This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice, nor does it promise or guarantee coverage, levels of reimbursement, payment, or charge. Similarly, all CPT* and HCPCS codes are supplied for informational purposes only and represent no statement, promise, or guarantee by Janssen Pharmaceuticals, Inc., that these codes will be appropriate or that reimbursement will be made. The fact that a drug, device, procedure, or service is assigned a HCPCS code and payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs) and/or State Medicaid program administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.†‡ It is not intended to increase or maximize reimbursement by any payer. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. We strongly recommend you consult the payer organization for its reimbursement policies.

Important Safety Information
INVEGA® SUSTENNA® (paliperidone palmitate) is indicated for the treatment of:

- Schizophrenia.
- Schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers or antidepressants.

**IMPORTANT SAFETY INFORMATION FOR INVEGA® SUSTENNA® (paliperidone palmitate)**

**WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS.**

See full Prescribing Information for complete Boxed Warning

- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.
- INVEGA® SUSTENNA® is not approved for the treatment of patients with dementia-related psychosis.

**Contraindications:** Paliperidone is contraindicated in patients with a known hypersensitivity to either paliperidone, risperidone, or to any excipients of the formulation.

**Cerebrovascular Adverse Reactions:** Cerebrovascular adverse reactions (e.g., stroke, transient ischemic attacks), including fatalities, were reported in placebo-controlled trials in elderly patients with dementia-related psychosis taking oral risperidone, aripiprazole, and olanzapine. The incidence of cerebrovascular adverse reactions was significantly higher than with placebo. INVEGA® SUSTENNA® is not approved for the treatment of patients with dementia-related psychosis.

**Neuroleptic Malignant Syndrome (NMS):** NMS, a potentially fatal symptom complex, has been reported with the use of antipsychotic medications, including paliperidone. Clinical manifestations include muscle rigidity, fever, altered mental status, and evidence of autonomic instability (see full Prescribing Information). Management should include immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy, intensive symptomatic treatment and close medical monitoring, and treatment of any concomitant serious medical problems.

**QT Prolongation:** Paliperidone causes a modest increase in the corrected QT (QTc) interval. Avoid the use of drugs that also increase QTc interval and in patients with risk factors for prolonged QTc interval. Paliperidone should also be avoided in patients with congenital long QT syndrome and in patients with a history of cardiac arrhythmias. Certain circumstances may increase the risk of the occurrence of torsades de pointes and/or sudden death in association with the use of drugs that prolong the QTc interval.

**Tardive Dyskinesia (TD):** TD is a syndrome of potentially irreversible, involuntary, dyskinetic movements that may develop in patients treated with antipsychotic medications. The risk of developing TD and the likelihood that dyskinetic movements will become irreversible are believed to increase with duration of treatment and total cumulative dose, but can develop after relatively brief treatment at low doses. Elderly female patients appeared to be at increased risk for TD, although it is impossible to predict which patients will develop the syndrome. Prescribing should be consistent with the need to minimize the risk of TD (see full Prescribing Information). Discontinue drug if clinically appropriate. The syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn.

**Metabolic Changes:** Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and body weight gain. While all of the drugs in the class have been shown to produce some metabolic changes, each drug has its own specific risk profile.

- Hyperglycemia and Diabetes Mellitus: Hyperglycemia and diabetes mellitus, in some cases severe and associated with ketoacidosis, hyperosmolar coma or death, have been reported in patients treated with all atypical antipsychotics (APS). Patients starting treatment with APS who have or are at risk for diabetes mellitus should undergo fasting blood glucose testing at the beginning of and during treatment. Patients who develop symptoms of hyperglycemia during treatment should also undergo fasting blood glucose testing. All patients treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia. Some patients require continuation of anti diabetic treatment despite discontinuation of the suspect drug.

- Dyslipidemia: Undesirable alterations have been observed in patients treated with atypical antipsychotics.

- Weight Gain: Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

See additional Important Safety Information on following page.

For more information on INVEGA® SUSTENNA® (paliperidone palmitate), click here for the full Prescribing Information, including Boxed WARNING.
Orthostatic Hypotension and Syncope: INVEGA® SUSTENNA® may induce orthostatic hypotension in some patients due to its alpha-blocking activity. INVEGA® SUSTENNA® should be used with caution in patients with known cardiovascular disease, cerebrovascular disease or conditions that would predispose patients to hypotension (e.g., dehydration, hypovolemia, treatment with antihypertensive medications). Monitoring should be considered in patients for whom this may be of concern.

Leukopenia, Neutropenia and Agranulocytosis have been reported with antipsychotics, including paliperidone. Patients with a history of clinically significant low white blood cell count (WBC) or drug-induced leukopenia/neutropenia should have frequent complete blood cell counts during the first few months of therapy. At the first sign of a clinically significant decline in WBC, and in the absence of other causative factors, discontinuation of INVEGA® SUSTENNA® should be considered. Patients with clinically significant neutropenia should be carefully monitored for fever or other symptoms or signs of infection and treated promptly if such symptoms or signs occur. Patients with severe neutropenia (absolute neutrophil count <1000/mm³) should discontinue INVEGA® SUSTENNA® and have their WBC followed until recovery.

Hyperprolactinemia: As with other drugs that antagonize dopamine D₂ receptors, INVEGA® SUSTENNA® elevates prolactin levels, and the elevation persists during chronic administration. Paliperidone has a prolactin-elevating effect similar to risperidone, which is associated with higher levels of prolactin elevation than other antipsychotic agents.

Potential for Cognitive and Motor Impairment: Somnolence, sedation, and dizziness were reported as adverse reactions in subjects treated with INVEGA® SUSTENNA®. INVEGA® SUSTENNA® has the potential to impair judgment, thinking, or motor skills. Patients should be cautioned about performing activities that require mental alertness such as operating hazardous machinery, including motor vehicles, until they are reasonably certain that INVEGA® SUSTENNA® does not adversely affect them.

Seizures: INVEGA® SUSTENNA® should be used cautiously in patients with a history of seizures or with conditions that potentially lower seizure threshold. Conditions that lower seizure threshold may be more prevalent in patients 65 years or older.

Administration: For intramuscular injection only by a healthcare professional. Care should be taken to avoid inadvertent injection into a blood vessel.

Drug Interactions: Strong CYP3A4/P-glycoprotein (P-gp) inducers: It may be necessary to increase the dose of INVEGA® SUSTENNA® when a strong inducer of both CYP3A4 and P-gp (e.g. carbamazepine, rifampin, St. John’s wort) is co-administered. Conversely, on discontinuation of the strong inducer, it may be necessary to decrease the dose of INVEGA® SUSTENNA®.

Pregnancy/Nursing: Patients should be advised to notify their physician if they become pregnant/intend to become pregnant or intend to nurse during treatment with INVEGA® SUSTENNA®.

Commonly Observed Adverse Reactions for INVEGA® SUSTENNA®: The most common adverse reactions in clinical trials in patients with schizophrenia (≥5% and twice placebo) were injection site reactions, somnolence/sedation, dizziness, akathisia and extrapyramidal disorder. No adverse events occurred at a rate of ≥5% and twice placebo during the long-term double-blind, placebo-controlled study in patients with schizoaffective disorder. The following adverse reactions occurred more frequently (a ≥2% difference vs. placebo) in the long-term study in patients with schizoaffective disorder: weight increased, nasopharyngitis, headache, hyperprolactinemia, and pyrexia.
RISPERDAL® CONSTA® (risperidone) long-acting injection is indicated for the treatment of schizophrenia and for the maintenance treatment of Bipolar I Disorder.

IMPORTANT SAFETY INFORMATION FOR RISPERDAL® CONSTA® (risperidone)

**WARNING: Increased Mortality in Elderly Patients with Dementia-Related Psychosis**

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. RISPERDAL® CONSTA® is not approved for the treatment of patients with dementia-related psychosis.

**Contraindications:** RISPERDAL® CONSTA® is contraindicated in patients with a known hypersensitivity to the product.

**Cerebrovascular Adverse Events (CAEs):** CAEs (e.g., stroke, transient ischemia attacks), including fatalities, were reported in placebo-controlled trials in elderly patients with dementia-related psychosis taking oral risperidone. The incidence of CAEs was significantly higher than with placebo. RISPERDAL® CONSTA® is not approved for the treatment of patients with dementia-related psychosis.

**Neuroleptic Malignant Syndrome (NMS):** NMS, a potentially fatal symptom complex, has been reported with the use of antipsychotic medications. Clinical manifestations include muscle rigidity, fever, altered mental status, and evidence of autonomic instability (see full Prescribing Information). Management should include immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy, intensive symptomatic treatment and close medical monitoring, and treatment of any concomitant serious medical problems.

**Tardive Dyskinesia (TD):** TD is a syndrome of potentially irreversible, involuntary, dyskinetic movements that may develop in patients treated with antipsychotic medications. The risk of developing TD and the likelihood that dyskinetic movements will become irreversible are believed to increase with duration of treatment and total cumulative dose, but can develop after relatively brief treatment at low doses. Elderly women patients appeared to be at increased risk for TD, although it is impossible to predict which patients will develop the syndrome. Prescribing should be consistent with the need to minimize the risk of TD (see full Prescribing Information). Discontinue drug if clinically appropriate. The syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn.

**Metabolic Changes:** Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and body weight gain. While all of the drugs in the class have been shown to produce some metabolic changes, each drug has its own specific risk profile.

- **Hyperglycemia and Diabetes Mellitus:** Hyperglycemia and diabetes mellitus, some cases extreme and associated with ketoacidosis, hyperosmolar coma or death have been reported in patients treated with atypical antipsychotics (APS), including RISPERDAL® CONSTA®. Patients starting treatment with APS who have or are at risk for diabetes mellitus should undergo fasting blood glucose testing at the beginning of and during treatment. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing. All patients treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia. Monitor glucose regularly in patients with diabetes or at risk for diabetes. Some patients require continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

- **Dyslipidemia:** Undesirable alterations have been observed in patients treated with atypical antipsychotics.

- **Weight Gain:** Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

See additional Important Safety Information on following page.

For more information on RISPERDAL® CONSTA® (risperidone), click here for the full Prescribing Information, including Boxed WARNING.
Hyperprolactinemia: As with other drugs that antagonize dopamine D₂ receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration. Risperidone is associated with higher levels of prolactin elevation than other antipsychotic agents.

