels above the normal range
 2. Hypercalcemia with parathyroid carcinoma (PC)
 3. Hypercalcemia with primary hyperparathyroidism (HPT) and unable to undergo parathyroidectomy
 - Calcium > 12.5mg/dL
- Prescriber to monitor calcium levels periodically throughout therapy

Initial approval is for 6 months»

Continued therapy:

- Patient is responding positively to therapy as evidenced by a decrease in iPTH (for secondary HPT) or a decrease in serum calcium level (for PC or primary HPT); and
- Patient's serum calcium level is not less than the lower limit of normal

Reauthorization is for 12 months.

Age Limits

Must be 18 year of age or older

Billing

HPCS code, J0604, Cinacalcet, oral, 1mg, (for ESRD on dialysis)

Prescribing Restrictions

Frequency of billing = Every 24 hours

Maximum billing unit(s) = 360mg/360 units

«Esketamine nasal spray (Spravato®)

Esketamine, the S-enantiomer of racemic ketamine, is a non-selective, non-competitive antagonist of the N-methyl-D-aspartate (NMDA) receptor, an ionotropic glutamate receptor. The mechanism by which esketamine exerts its antidepressant effect is unknown. The major circulating metabolite of esketamine (noresketamine) demonstrated activity at the same receptor with less affinity.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages»»

«TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

TAR Criteria

The TAR must include clinical documentation that demonstrates all of the following:

- Must be used for FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Patient must have a diagnosis of one of the following:
 - Treatment-resistant depression (TRD)
 - Major depressive disorder (MDD) with acute suicidal ideation or behavior
- Diagnosis must be confirmed by baseline depression assessment using any validated rating scale
- Must be prescribed by or in consultation with a psychiatrist or other specialist in the treatment of the disease

A. Treatment-Resistant Depression (TRD)

Must meet the following criteria:

1. Diagnosis of Major Depressive Disorder (MDD) by Diagnostic and Statistical Manual of Mental Disorders (DSM-5) diagnostic criteria;
2. Patient must meet the DSM-5 diagnostic criteria for single-episode major depressive disorder (MDD) (if single-episode MDD, the duration must be two years or more) or recurrent MDD, without psychotic features, based upon clinical assessment.
3. Must have a documentation of inadequate response with a therapeutic trial of two or more antidepressants from different classes, given at adequate dose and duration (at least six weeks), including in the current depressive episode, unless contraindicated or clinically significant adverse effects are experienced. Inadequate response is defined as less than or equal to 25 percent reduction on Montgomery-Asberg Depression Rating Scale [MADRS] with minimum score greater than or equal to 28 for adults, or greater than or equal to 24 for geriatrics).»

4. «Must have a documented therapeutic trial (duration of at least six weeks) of antidepressant augmentation therapy in the current depressive episode with one or more of the following, unless contraindicated, clinically significant adverse effects are experienced, or patient is at high risk for suicidality:
 - I. Atypical antipsychotic
 - II. Lithium
 - III. Antidepressant from a different class used in the previous therapeutic trials
 - IV. Electroconvulsive therapy
 - V. Transcranial Magnetic Stimulation (TMS)

B. Depressive symptoms with major depressive disorder (MDD) with acute suicidal ideation or behavior.

Must meet the following criteria:

1. Patient has a severe depressive episode (cannot care for self, participate in life, has persistent thoughts of hopelessness, persistently sad, anxious or has an "empty" mood, thoughts of suicide, etc.)
2. Provider has attested that acute psychiatric hospitalization is clinically warranted due to patient's imminent risk of suicide

For both diagnoses

- Patient must have documentation of concurrent antidepressant therapy
- Prescriber must attest that:
 - An accessible treatment center certified in the Spravato Risk Evaluation and Mitigation Strategies (REMS) program has been identified
 - Dosing schedule has been reviewed with the patient
 - The patient understands and is committed to dosing schedule and requirements (e.g., treatment visits, transportation)
- Patient does not have any of the following conditions:
 - Pregnancy
 - History of psychotic disorder (including MDD with psychotic symptoms), bipolar disorder, obsessive-compulsive disorder, intellectual disability, autism, borderline personality disorder, dementia or intellectual disability.
 - Other major medical conditions including coronary artery disease.

Initial approval is for three months»»

«Continued therapy

- Patient continues to meet initial approval criteria
- Prescriber attestation of patient compliance with doses and treatment visits
- Attestation or documentation of clinical improvement as evidenced by improvement in the same validated rating scale used for baseline depression assessment
- Documentation of concurrent use of antidepressant

Reauthorization is for 12 months

REMS

Spravato is available through a Risk Evaluation and Mitigation Strategy (REMS) program to mitigate the risks of serious adverse outcomes resulting from sedation and dissociation caused by Spravato administration, and abuse and misuse of Spravato by ensuring that:

- Spravato is only dispensed and administered to patients in a medically supervised healthcare setting that monitors these patients.
- Ensuring pharmacies and healthcare settings that dispense Spravato are certified.
- Each patient is informed about the serious adverse outcomes resulting from sedation and dissociation and need for monitoring.
- All patients who receive treatment are enrolled in an outpatient healthcare setting in a registry to further characterize the risks and support safe use.

Age Limits

Must be 18 years of age or older

Billing

HCPCS code S0013 (esketamine, nasal spray, 1 mg)

Prescribing Restrictions

Frequency of billing = 84 mg / 84 units twice weekly

Maximum billing unit(s) = 84 mg/ 84 units»

Legend

Symbols used in the document above are explained in the following table.

Symbol	Description
«	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
»	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.