Orthostatic Hypotension and Syncope: RISPERDAL® CONSTA® may induce orthostatic hypotension associated with dizziness, tachycardia, and in some patients, syncope, especially during the initial dose-titration period. RISPERDAL® CONSTA® should be used with caution in patients with known cardiovascular disease (e.g., heart failure, history of MI or ischemia, conduction abnormalities), cerebrovascular disease or conditions that would predispose patients to hypotension (e.g., dehydration, hypovolemia) and additionally elderly patients with renal or hepatic impairment. Monitoring should be considered in patients for whom this may be of concern.

Leukopenia, Neutropenia and Agranulocytosis have been reported with antipsychotics, including RISPERDAL® CONSTA®. Patients with a history of clinically significant low white blood cell count (WBC) or drug-induced leukopenia/neutropenia should have frequent complete blood cell counts during the first few months of therapy. At the first sign of a clinically significant decline in WBC, and in the absence of other causative factors, discontinuation of RISPERDAL® CONSTA® should be considered. Patients with clinically significant neutropenia should be carefully monitored for fever or other symptoms or signs of infection and treated promptly if such symptoms or signs occur. Patients with severe neutropenia (absolute neutrophil count <1000/mm³) should discontinue RISPERDAL® CONSTA® and have their WBC followed until recovery.

Potential for Cognitive and Motor Impairment: Somnolence was reported in multiple trials in subjects treated with RISPERDAL® CONSTA®. Since RISPERDAL® CONSTA® has the potential to impair judgment, thinking, or motor skills, patients should be cautioned about operating hazardous machinery, including motor vehicles, until they are reasonably certain that RISPERDAL® CONSTA® does not adversely affect them.

Seizures: RISPERDAL® CONSTA® should be used cautiously in patients with a history of seizures.

Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in patients with advanced Alzheimer’s dementia. Use cautiously in patients at risk for aspiration pneumonia.

Priapism has been reported. Severe priapism may require surgical intervention.

Thrombotic Thrombocytopenic Purpura (TTP) has been reported.

Administration: For intramuscular injection only. Care should be taken to avoid inadvertent injection into a blood vessel.

Suicide: The possibility of suicide attempt is inherent in schizophrenia or bipolar disorder. Close supervision of high-risk patients should accompany drug therapy.

Increased sensitivity in patients with Parkinson’s disease or those with dementia with Lewy bodies has been reported. Manifestations and features are consistent with NMS.

Use RISPERDAL® CONSTA® with caution in patients with conditions and medical conditions that could affect metabolism or hemodynamic responses (e.g., recent myocardial infarction or unstable cardiac disease).

Commonly Observed Adverse Reactions for RISPERDAL® CONSTA®: The most common adverse reactions in clinical trials in patients with schizophrenia (≥5%) were headache, Parkinsonism, dizziness, akathisia, fatigue, constipation, dyspepsia, sedation, weight increase, pain in extremities, and dry mouth. The most common adverse reactions in clinical trials in patients with bipolar disorder were weight increased (≥5% in monotherapy trial) and tremor and Parkinsonism (≤10% in adjunctive therapy trial).
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How to Use the Reimbursement and Billing Guide
How to Use the Reimbursement and Billing Guide

Janssen Pharmaceuticals, Inc. has developed this guide to assist providers in understanding coding, coverage, and payment of INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable and RISPERDAL® CONSTA® (risperidone) long-acting injection for key payers. This guide specifically applies to the following provider types:

- Physician offices
- Community Mental Health Centers (CMHCs)
- Hospital inpatient departments
- Hospital outpatient departments
- Partial hospitalization programs where the CMS-1450 (UB-04) Claim Form is used

Using the Reimbursement and Billing Guide

The Reimbursement and Billing Guide is intended to help you navigate through the reimbursement process for INVEGA® SUSTENNA® and RISPERDAL® CONSTA®. The guide begins with a general introduction to government (Medicare and Medicaid) and private payer reimbursement concepts specific to physician-administered therapies. An important first step to initiating INVEGA® SUSTENNA® or RISPERDAL® CONSTA® therapy is identifying the patient’s benefits. An initial benefit verification will identify the following:

- Coverage for INVEGA® SUSTENNA® and/or RISPERDAL® CONSTA®
- Prior authorization requirements
- General coding information
- Patient co-pay and deductible information

The subsequent chapters are designed to provide INVEGA® SUSTENNA® and RISPERDAL® CONSTA® reimbursement information specific to each provider and payer type. You may refer to the chapter this guide that corresponds to the patient’s specific payer type for additional details. This guide also includes reimbursement tools that may be helpful for verifying benefits, submitting claims, and assisting with claims appeals.

Beyond the Reimbursement and Billing Guide

This guide represents one component of the reimbursement resources offered by Janssen. In its ongoing commitment to providers and patients, additional support is available through the Janssen CNS website, http://www.janssencns.com.
Overview
Reimbursement for INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable and RISPERDAL® CONSTA® (risperidone) long-acting injection differs from oral therapies primarily because they are injected by a healthcare professional rather than dispensed to the patient for self-administration. There are a number of factors that influence how payers will cover and pay for INVEGA® SUSTENNA® and RISPERDAL® CONSTA® including site of service, payer type, and benefit category.

Site of Service
Physician offices, Community Mental Health Centers (CMHCs), and hospital inpatient and outpatient departments are key sites of service for patients with severe mental illness. The term CMHC may encompass several different provider types. A CMHC may be an outpatient clinic similar to a physician’s office, but it may also act as a hospital outpatient department, pharmacy, or other unique provider. Understanding how the payer recognizes or classifies the CMHC is crucial for understanding how INVEGA® SUSTENNA® and RISPERDAL® CONSTA® will be covered and reimbursed.

In this guide, we discuss coverage and reimbursement for INVEGA® SUSTENNA® and RISPERDAL® CONSTA® and associated services provided in physician offices and CMHCs. We also discuss coverage and reimbursement for services performed in the hospital inpatient and outpatient departments, and in CMHCs providing partial hospitalization services.

Payer Type
The type of payer also determines how a therapy is covered. Coverage, as defined by each payer type and benefit package, will vary according to site of service, patient condition, and medical history. Most payers will cover therapies and medical services associated with mental illnesses in the CMHC or physician office setting.

Medicare: Medicare is an important payer for many patients with severe mental health diseases. Medicare is a federal program that provides health insurance coverage to qualified elderly and disabled individuals. However, there may be restrictions to coverage such as dose limitations, special requirements for distribution, and prior authorization. Be sure to verify the patient’s benefits to determine coverage levels and limitations.

Medicaid: For many individuals diagnosed with a mental illness, Medicaid is an important payer either as a primary or secondary source of coverage. Federal and state governments jointly administer the Medicaid program. Various groups of individuals such as the disabled, children, pregnant women, and those who have little income may be eligible for coverage. Medicaid coverage and payment for INVEGA® SUSTENNA® and RISPERDAL® CONSTA® varies by state. However, there may be restrictions to coverage such as dose limitations, special requirements for distribution, and prior authorization. Be sure to verify the patient’s benefits to determine coverage levels and limitations.

Private Payer: Private payers, including those that administer plans offered in the Marketplace, may cover INVEGA® SUSTENNA® and RISPERDAL® CONSTA® and the medical services associated with their administration. However, there may be restrictions to coverage such as dose limitations, special requirements for distribution, and prior authorization. Be sure to verify the patient’s benefits to determine coverage levels and limitations.

Benefit Category
Providers can obtain INVEGA® SUSTENNA® and RISPERDAL® CONSTA® for their patients in a variety of ways depending upon the patient’s insurance plan benefits. There are 2 benefit structures commonly used: medical and pharmacy. When providing care in a physician’s office or hospital, payers may cover physician-administered products like INVEGA® SUSTENNA® and RISPERDAL® CONSTA® through a medical (or pharmacy) benefit. CMHCs with partial hospitalization programs generally handle physician-administered products under the medical benefit. Contacting the payer directly is the best way to determine how the provider may obtain INVEGA® SUSTENNA® and RISPERDAL® CONSTA®. This may also be done as part of an insurance benefit verification. A benefit verification provides important reimbursement information such as benefit structure and coverage, and is typically performed prior to treatment. Benefit verifications should be conducted on a patient-specific basis.
Medical Benefit

If INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable or RISPERDAL® CONSTA® (risperidone) long-acting injection is covered as a medical benefit, as determined through a patient-specific benefit verification, providers may have 1 of 2 options for processing: buy-and-bill or specialty pharmacy. The more common approach to processing a medical benefit is “buy-and-bill”; however, both processes are explained below.

Buy-and-Bill

Simply stated, buy-and-bill means the provider purchases drugs from a distributor and bills the insurance company for those products. To acquire INVEGA® SUSTENNA® or RISPERDAL® CONSTA® using the buy-and-bill process, the provider will need to set up an agreement with the distributor to provide the drug. This can be done independent of a prescription for INVEGA® SUSTENNA® or RISPERDAL® CONSTA®.

When a patient has been identified for INVEGA® SUSTENNA® or RISPERDAL® CONSTA® therapy and the benefit verification specifies coverage under the medical benefit, the provider may then place an order for INVEGA® SUSTENNA® or RISPERDAL® CONSTA® from the distributor. The distributor will deliver the product directly to the site of care. Once the injection is administered, the provider may bill the patient’s insurer for the medication. In addition to the drug, the provider may also be able to bill for the administration procedure. Finally, the provider pays the distributor for the medication ordered.

Medical Benefit 6-Step Process:

1) Site verifies patient-specific benefits.
2) Site obtains benefits and potential medication coverage from the payer.
3) Site orders the drug from a distributor.*
   • INVEGA® SUSTENNA® or RISPERDAL® CONSTA® is available through a distributor of your choice.
   • Distributor ships drug to site (RISPERDAL® CONSTA® requires refrigeration during shipment, see full Prescribing Information for Storage and Handling [16]).
4) Appropriate healthcare provider administers the drug to the patient.
5) Site submits a claim to the payer for service(s) and for drug reimbursement.
   • Billing process varies by payer type.
6) Site pays distributor for the drug within their payment terms.

The site may also choose to obtain a benefit verification directly from the applicable payer(s) in addition to, or in lieu of, obtaining benefit verification through Janssen’s reimbursement support program.

* Must establish a distributor account.

Pharmacy Benefit: Obtaining the Drug Through a Specialty Pharmacy

If INVEGA® SUSTENNA® or RISPERDAL® CONSTA® is covered as a pharmacy benefit, or the payer requires that the drug be obtained through a specialty pharmacy as identified through a patient-specific benefit verification, both the provider and the pharmacy are part of the reimbursement process. The physician writes a prescription for INVEGA® SUSTENNA® or RISPERDAL® CONSTA® and orders the drug for the patient. The pharmacy fills the order and sends the drug to the physician, CMHC, or hospital outpatient department. The pharmacy bills the insurance company for the drug.
Pharmacies typically require patient demographic information, insurance policy information, and details specific to the drug being purchased including National Drug Code (NDC), quantity, strength, dosage, and supply (number of days or injections). Pharmacies generally submit these claims electronically. This process provides a notification of coverage as well as an advisement of the patient’s co-insurance and deductible responsibility. The healthcare professional administers the drug and may submit a claim for the administration procedure. The pharmacy submits the claim for the drug.

**Pharmacy Benefit 6-Step Process**

1. Site obtains the patient’s pharmacy benefits from the payer.
2. Healthcare provider writes the prescription.
3. Site calls or faxes the prescription to the pharmacy, and then the pharmacy ships drug to the site (RISPERDAL® CONSTA® (risperidone) long-acting injection requires refrigeration during shipment, see full Prescribing Information for Storage and Handling [16]).
4. Healthcare provider administers the drug to the patient.
5. Site submits a claim to the payer for service(s) reimbursement.
6. Specialty pharmacy submits the claim to the payer for the drug.

The site may also choose to obtain a benefit verification directly from the applicable payer(s) in addition to, or in lieu of, obtaining benefit verification through Janssen’s reimbursement support program.

**Benefit Verification**

A benefit verification provides patient-specific information regarding payer coverage. The benefit verification process provides research on a patient’s insurance plan and reimbursement for INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable or RISPERDAL® CONSTA® (risperidone) and associated services. The benefit verification is an important first step in initiating INVEGA® SUSTENNA® or RISPERDAL® CONSTA® therapy and is usually performed before INVEGA® SUSTENNA® or RISPERDAL® CONSTA® is ordered or prescribed. The benefit verification can provide valuable information that is specific to the site of service and may assist the physician, CMHC, or hospital with acquiring and submitting claims for INVEGA® SUSTENNA® or RISPERDAL® CONSTA®.
The Payers for INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable and RISPERDAL® CONSTA® (risperidone) long-acting injection
Overview

Medicare provides medical coverage for individuals 65 years of age and older, certain disabled individuals, and those diagnosed with end stage renal disease. Medicare is an important payer for eligible patients who may be receiving INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable or RISPERDAL® CONSTA® (risperdone) long-acting injection.

Inpatient departments typically are reimbursed for INVEGA® SUSTENNA® and RISPERDAL® CONSTA® under Medicare Part A (hospital insurance). Hospital outpatient departments and Medicare-certified CMHCs typically are reimbursed for INVEGA® SUSTENNA® and RISPERDAL® CONSTA® under the Medicare Part B (medical insurance) or Part C (Managed Medicare or Medicare Advantage) benefit. Physician offices and CMHCs classified as a physician’s office may be reimbursed for INVEGA® SUSTENNA® and RISPERDAL® CONSTA® and administration services under Part B or C. Medicare Part D is the prescription drug benefit that provides coverage for prescription medicines that are obtained through a pharmacy. The various parts of Medicare are outlined below:

Medicare Part A

Medicare Part A covers inpatient services in the following sites of care:

- Acute care and psychiatric hospitals
- In the home when provided by a home health agency or hospice organization
- Skilled nursing facility

Services provided in an inpatient hospital setting are covered and reimbursed under a Prospective Payment System (PPS) and are based on Diagnosis-Related Groups (DRGs). Drugs administered during a hospital stay are not covered separately, but are bundled into the payment based on the DRG. Medicare Part A services are billed to Medicare using a CMS-1450 (UB-04) Claim Form.

Medicare Part B

Medicare Part B is available for Medicare-eligible individuals and covers physician services and outpatient care including physician-administered (injected and infused) drugs and the services associated with administering those therapies. These drugs must be purchased and billed for by the healthcare provider. Medicare Part B covers drugs and biologics that are “incident to” a physician service and meet the following criteria:

- Defined as a drug or biologic
- Not usually self-administered
- Furnished by the physician
- Administered by the physician or a healthcare provider employed by and under the physician's personal supervision
- Reasonable and necessary for the diagnosis or treatment of an illness or injury and administered according to accepted standards of medical practice
- Not determined by the FDA to be less than effective

Additionally, Medicare Part B covers the following services:

- Certain outpatient hospital care
- Outpatient mental health care
- Clinical diagnostic services
- Certain home health services
- Partial hospitalization by CMHC

Healthcare providers purchase drugs covered under Medicare Part B and bill them along with any administration services to Medicare using a CMS-1500 Claim Form.
Medicare Part C (Medicare Advantage)

Medicare Part C, or Medicare Advantage, offers Medicare Parts A and B covered benefits through managed care plans. Medicare Advantage plans may also offer a prescription drug benefit under Medicare Part D. These plans are known as Medicare Advantage Prescription Drug plans (MA-PDs). The individual plan will determine how INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable and RISPERDAL® CONSTA® (risperidone) long-acting injection will be covered and reimbursed. Some plans may offer INVEGA® SUSTENNA® and RISPERDAL® CONSTA® under either the medical or pharmacy benefit or require prior authorization. Providers should refer to each patient’s policy to determine coverage.

Another type of MA-PD plan is a “Special Needs” plan. These plans also administer all of the beneficiary’s Medicare healthcare services. In addition, they provide more focused care for patients who may be institutionalized, are eligible for both Medicare and Medicaid, or who have chronic conditions.

Medicare Part D

Medicare Part D offers prescription drug coverage to Medicare beneficiaries. The Medicare Part D benefit is administered by private insurance plans that contract with the Centers for Medicare & Medicaid Services (CMS). Certain low-income beneficiaries are automatically enrolled in Part D plans whereas other Medicare beneficiaries must elect to enroll in a Part D plan.

The following factors may impact coverage and acquisition of INVEGA® SUSTENNA® and RISPERDAL® CONSTA® under Medicare Part D:

- **Formulary Inclusion**: Part D prescription drug plans may or may not include INVEGA® SUSTENNA® and RISPERDAL® CONSTA® on the formulary.
- **Quantity Limits**: Some plans may restrict the number of units of INVEGA® SUSTENNA® and RISPERDAL® CONSTA® allowed per month.
- **Prior Authorization**: Plans may require the physician or pharmacist to obtain prior authorization before approving the drug for coverage and payment.
- **Step Therapy**: Plans may require that other drugs or treatments be tried before covering and paying for INVEGA® SUSTENNA® and RISPERDAL® CONSTA®.
- **Tier Assignment**: The co-pay will vary depending on the plan structure and the tier on which INVEGA® SUSTENNA® and RISPERDAL® CONSTA® are placed. (Please refer to the dual-eligible section of this guide for more information on co-pays for this special population.)
Overview

Medicaid is a form of medical assistance that helps cover some or all of the costs of healthcare-related services for eligible individuals. Medicaid covers these basic groups: children and pregnant women, elderly individuals, and people with disabilities. Some states have also elected to extend coverage to non-disabled adults with limited incomes. States have some flexibility in terms of setting guidelines for eligibility, benefits, coverage, and payment policies under Medicaid. This typically includes coverage and reimbursement for all services related to INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable and RISPERDAL® CONSTA® (risperidone) long-acting injection.

States are required to cover certain benefits for Medicaid beneficiaries such as inpatient and outpatient hospital services, physician services, and periodic screening, diagnosis, and treatment of specific diseases. Optional benefits that are determined at the state level include prescription or pharmacy benefits, durable medical equipment, intermediate facility care, mental health services, clinic services, and prosthetic devices. Medicaid coverage and eligibility guidelines vary from state to state, and also vary according to a patient’s individual circumstances. For instance, INVEGA® SUSTENNA® and RISPERDAL® CONSTA® may be covered through the pharmacy benefit, medical benefit, or both, depending on program restrictions, so it is important to verify coverage and reimbursement through the individual state Medicaid office for each patient prescribed therapy with INVEGA® SUSTENNA® or RISPERDAL® CONSTA®. Generally, Medicaid recipients receiving INVEGA® SUSTENNA® or RISPERDAL® CONSTA® therapy will have one of several types of Medicaid described below.

Medicaid Eligibility and Pathways

There are various pathways for patients to qualify for Medicaid, as well as different levels of Medicaid eligibility and coverage. Understanding the type of Medicaid a patient has will be key for determining how the patient may be able to access INVEGA® SUSTENNA® or RISPERDAL® CONSTA®. For example, there are full benefit Medicaid beneficiaries who are deemed eligible by their state. There are also Medicare Part B beneficiaries who have limited income and resources and therefore qualify for supplemental coverage through their state Medicaid programs. It is also worth noting that some Medicare beneficiaries who also qualify for Medicaid may be automatically enrolled in Medicare’s Low-Income Subsidy (LIS). LIS is a program that helps to cover the costs associated with the Medicare Part D prescription drug benefit for those who qualify for the subsidy. For more information on LIS, please refer to the section in this billing guide that discusses Federal Poverty Levels (FPLs) and LIS eligibility.

Types of Medicaid Eligibility

Full Medicaid

Those who are considered to have “full” Medicaid do not have other supplemental insurance and receive their healthcare benefits only under the state Medicaid program. These Medicaid beneficiaries have met certain income and resource requirements. These individuals are often referred to as “categorically needy,” because they fall into a category of people, such as those applying for state assistance programs like welfare, who qualify automatically for Medicaid. Beneficiaries or their caregivers must apply for assistance through their state Medicaid offices. Once the application process is completed, beneficiaries are enrolled in the appropriate level or type of Medicaid program that best meets their needs.

Medically Needy

Medically needy patients qualify for Medicaid through special consideration. Typically, they have incomes that are too high to allow them to qualify for Medicaid under existing pathways, but they also have significant medical expenses. This program, which is optional and not offered in all states, requires beneficiaries to spend a certain portion of their income on their medical costs before they can be eligible for Medicaid. This amount is known as a “spend down.” Individuals who have met their spend down would be eligible for full Medicaid benefits. INVEGA® SUSTENNA® and RISPERDAL® CONSTA® may be covered and reimbursed under this program.
Dual-Eligible Patients and Low-Income Subsidy (LIS)

Patients who are eligible for both Medicare and Medicaid are referred to as dual eligible. There are different types of dual-eligible patients where Medicaid may cover some or all of their out-of-pocket Medicare cost share such as premiums, deductibles, and co-insurance. The state Medicaid offices determine which level or type of eligibility is most appropriate for the patient. Some dual-eligible patients may be automatically enrolled by their states into LIS, which provides assistance with Medicare Part D prescription drug plan premiums, deductibles, co-payments, and co-insurances. Those who are automatically eligible for LIS include “full benefit” dual eligibles, who have no Medicare cost share since Medicaid covers all of their Part B premiums, deductibles, and co-insurances; recipients of Supplemental Security Income (SSI) who also have Medicare; and those who participate in Medicare Savings Programs.

When filing claims for dual-eligible patients, Medicare will pay first and Medicaid will cover some or all of the difference, since Medicaid is considered to be a payer of last resort. The state Medicaid offices determine the level of eligibility. Individuals who are dually eligible may fall into one of the several categories listed below:

- **Full Benefit Dual-Eligible**: Full benefit dual-eligible patients are those who qualify for Medicare and full Medicaid coverage. As a result, they have no Medicare cost share due to their limited income and resources. These individuals are eligible for LIS and are automatically enrolled in a Medicare Part D plan.

- **Qualified Medicare Beneficiaries (QMBs)**: This program covers the beneficiary’s co-insurances, deductibles, and premiums under Medicare. The QMB’s full cost of therapy associated with INVEGA® SUSTENNA® (paliperidone palmitate) and RISPERDAL® CONSTA® (risperidone) may be covered.

- **Specified Low-Income Medicare Beneficiaries (SLMBs)**: The SLMB has limited Medicaid benefits. SLMB covers the Medicare Part B premium for those who qualify. The SLMB patient is responsible for other costs such as co-insurance associated with INVEGA® SUSTENNA® and RISPERDAL® CONSTA® or other therapies.

- **Qualified Individual 1 (QI)**: QI Medicaid covers the Medicare Part B premium for those who qualify. QI patients are responsible for other costs such as co-insurance.

**Medicaid: Medical Benefit (Buy-and-Bill)**

Physician offices and CMHCs that purchase and administer INVEGA® SUSTENNA® and RISPERDAL® CONSTA® in a physician’s office setting using their own provider number may typically bill separately for each of the following components:

- Injection/administration
- INVEGA® SUSTENNA®
- RISPERDAL® CONSTA®
- Other services, if separately identifiable from the injection administration

Since reimbursement processes vary significantly by payer type and state for Medicaid beneficiaries, it is important to thoroughly investigate and understand the individual patient’s insurance plan requirements prior to acquiring and administering INVEGA® SUSTENNA® and RISPERDAL® CONSTA®. For assistance with individual patient benefit information or questions regarding access to INVEGA® SUSTENNA® and RISPERDAL® CONSTA®, please visit [http://www.janssencns.com](http://www.janssencns.com).

**Medicaid: Pharmacy Benefit (Specialty Pharmacy)**

If INVEGA® SUSTENNA® and RISPERDAL® CONSTA® are covered as a pharmacy benefit under a patient’s Medicaid plan, the physician writes a prescription that is processed by a pharmacy (specialty, retail, or mail order). In these cases, the pharmacy is responsible for submitting the claim for INVEGA® SUSTENNA® and RISPERDAL® CONSTA®. However, the physician or CMHC may bill for administering the injection and other professional services provided. Some Medicaid programs have adopted Preferred Drug Lists (PDLs) as a means to control access to certain prescription drugs. Drugs not listed on a PDL may either require prior authorization or they may not be covered at all. For assistance with individual patient benefit information or questions regarding access to INVEGA® SUSTENNA® and RISPERDAL® CONSTA®, please visit [http://www.janssencns.com](http://www.janssencns.com).
Professional services administered by a healthcare provider are standard, covered benefits for most private commercial insurance plans, including those offered through the Marketplace. These private plans will have varying benefit designs and coverage restrictions. Patient co-insurance and deductible requirements can vary dramatically by plan. There may be restrictions to coverage such as quantity limitations, special requirements for distribution, and prior authorization. Additionally, private plans or managed care plans may restrict patient access to certain hospitals or facilities and require the use of in-network providers. Be sure to verify the patient’s benefits by site of service to determine coverage levels and limitations.

INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable and RISPERDAL® CONSTA® (risperidone) long-acting injection may be covered through a pharmacy benefit, medical benefit, or both, depending on a plan’s policies, requirements, and restrictions.

**Private Payer: Medical Benefit (Buy-and-Bill)**

When covered as a medical benefit, physicians, CMHCs, and hospitals will purchase INVEGA® SUSTENNA® and RISPERDAL® CONSTA® from a distributor and bill the payer for the cost of the drug. Providers typically may bill separately for each of the following components:

- INVEGA® SUSTENNA®
- RISPERDAL® CONSTA®
- Injection/administration
- An office visit, if separately identifiable from the injection administration
- Other professional services that were provided, with supporting documentation

**Private Payer: Pharmacy Benefit (Specialty Pharmacy)**

If covered as a pharmacy benefit or if the payer requires the drug to be obtained through a specialty pharmacy, a prescription should be sent directly to the pharmacy. It is important to note that the payer may require prior authorization, have quantity limitations, or other utilization criteria. Be sure to verify the patient’s benefits to determine coverage levels and any restrictions or limitations. Although the pharmacy is responsible for submitting the claim for the drug when processed as a pharmacy benefit, the physician’s office, CMHC, or hospital outpatient clinic may bill for the administration of the drug and other professional services provided.
Coverage for INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable and RISPERDAL® CONSTA® (risperidone) long-acting injection
Coverage for therapies is determined by factors including payer type, site of service, and payer clinical guidelines. Medicare, Medicaid, and private insurers typically cover INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable and RISPERDAL® CONSTA® (risperidone) long-acting injection as a therapy option for patients who are identified as appropriate candidates for treatment. Medicare and Medicaid cover patients who are eligible for those respective programs. Private payers provide coverage for therapies such as INVEGA® SUSTENNA® and RISPERDAL® CONSTA® based on the patient’s diagnosis, the specific benefits offered by the plan, and additional documentation that may be required to support medical necessity. See previous sections on Medicare, Medicaid, and Private Payers.

**Medicare Coverage**

Generally, INVEGA® SUSTENNA® and RISPERDAL® CONSTA® are covered under the Medicare Part B benefit when it is administered in outpatient settings to patients eligible for traditional Medicare. (Please refer to the Medicare section of this guide for specific information on Medicare eligibility.) Prior to January 2010, Medicare allowed for a limited reimbursement for Part B services in connection with treatment of mental psychoneurotic and personality disorders. The limitation is called the outpatient mental health treatment limitation. The outpatient mental health treatment limitation limits Medicare payment for outpatient mental health services to 62.5% of covered expenses incurred in any calendar year. The 62.5% limitation has been in place since the inception of the Medicare Part B program. The Mental Health Parity and Addiction Equity Act of 2008 required coverage and reimbursement parity with other diagnoses by 2010. Effective January 1, 2010, through January 1, 2014, the limitation will be phased out. 15

**Medicaid Coverage**

Medicaid coverage and eligibility varies from state to state, and also varies according to the patient’s individual circumstances, so it is important to verify coverage and reimbursement through the individual state Medicaid office. INVEGA® SUSTENNA® and RISPERDAL® CONSTA® may be covered under the pharmacy benefit or medical benefit as previously described in the Medicaid section. (Please refer to the Medicaid section of this guide for specific information on Medicaid eligibility.)

**Private Payer Coverage**

Professional services are a standard, covered benefit for most private commercial insurers, although managed care plans will have varying network and coverage restrictions. Patient co-insurance and deductible requirements can vary dramatically by plan. There may be restrictions to coverage such as quantity limitations, special requirements for distribution, and prior authorization. Additionally, managed care organizations may require that patients go to certain hospitals or facilities that are within the plan’s network to receive care. Be sure to verify the patient’s benefits by site of service to determine coverage levels and limitations prior to initiating therapy with INVEGA® SUSTENNA® and RISPERDAL® CONSTA®.
Coding for INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable

This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice, nor does it promise or guarantee coverage, levels of reimbursement, payment, or charge. Similarly, all CPT* and HCPCS codes are supplied for informational purposes only and represent no statement, promise, or guarantee by Janssen Pharmaceuticals, Inc., that these codes will be appropriate or that reimbursement will be made. The fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs), and/or State Medicaid program administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.† It is not intended to increase or maximize reimbursement by any payer. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. We strongly recommend you consult the payer organization for its reimbursement policies.

General Coding Practices

It is important to submit accurate codes that reflect the patient’s condition, treatment, and services rendered on the claim form. Various coding systems describe a patient’s medical condition, as well as drugs administered and services rendered. Submitting inaccurate or incomplete codes may result in payment delays, claim denials, and incorrect payment levels. The vast majority of payers use nationally recognized code sets to report medical conditions, services, and drugs.

Healthcare Common Procedure Coding System (HCPCS)

Medicare requires the use of HCPCS codes to report physician-administered drugs. The type of code used will depend on the site of service.

Physician Office and Hospital Outpatient Department:

J2426, Injection, paliperidone palmitate, extended release, 1 mg

National Drug Code (NDC)

Although the National Drug Code (NDC) is usually reserved for billing by pharmacies, some private payers and the majority of Medicaid fee-for-service programs require an NDC for billing instead of, or in addition to, an HCPCS code, for physicians and other service providers as well. Although the FDA uses a 10-digit format when registering NDCs, payers often require an 11-digit NDC format on claim forms for billing purposes. It is important to confirm with your payer if the NDC is required and the format the payer requires. Payers, including some Medicaid fee-for-service programs, also require that healthcare providers report the quantity and unit of measure for each NDC. Guidelines for reporting the NDC in the appropriate format, quantity, and unit of measure vary by state and by payer, and should be reviewed prior to submitting a claim. Contact your local Medicaid office for more information on correct billing and claims submission.

Each package size and strength of INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable has a unique 10-digit NDC. To convert the 10-digit NDC registered with the FDA to an 11-digit NDC, your payer may require that a leading 0 or an asterisk (*) be added to the first position in the middle set of numbers. For example, the 10-digit NDC for INVEGA® SUSTENNA®, 50458-560-01, which has a 5-3-2 format, can be converted to the following 11-digit 5-4-2 format, 50458-0560-01.
National Drug Code (NDC)\textsuperscript{17}, continued

The 10-digit NDCs and one possible 11-digit alternative NDC format for INVEGA\textsuperscript{®} SUSTENNA\textsuperscript{®} (paliperidone palmitate) extended-release injectable products are listed in Table 1.

<table>
<thead>
<tr>
<th>NDCs for INVEGA\textsuperscript{®} SUSTENNA\textsuperscript{®} (paliperidone palmitate) products</th>
<th>FDA-specified 10-digit NDC (5-3-2 format)</th>
<th>11-digit NDC (5-4-2 format)</th>
</tr>
</thead>
<tbody>
<tr>
<td>39-mg INVEGA\textsuperscript{®} SUSTENNA\textsuperscript{®} (paliperidone palmitate) kit</td>
<td>50458-560-01</td>
<td>50458-0560-01</td>
</tr>
<tr>
<td>78-mg INVEGA\textsuperscript{®} SUSTENNA\textsuperscript{®} (paliperidone palmitate) kit</td>
<td>50458-561-01</td>
<td>50458-0561-01</td>
</tr>
<tr>
<td>117-mg INVEGA\textsuperscript{®} SUSTENNA\textsuperscript{®} (paliperidone palmitate) kit</td>
<td>50458-562-01</td>
<td>50458-0562-01</td>
</tr>
<tr>
<td>156-mg INVEGA\textsuperscript{®} SUSTENNA\textsuperscript{®} (paliperidone palmitate) kit</td>
<td>50458-563-01</td>
<td>50458-0563-01</td>
</tr>
<tr>
<td>234-mg INVEGA\textsuperscript{®} SUSTENNA\textsuperscript{®} (paliperidone palmitate) kit</td>
<td>50458-564-01</td>
<td>50458-0564-01</td>
</tr>
</tbody>
</table>

Please contact your payer to determine the appropriate format for submitting the NDC on a claim form submitted to that payer.

**Intramuscular Injection Procedure**

To report the administration of an intramuscular injection of INVEGA\textsuperscript{®} SUSTENNA\textsuperscript{®}, the following Current Procedural Terminology (CPT\textsuperscript{*}) code may be appropriate:

\texttt{96372, Therapeutic, prophylactic, or diagnostic injection (specify material injected); subcutaneous or intramuscular}\textsuperscript{18}

A therapeutic, prophylactic, or diagnostic IV infusion or injection (other than hydration) is for the administration of substances/drugs. When fluids are used to administer the drug(s), the administration of the fluid is considered incidental hydration and is not separately reportable. These services typically require direct physician supervision for any or all purposes of patient assessment, provision of consent, safety oversight, and intra-service supervision of staff. Typically, such infusions require special considerations to prepare, dose or dispose of; require practice training and competency for staff who administer the infusions; and require periodic patient assessment with vital sign monitoring during the infusion. These codes are not intended to be reported by the physician in the facility setting.\textsuperscript{18}

To report services provided in the hospital, most payers use ICD-9-CM (International Classification of Diseases, 9th Revision, Clinical Modification) procedure codes on claims with dates of service (DOS) through September 30, 2015. Starting on DOS October 1, 2015, the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) code will be required on claims to payers that require the use of the ICD code set. The ICD-9-CM codes reported to payers on claims with DOS through September 30, 2015, and ICD-10-PCS codes to be used effective DOS October 1, 2015, are listed in Table 2 and Table 3.

<table>
<thead>
<tr>
<th>ICD-9-CM Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>99.29</td>
<td>Injection or infusion of other therapeutic or prophylactic substance</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10-PCS Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3E023GC</td>
<td>Introduction of Other Therapeutic Substance into Muscle, Percutaneous Approach</td>
</tr>
</tbody>
</table>

Diagnosis

Physician offices and CMHCs may use either International Classification of Diseases (ICD) or Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnosis code sets, as appropriate, to report the patient’s specific mental health disorder. Diagnosis codes should represent the diseases and conditions as supported by the patient’s medical record in the healthcare professional’s clinical judgment.

The International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) code is used on claims with dates of service (DOS) through September 30, 2015. Starting on DOS October 1, 2015, the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) code will be required on claims to payers that require the use of the ICD code set.

The diagnosis codes for mental health disorders have been updated in the DSM-5, as of May 2013. DSM-5 codes and descriptions should be used as required by the payer.

The full constellation of symptoms and the relevant diagnostic criteria should be consulted and are available in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5 or current version), where applicable.

Schizophrenia

ICD Code Set

In ICD-9-CM, schizophrenia is reported on claims to payers with a 5-digit code. The subtype of schizophrenia (disorganized, catatonic, paranoid, residual) is identified by the 4th digit, while the severity is identified by the 5th digit. Reporting with less than 5 digits renders the code invalid.

There are fewer codes for schizophrenia in the ICD-10-CM code set. ICD-10-CM no longer distinguishes the severity (chronic, subchronic, or w/w/o acute exacerbation) as does the 5th digit in ICD-9-CM. Multiple ICD-9-CM codes are mapped to one ICD-10-CM, e.g., simple and latent types of schizophrenia are now categorized under “other schizophrenia.”

The ICD-9-CM codes reported to payers on claims with DOS through September 30, 2015, and the ICD-10-CM codes to be used effective DOS October 1, 2015, are listed in Table 4, Table 5, Table 6, and Table 7.

ICD Codes for Schizophrenia

<table>
<thead>
<tr>
<th>ICD-9-CM Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>295.0x</td>
<td>Simple type</td>
</tr>
<tr>
<td>295.1x</td>
<td>Disorganized type</td>
</tr>
<tr>
<td>295.2x</td>
<td>Catatonic type</td>
</tr>
<tr>
<td>295.3x</td>
<td>Paranoid type</td>
</tr>
<tr>
<td>295.5x</td>
<td>Latent type</td>
</tr>
<tr>
<td>295.6x</td>
<td>Residual type</td>
</tr>
<tr>
<td>295.8x</td>
<td>Other specified</td>
</tr>
<tr>
<td>295.9x</td>
<td>Unspecified type</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10-CM Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>F20.0</td>
<td>Paranoid schizophrenia</td>
</tr>
<tr>
<td>F20.1</td>
<td>Disorganized schizophrenia</td>
</tr>
<tr>
<td>F20.2</td>
<td>Catatonic schizophrenia</td>
</tr>
<tr>
<td>F20.3</td>
<td>Undifferentiated schizophrenia</td>
</tr>
<tr>
<td>F20.5</td>
<td>Residual schizophrenia</td>
</tr>
<tr>
<td>F20.89</td>
<td>Other schizophrenia</td>
</tr>
<tr>
<td>F20.9</td>
<td>Unspecified schizophrenia</td>
</tr>
</tbody>
</table>

* In ICD-9-CM codes, the 5th digit “x” options include: 0=unspecified, 1=subchronic, 2=chronic, 3=subchronic with acute exacerbation, 4=chronic with acute exacerbation, and 5=in remission.

INVEGA® SUSTENNA® (paliperidone palmitate) is indicated for the treatment of schizophrenia and/or schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers or antidepressants.

The full constellation of symptoms and the relevant diagnostic criteria should be consulted and are available in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5 or current version), where applicable.
DSM Code Set

DSM-5 has eliminated the subtypes of schizophrenia previously used in DSM-IV as listed in Table 8 below. In DSM-5, two Criterion A symptoms are required (versus one required in DSM-IV), with one of them being delusions (DSM-5: 297.1), hallucinations (DSM-5: 292.82), or disorganized speech (DSM-5: 315.39). There is only one code in DSM-5 applicable to report schizophrenia on claims to payers as listed in Table 9 below.

DSM Codes for Schizophrenia

<table>
<thead>
<tr>
<th>ICD-9-CM Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>295.10</td>
<td>Disorganized type</td>
</tr>
<tr>
<td>295.20</td>
<td>Catatonic type</td>
</tr>
<tr>
<td>295.30</td>
<td>Paranoid type</td>
</tr>
<tr>
<td>295.60</td>
<td>Residual type</td>
</tr>
<tr>
<td>295.70</td>
<td>Schizoaffective disorder</td>
</tr>
<tr>
<td>295.80</td>
<td>Other specified</td>
</tr>
<tr>
<td>295.90</td>
<td>Unspecified type</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10-CM Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>F25.0</td>
<td>Bipolar type</td>
</tr>
<tr>
<td>F25.1</td>
<td>Depressive type</td>
</tr>
<tr>
<td>F25.8</td>
<td>Other schizoaffective disorders</td>
</tr>
<tr>
<td>F25.9</td>
<td>Schizoaffective disorder, unspecified</td>
</tr>
</tbody>
</table>

INVEGA® SUSTENNA® (paliperidone palmitate) is indicated for the treatment of schizophrenia and/or schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers or antidepressants.

The full constellation of symptoms and the relevant diagnostic criteria should be consulted and are available in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5 or current version), where applicable.
Coding for Other Services
In addition to billing for INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable and its administration, physicians, CMHCs, and hospital outpatient clinics may bill for other types of services provided to the patient as documented in the medical record. Rules regarding coverage and payment for services provided in any given patient encounter vary according to the payer (including when it is not appropriate to bill for services provided in the same visit) and should be verified prior to submitting claims. The following section offers examples of services that may be provided in addition to an injection of INVEGA® SUSTENNA®.

Evaluation and Management Services
In some instances a physician, CMHC, or hospital outpatient clinic may also bill for an Evaluation and Management (E/M) or office visit in addition to the drug and drug administration service. The separate service must be clearly documented in the patient’s medical record. Selection of an E/M code may be based on the following criteria:

- Patient status (new or established)
- Site of service
- Level of history taken
- Level of exam performed
- Complexity of medical decision-making required
- Time spent directly with the patient

Physician offices and CMHCs should ensure they have a copy of the CPT* Manual from the AMA in order to ensure selection of the correct E/M code for each visit. Please refer to Table 10 on the following pages.

Table 10: Examples of E/M codes for established patients seen in the physician’s office, CMHC, or hospital outpatient clinic.\textsuperscript{18}

<table>
<thead>
<tr>
<th>E/M Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>99211</td>
<td>Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified healthcare professional. Usually, the presenting problem(s) are minimal. Typically, 5 minutes are spent performing or supervising these services.</td>
</tr>
</tbody>
</table>
| 99212    | Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components:  
• A problem-focused history.  
• A problem-focused examination.  
• Straightforward medical decision-making.  
Counseling and/or coordination of care with other physicians, other qualified healthcare professionals, or agencies are provided consistent with the nature of the problem(s) and the patient’s family’s needs. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family. |
| 99213    | Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components:  
• An expanded problem-focused history.  
• An expanded problem-focused examination.  
• Medical decision-making of low complexity.  
Counseling and/or coordination of care with other physicians, other qualified healthcare professionals, or agencies are provided consistent with the nature of the problem(s) and the patient’s family’s needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent face-to-face with the patient and/or family. |
| 99214    | Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components:  
• A detailed history.  
• A detailed examination.  
• Medical decision-making of moderate complexity.  
Counseling and/or coordination of care with other physicians, other qualified healthcare professionals, or agencies are provided consistent with the nature of the problem(s) and the patient’s family’s needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 25 minutes are spent face-to-face with the patient and/or family. |
| 99215    | Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components:  
• A comprehensive history.  
• A comprehensive examination.  
• Medical decision-making of high complexity.  
Counseling and/or coordination of care with other physicians, other qualified healthcare professionals, or agencies are provided consistent with the nature of the problem(s) and the patient’s family’s needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family. |

Modifier

When an E/M service is provided separately from a procedural service, a modifier may be used to identify a significant and separately identifiable service that must be attached to the E/M service:

-25, Significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service

Revenue Codes

Revenue codes categorize hospital services by revenue center. These codes are used for reporting purposes to capture cost data. For many payers, claims must include revenue codes for each service provided in the hospital setting. A sample of revenue codes that may be relevant for the administration of INVEGA® SUSTENNA® (paliperidone palmitate) in the hospital setting is listed in Table 11:

<table>
<thead>
<tr>
<th>Revenue Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0250</td>
<td>General classification, Pharmacy</td>
</tr>
<tr>
<td>0510</td>
<td>Clinic</td>
</tr>
<tr>
<td>0636</td>
<td>Drugs requiring detailed coding</td>
</tr>
</tbody>
</table>

Please consult with your counsel or reimbursement specialist for any reimbursement or billing questions.

Place of Service (POS) Codes

Place of Service (POS) codes are required to designate where a service is rendered. For physician offices and non-certified CMHCs, the following POS code may be appropriate to report on the CMS-1500 Claim Form:

POS 11, Office, this code applies to physician offices or other sites that provide services to patients who do not require hospitalization.

For physician services performed in hospital outpatient clinics, the following POS codes may be appropriate to report on the CMS-1450 (UB-04) Claim Form:

POS 22, Outpatient hospital, this applies to outpatient sites of care where the patient is not required to be hospitalized or institutionalized.

POS 52, Psychiatric Facility–Partial Hospitalization, this code applies to qualified facilities for patients who do not require full-time hospitalization but do need partial hospitalization services.

POS 53, Community Mental Health Center, this code applies to CMHCs that meet specific qualifications to conduct partial hospitalization services.

Please see the POS guidance document published by CMS for additional information and descriptions associated with individual POS codes. Additional guidance can be accessed at: https://www.cms.gov/Medicare/Coding/place-of-service-codes/index.html
Claim Forms CMS-1500 and CMS-1450 (UB-04)

Healthcare providers in a physician’s office who treat Medicare beneficiaries are required to use version CMS-1500 (08/05). Institutional providers such as hospitals, skilled nursing facilities, hospice, and others who treat Medicare beneficiaries are required to use version CMS-1450 (UB-04). These claim forms are used by some Medicaid programs and payers in the private insurance industry as well. Please check with your private payers for their specific claim submission forms and processes.

National Provider Identifier

The NPI is a unique 10-digit identification number for each healthcare provider that is recognized by all health plans. Healthcare providers using a billing service or clearinghouse should work with them to ensure claims will be submitted correctly to their Medicare contractor.

Healthcare providers are responsible for selecting appropriate codes for any particular claim. All codes are subject to change. We strongly suggest that you consult your payer organization with regard to coding guidelines. This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While Janssen Pharmaceuticals, Inc., has made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it.

Electronic Claims Reporting Overview

Physicians and CMHCs should submit all electronic claims using Version 5010. Some of the key drug-specific fields in the electronic version 5010 and their coordinating location on the CMS-1500 and the CMS-1450 (UB-04) forms are listed in Table 12 and Table 13:

<table>
<thead>
<tr>
<th>Category</th>
<th>Example</th>
<th>Location on CMS-1500</th>
<th>Location on 5010</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HCPCS code</strong></td>
<td>J2426</td>
<td>Box 24D</td>
<td>Loop 2400, SV101-2</td>
</tr>
<tr>
<td><em><em>CPT</em> code</em>*</td>
<td>96372</td>
<td>Box 24D</td>
<td>Loop 2400, SV101-2</td>
</tr>
<tr>
<td><strong>Units</strong></td>
<td>39 (for 39-mg injection of INVEGA® SUSTENNA®)</td>
<td>Box 24G</td>
<td>Loop 2400, SV104</td>
</tr>
<tr>
<td><strong>ICD-9-CM/ICD-10-CM code</strong></td>
<td>295.01/F20.0</td>
<td>Box 21</td>
<td>Loop 2300, HI01-2</td>
</tr>
<tr>
<td><strong>Reserved for Local Use</strong></td>
<td>Payer requirements may vary</td>
<td>Box 19</td>
<td>Loop 2300, PWK01</td>
</tr>
</tbody>
</table>

Table 13: CMS-1450 (UB-04)

<table>
<thead>
<tr>
<th>Category</th>
<th>Example</th>
<th>Location on UB-04</th>
<th>Location on 5010</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HCPCS code</strong></td>
<td>J2426</td>
<td>Field 44</td>
<td>Loop 2400, SV202-2</td>
</tr>
<tr>
<td><em><em>CPT</em> code</em>*</td>
<td>96372</td>
<td>Field 44</td>
<td>Loop 2400, SV202-2</td>
</tr>
<tr>
<td><strong>Units</strong></td>
<td>39 (for 39-mg injection of INVEGA® SUSTENNA®)</td>
<td>Field 46</td>
<td>Loop 2400, SV205</td>
</tr>
<tr>
<td><strong>ICD-9-CM/ICD-10-CM code</strong></td>
<td>295.01/F20.0</td>
<td>Field 66</td>
<td>Loop 2300, HI01-2</td>
</tr>
<tr>
<td><strong>Revenue code</strong></td>
<td>Payer requirements may vary</td>
<td>Field 42</td>
<td>Loop 2400, SV201</td>
</tr>
</tbody>
</table>

Sample CMS-1500 Claim Form for INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable

**Box 21 – Diagnosis or Nature of Illness or Injury**
Enter the appropriate ICD code(s). Be sure to indicate the applicable ICD indicator (9 or 0) to identify which version of ICD codes is being reported.
Note: October 1, 2015 is the compliance date for healthcare providers to begin using the ICD-10-CM/PCS code sets. Claims for dates of service through September 30, 2015 should be reported using the ICD-9-CM code set.

**Box 24D – Procedures, Services, or Supplies**
Enter the appropriate HCPCS and CPT* codes. Example:
- J2426 (injection, paliperidone palmitate, extended release, 1 mg)
- 96372 Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular.

**Box 24G – Days or Units**
Enter the appropriate number of days or units. Note: One unit of J2426 is equal to 1 mg. Enter 39 units for 39 mg, 78 units for 78 mg, 117 units for 117 mg, 156 units for 156 mg, and 234 units for 234 mg.

Sample CMS-1450 (UB-04) Claim Form for INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable

**Field 46 – Service Units**
Enter the appropriate number of units. When billing for INVEGA® SUSTENNA®, list the number of units based on the milligram dose of the pre-filled syringe used, unless otherwise indicated by the payer.

Note: One unit of J2426 is equal to 1 mg. Enter 39 units for 39 mg, 78 units for 78 mg, 117 units for 117 mg, 156 units for 156 mg, and 234 units for 234 mg.

**Fields 42-44: Revenue Code, Description, HCPCS**
Enter the appropriate revenue code(s), and description relevant to the HCPCS code(s).

**Revenue Code Example:**
For Medicare, revenue code 0636 (drugs that require detailed coding) may be used. Non-Medicare payers may require revenue code 0250 (general pharmacy). Injection services may be reported with revenue code 0510 (clinic, general service). Check with your local contractor for specific guidance.

**HCPCS Drug Example:**
For Medicare, HCPCS code J2426, injection, paliperidone palmitate, extended release, 1 mg may be used.

**HCPCS Procedure Example:**
J0077 Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular.

**Field 66 – Diagnosis Code**
Enter appropriate ICD diagnosis code. Note: Enter the appropriate diagnosis as reflected in the patient’s medical record.
Coding for RISPERDAL® CONSTA® (risperidone) long-acting injection

This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice, nor does it promise or guarantee coverage, levels of reimbursement, payment, or charge. Similarly, all CPT* and HCPCS codes are supplied for informational purposes only and represent no statement, promise, or guarantee by Janssen Pharmaceuticals, Inc., that these codes will be appropriate or that reimbursement will be made. The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs), and/or State Medicaid program administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.† It is not intended to increase or maximize reimbursement by any payer. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. We strongly recommend you consult the payer organization for its reimbursement policies.

General Coding Practices

It is important to submit accurate codes that reflect the patient’s condition, treatment, and services rendered on the claim form. Various coding systems describe a patient’s medical condition, as well as drugs administered and services rendered. Submitting inaccurate or incomplete codes may result in payment delays, claim denials, and incorrect payment levels. The vast majority of payers use nationally recognized code sets to report medical conditions, services, and drugs.

Healthcare Common Procedure Coding System (HCPCS)

Medicare requires the use of HCPCS codes to report physician-administered drugs.

\[ \text{J2794, Injection, risperidone long-acting, 0.5 mg} \]

Note: J2794 is a fractional code representing a 0.5-mg unit. Because RISPERDAL® CONSTA® (risperidone) long-acting injection is available in 12.5-, 25-, 37.5-, and 50-mg doses, pay careful attention to the number of units indicated on the claim form. The following provides the unit dose with the corresponding number of units for RISPERDAL® CONSTA®:

<table>
<thead>
<tr>
<th>RISPERDAL® CONSTA®</th>
<th># of Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.5-mg injection</td>
<td>25</td>
</tr>
<tr>
<td>25-mg injection</td>
<td>50</td>
</tr>
<tr>
<td>37.5-mg injection</td>
<td>75</td>
</tr>
<tr>
<td>50-mg injection</td>
<td>100</td>
</tr>
</tbody>
</table>

National Drug Code (NDC)

Although the National Drug Code (NDC) is usually reserved for billing by pharmacies, some private payers and the majority of Medicaid fee-for-service programs require an NDC for billing instead of, or in addition to, an HCPCS code, for physicians and other service providers as well. Although the FDA uses a 10-digit format when registering NDCs, payers often require an 11-digit NDC format on claim forms for billing purposes. It is important to confirm with your payer if the NDC is required and the format the payer requires. Payers, including some Medicaid fee-for-service programs, also require that healthcare providers report the quantity and unit of measure for each NDC. Guidelines for reporting the NDC in the appropriate format, quantity, and unit of measure vary by state and by payer, and should be reviewed prior to submitting a claim. Contact your local Medicaid office for more information on correct billing and claims submission.

Each package size and strength of RISPERDAL® CONSTA® has a unique 10-digit NDC. To convert the 10-digit NDC registered with the FDA to an 11-digit NDC, your payer may require that a leading 0 or an asterisk (*) be added to the first position in the middle set of numbers. For example, the 10-digit NDC for RISPERDAL® CONSTA®, 50458-309-11, which has a 5-3-2 format, can be converted to the following 11-digit 5-4-2 format, 50458-0309-11.

The 10-digit NDCs and one possible 11-digit alternative NDC format for RISPERDAL® CONSTA® (risperidone) are listed in Table 1.

<table>
<thead>
<tr>
<th>NDCs for RISPERDAL® CONSTA® (risperidone) products</th>
<th>FDA-specified 10-digit NDC (5-3-2 format)</th>
<th>11-digit NDC (5-4-2 format)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.5-mg RISPERDAL® CONSTA® (risperidone)</td>
<td>50458-309-11</td>
<td>50458-0309-11</td>
</tr>
<tr>
<td>25-mg RISPERDAL® CONSTA® (risperidone)</td>
<td>50458-306-11</td>
<td>50458-0306-11</td>
</tr>
<tr>
<td>37.5-mg RISPERDAL® CONSTA® (risperidone)</td>
<td>50458-307-11</td>
<td>50458-0307-11</td>
</tr>
<tr>
<td>50-mg RISPERDAL® CONSTA® (risperidone)</td>
<td>50458-308-11</td>
<td>50458-0308-11</td>
</tr>
</tbody>
</table>

Please contact your payer to determine the appropriate format for submitting the NDC on a claim form submitted to that payer.
Intramuscular Injection Procedure

To report the administration of an intramuscular injection of Risperdal® Consta® (risperidone) long-acting injection, the following Current Procedural Terminology (CPT*) code may be appropriate:

96372, Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

A therapeutic, prophylactic, or diagnostic IV infusion or injection (other than hydration) is for the administration of substances/drugs. When fluids are used to administer the drug(s), the administration of the fluid is considered incidental hydration and is not separately reportable. These services typically require direct physician supervision for any or all purposes of patient assessment, provision of consent, safety oversight, and intra-service supervision of staff. Typically, such infusions require special considerations to prepare, dose or dispose of; require practice training and competency for staff who administer the infusions; and require periodic patient assessment with vital sign monitoring during the infusion. These codes are not intended to be reported by the physician in the facility setting.

To report services provided in the hospital, most payers use ICD-9-CM (International Classification of Diseases, 9th Revision, Clinical Modification) procedure codes on claims with dates of service (DOS) through September 30, 2015. Starting on DOS October 1, 2015, the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) code will be required on claims to payers that require the use of the ICD code set. The ICD-9-CM codes reported to payers on claims with DOS through September 30, 2015, and ICD-10-PCS codes to be used effective DOS October 1, 2015, are listed in Table 2 and Table 3.

Diagnosis

Physician offices and CMHCs may use either International Classification of Diseases (ICD) or Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnosis code sets, as appropriate, to report the patient’s specific mental health disorder. Diagnosis codes should represent the diseases and conditions as supported by the patient’s medical record in the healthcare professional’s clinical judgment.

The International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) code is used on claims with dates of service (DOS) through September 30, 2015. Starting on DOS October 1, 2015, the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) code will be required on claims to payers that require the use of the ICD code set. The diagnosis codes for mental health disorders have been updated in the DSM-5, as of May 2013. DSM-5 codes and descriptions should be used as required by the payer.

The full constellation of symptoms and the relevant diagnostic criteria should be consulted and are available in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5 or current version), where applicable.

Schizophrenia

ICD Code Set

In ICD-9-CM, schizophrenia is reported on claims to payers with a 5-digit code. The subtype of schizophrenia (disorganized, catatonic, paranoid, residual) is identified by the 4th digit, while the severity is identified by the 5th digit. Reporting with less than 5 digits renders the code invalid.

There are fewer codes for schizophrenia in the ICD-10-CM code set. ICD-10-CM no longer distinguishes the severity (chronic, subchronic, or w/w/o acute exacerbation) as does the 5th digit in ICD-9-CM. Multiple ICD-9-CM codes are mapped to one ICD-10-CM, eg, simple and latent types of schizophrenia are now categorized under “other schizophrenia.”

The ICD-9-CM codes reported to payers on claims with DOS through September 30, 2015, and the ICD-10-CM codes to be used effective DOS October 1, 2015, are listed in Table 4 and Table 5.

ICD Codes for Schizophrenia

<table>
<thead>
<tr>
<th>ICD-9-CM Code*</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>295.0x</td>
<td>Simple type</td>
</tr>
<tr>
<td>295.1x</td>
<td>Disorganized type</td>
</tr>
<tr>
<td>295.2x</td>
<td>Catatonic type</td>
</tr>
<tr>
<td>295.3x</td>
<td>Paranoid type</td>
</tr>
<tr>
<td>295.5x</td>
<td>Latent type</td>
</tr>
<tr>
<td>295.6x</td>
<td>Residual type</td>
</tr>
<tr>
<td>295.8x</td>
<td>Other specified</td>
</tr>
<tr>
<td>295.9x</td>
<td>Unspecified type</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10-CM Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>F20.0</td>
<td>Paranoid schizophrenia</td>
</tr>
<tr>
<td>F20.1</td>
<td>Disorganized schizophrenia</td>
</tr>
<tr>
<td>F20.2</td>
<td>Catatonic schizophrenia</td>
</tr>
<tr>
<td>F20.3</td>
<td>Undifferentiated schizophrenia</td>
</tr>
<tr>
<td>F20.5</td>
<td>Residual schizophrenia</td>
</tr>
<tr>
<td>F20.89</td>
<td>Other schizophrenia</td>
</tr>
<tr>
<td>F20.9</td>
<td>Unspecified schizophrenia</td>
</tr>
</tbody>
</table>

* In ICD-9-CM codes, the 5th digit "x" options include: 0=unspecified, 1=subchronic, 2=chronic, 3=subchronic with acute exacerbation, 4=chronic with acute exacerbation, and 5=in remission.

DSM Code Set

DSM-5 has eliminated the subtypes of schizophrenia previously used in DSM-IV as listed in Table 6 below. In DSM-5, two Criterion A symptoms are required (versus one required in DSM-IV), with one of them being delusions (DSM-5: 297.1), hallucinations (DSM-5: 292.82), or disorganized speech (DSM-5: 315.39). There is only one code in DSM-5 applicable to report schizophrenia on claims to payers as listed in Table 7 below.

DSM Codes for Schizophrenia

Table 6: DSM-IV Codes for Schizophrenia

<table>
<thead>
<tr>
<th>ICD-9-CM Code*</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>295.10</td>
<td>Disorganized type</td>
</tr>
<tr>
<td>295.20</td>
<td>Catatonic type</td>
</tr>
<tr>
<td>295.30</td>
<td>Paranoid type</td>
</tr>
<tr>
<td>295.60</td>
<td>Residual type</td>
</tr>
<tr>
<td>295.80</td>
<td>Other specified</td>
</tr>
<tr>
<td>295.90</td>
<td>Unspecified type</td>
</tr>
</tbody>
</table>

Table 7: DSM-5 Codes for Schizophrenia

<table>
<thead>
<tr>
<th>DSM-5 Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>295.90</td>
<td>Schizophrenia</td>
</tr>
</tbody>
</table>

RISPERDAL® CONSTA® (risperidone) long-acting injection is indicated for the treatment of schizophrenia and for the maintenance treatment of Bipolar I Disorder.

The full constellation of symptoms and the relevant diagnostic criteria should be consulted and are available in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5 or current version), where applicable.
Bipolar I

In ICD-9-CM, Bipolar I is reported on claims to payers with a 5-digit code. Reporting with less than 5 digits renders the code invalid. There are more codes used to report Bipolar I in the ICD-10-CM code set. “Manic” versus “hypomanic” episodes are reported with separate codes in ICD-10-CM.

The ICD-9-CM codes reported to payers on claims reported with DOS through September 30, 2015, and the ICD-10-CM codes to be used effective DOS October 1, 2015, are listed in Table 8 and Table 9.

ICD Codes for Bipolar I

Table 8: ICD-9-CM Codes for Bipolar I

<table>
<thead>
<tr>
<th>ICD-9-CM Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>296.05</td>
<td>Bipolar I disorder, single manic episode, in partial or unspecified remission</td>
</tr>
<tr>
<td>296.06</td>
<td>Bipolar I disorder, single manic episode, in full remission</td>
</tr>
<tr>
<td>296.15</td>
<td>Manic disorder, recurrent episode, in partial or unspecified remission</td>
</tr>
<tr>
<td>296.16</td>
<td>Manic disorder, recurrent episode, in full remission</td>
</tr>
<tr>
<td>296.45</td>
<td>Bipolar I disorder, most recent episode (or current) manic, in partial or unspecified remission</td>
</tr>
<tr>
<td>296.46</td>
<td>Bipolar I disorder, most recent episode (or current) manic, in full remission</td>
</tr>
<tr>
<td>296.55</td>
<td>Bipolar I disorder, most recent episode (or current) depressed, in partial or unspecified remission</td>
</tr>
<tr>
<td>296.56</td>
<td>Bipolar I disorder, most recent episode (or current) depressed, in full remission</td>
</tr>
<tr>
<td>296.65</td>
<td>Bipolar I disorder, most recent episode (or current) mixed, in partial or unspecified remission</td>
</tr>
<tr>
<td>296.66</td>
<td>Bipolar I disorder, most recent episode (or current) mixed, in full remission</td>
</tr>
</tbody>
</table>

* In ICD-9-CM codes, the 5th digit “x” options include: 0=unspecified, 1=subchronic, 2=chronic, 3=subchronic with acute exacerbation, 4=chronic with acute exacerbation, and 5=in remission.

Table 9: ICD-10-CM Codes for Bipolar I

<table>
<thead>
<tr>
<th>ICD-10-CM Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>F30.3</td>
<td>Manic episode in partial remission</td>
</tr>
<tr>
<td>F30.4</td>
<td>Manic episode in full remission</td>
</tr>
<tr>
<td>F31.70</td>
<td>Bipolar disorder currently in remission, most recent episode unspecified</td>
</tr>
<tr>
<td>F31.71</td>
<td>Bipolar disorder in partial remission, most recent episode hypomanic</td>
</tr>
<tr>
<td>F31.72</td>
<td>Bipolar disorder in full remission, most recent episode hypomanic</td>
</tr>
<tr>
<td>F31.73</td>
<td>Bipolar disorder in partial remission, most recent episode manic</td>
</tr>
<tr>
<td>F31.74</td>
<td>Bipolar disorder in full remission, most recent episode manic</td>
</tr>
<tr>
<td>F31.75</td>
<td>Bipolar disorder, in partial remission, most recent episode depressed</td>
</tr>
<tr>
<td>F31.76</td>
<td>Bipolar disorder, in full remission, most recent episode depressed</td>
</tr>
<tr>
<td>F31.77</td>
<td>Bipolar disorder, in partial remission, most recent episode mixed</td>
</tr>
<tr>
<td>F31.78</td>
<td>Bipolar disorder, in full remission, most recent episode mixed</td>
</tr>
<tr>
<td>F31.9</td>
<td>Bipolar disorder, unspecified</td>
</tr>
</tbody>
</table>

Risperdal® Consta® (risperidone) long-acting injection is indicated for the treatment of schizophrenia and for the maintenance treatment of Bipolar I Disorder.

The full constellation of symptoms and the relevant diagnostic criteria should be consulted and are available in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5 or current version), where applicable.
There are fewer codes in DSM-5 compared to DSM-IV. The DSM-IV diagnoses describing “mixed” episodes are replaced with a new specifier “with mixed features.” Several conditions are now reported under “Other specified Bipolar I and related disorders.” The codes in DSM-IV and DSM-5 are applicable to report Bipolar I on claims to payers as listed in Table 10 and Table 11.

**DSM Codes for Bipolar I**

**Table 10: DSM-IV Codes for Bipolar I**

<table>
<thead>
<tr>
<th>DSM-IV Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>296.05</td>
<td>Bipolar I disorder, single manic episode, in partial remission</td>
</tr>
<tr>
<td>296.06</td>
<td>Bipolar I disorder, single manic episode, in full remission</td>
</tr>
<tr>
<td>296.45</td>
<td>Bipolar I disorder, most recent episode manic, in partial remission</td>
</tr>
<tr>
<td>296.46</td>
<td>Bipolar I disorder, most recent episode manic, in full remission</td>
</tr>
<tr>
<td>296.55</td>
<td>Bipolar I disorder, most recent episode depressed, in partial remission</td>
</tr>
<tr>
<td>296.56</td>
<td>Bipolar I disorder, most recent episode depressed, in full remission</td>
</tr>
<tr>
<td>296.65</td>
<td>Bipolar I disorder, most recent episode mixed, in partial remission</td>
</tr>
<tr>
<td>296.66</td>
<td>Bipolar I disorder, most recent episode mixed, in full remission</td>
</tr>
</tbody>
</table>

**Table 11: DSM-5 Codes for Bipolar I**

<table>
<thead>
<tr>
<th>DSM-5 Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>296.45</td>
<td>Bipolar I disorder, current or most recent episode manic, in partial remission</td>
</tr>
<tr>
<td>296.46</td>
<td>Bipolar I disorder, current or most recent episode manic, in full remission</td>
</tr>
<tr>
<td>296.55</td>
<td>Bipolar I disorder, current or most recent episode depressed, in partial remission</td>
</tr>
<tr>
<td>296.56</td>
<td>Bipolar I disorder, current or most recent episode depressed, in full remission</td>
</tr>
<tr>
<td>296.89</td>
<td>Other specified bipolar and related disorder</td>
</tr>
<tr>
<td>296.7</td>
<td>Bipolar I disorder, current or most recent episode, unspecified</td>
</tr>
</tbody>
</table>

**IMPORTANT:** October 1, 2015 is the compliance date for healthcare providers to begin using the ICD-10-CM/PCS code sets. ICD-10-CM uses 3 to 7 digits instead of the 3 to 5 used with ICD-9-CM, but the format of the codes is similar. ICD-10-PCS, for use in hospital inpatient settings only, also uses 7 alphanumeric digits instead of the 3 to 4 numeric digits used under ICD-9-CM procedure coding. For more information on the transition from ICD-9 to ICD-10 code sets, visit [http://www.cms.gov/Medicare/Coding/ICD10/index.html](http://www.cms.gov/Medicare/Coding/ICD10/index.html).

**RISPERDAL® CONSTA®** (risperidone) long-acting injection is indicated for the treatment of schizophrenia and for the maintenance treatment of Bipolar I Disorder.

The full constellation of symptoms and the relevant diagnostic criteria should be consulted and are available in the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5 or current version), where applicable.
Coding for Other Services

In addition to billing for RISPERDAL® CONSTA® (risperidone) long-acting injection and its administration, physicians, CMHCs, and hospital outpatient clinics may bill for other types of services provided to the patient. All services provided to the patient should be documented in the medical record. Rules regarding coverage and payment for services provided in any given patient encounter vary according to the payer (including when it is not appropriate to bill for services provided in the same visit) and should be verified prior to submitting claims. The following section offers examples of services that may be provided in addition to an injection of RISPERDAL® CONSTA®.

Evaluation and Management Services

In some instances a physician, CMHC, or hospital outpatient clinic may also bill for an Evaluation and Management (E/M) or office visit in addition to the drug and drug administration service. The separate service must be clearly documented in the patient’s medical record. Selection of an E/M code may be based on the following criteria:

• Patient status (new or established)
• Site of service
• Level of history taken
• Level of exam performed
• Complexity of medical decision-making required
• Time spent directly with the patient

Physician offices and CMHCs should ensure they have a copy of the CPT* Manual from the AMA in order to ensure selection of the correct E/M code for each visit. Please refer to Table 12 on the following page.

Table 12: Examples of E/M codes for established patients seen in the physician’s office, CMHC, or hospital outpatient clinic.18

<table>
<thead>
<tr>
<th>E/M Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>99211</td>
<td>Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified healthcare professional. Usually, the presenting problem(s) are minimal. Typically, 5 minutes are spent performing or supervising these services.</td>
</tr>
</tbody>
</table>
| 99212    | Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components:  
- A problem-focused history.  
- A problem-focused examination.  
- Straightforward medical decision-making.  
Counseling and/or coordination of care with other physicians, other qualified healthcare professionals, or agencies are provided consistent with the nature of the problem(s) and the patient’s family’s needs. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family. |
| 99213    | Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components:  
- An expanded problem-focused history.  
- An expanded problem-focused examination.  
- Medical decision-making of low complexity.  
Counseling and/or coordination of care with other physicians, other qualified healthcare professionals, or agencies are provided consistent with the nature of the problem(s) and the patient’s family’s needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent face-to-face with the patient and/or family. |
| 99214    | Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components:  
- A detailed history.  
- A detailed examination.  
- Medical decision-making of moderate complexity.  
Counseling and/or coordination of care with other physicians, other qualified healthcare professionals, or agencies are provided consistent with the nature of the problem(s) and the patient’s family’s needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 25 minutes are spent face-to-face with the patient and/or family. |
| 99215    | Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components:  
- A comprehensive history.  
- A comprehensive examination.  
- Medical decision-making of high complexity.  
Counseling and/or coordination of care with other physicians, other qualified healthcare professionals, or agencies are provided consistent with the nature of the problem(s) and the patient’s family’s needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family. |

Modifier

When an E/M service is provided separately from a procedural service, a modifier may be used to identify a significant and separately identifiable service that must be attached to the E/M service:

-25, Significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service

Revenue Codes

Revenue codes categorize hospital services by revenue center. These codes are used for reporting purposes to capture cost data. For many payers, claims must include revenue codes for each service provided in the hospital setting. A sample of revenue codes that may be relevant for the administration of RISPERDAL® CONSTA® (risperidone) long-acting injection in the hospital setting is listed in Table 13.

Please consult with your counsel or reimbursement specialist for any reimbursement or billing questions.

Place of Service (POS) Codes

Place of Service (POS) codes are required to designate where a service is rendered. For physician offices and noncertified CMHCs, the following POS code may be appropriate to report on the CMS-1500 Claim Form:

POS 11, Office, this code applies to physician offices or other sites that provide services to patients who do not require hospitalization.

For physician services performed in hospital outpatient clinics, the following POS codes may be appropriate to report on the CMS-1450 (UB-04) Claim Form:

POS 22, Outpatient hospital, this code applies to outpatient sites of care where the patient is not required to be hospitalized or institutionalized.

POS 52, Psychiatric Facility—Partial Hospitalization, this code applies to qualified facilities for patients who do not require full-time hospitalization but do need partial hospitalization services.

POS 53, Community Mental Health Center, this code applies to CMHCs that meet specific qualifications to conduct partial hospitalization services.

Please see the POS guidance document published by CMS for additional information and descriptions associated with individual POS codes. Additional guidance can be accessed at: https://www.cms.gov/Medicare/Coding/place-of-service-codes/index.html
Claim Forms CMS-1500 and CMS-1450 (UB-04)

Healthcare providers in a physician's office who treat Medicare beneficiaries are required to use version CMS-1500 (08/05). Institutional providers such as hospitals, skilled nursing facilities, hospices, and others who treat Medicare beneficiaries are required to use version CMS-1450 (UB-04). These claim forms are used by some Medicaid programs and payers in the private insurance industry as well. Please check with your private payers for their specific claim submission forms and processes.

National Provider Identifier

The NPI is a unique 10-digit identification number for each healthcare provider that is recognized by all health plans. Healthcare providers using a billing service or clearinghouse should work with them to ensure claims will be submitted correctly to their Medicare contractor.

Healthcare providers are responsible for selecting appropriate codes for any particular claim. All codes are subject to change. We strongly suggest that you consult your payer organization with regard to coding guidelines. This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While Janssen Pharmaceuticals, Inc., has made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it.

Electronic Claims Reporting Overview

Physicians and CMHCs should submit all electronic claims using Version 5010. Some of the key drug-specific fields in the electronic version 5010 and their coordinating location on the CMS-1500 and the CMS-1450 (UB-04) forms are listed in Table 14 and Table 15:

<table>
<thead>
<tr>
<th>Category</th>
<th>Example</th>
<th>Location on CMS-1500</th>
<th>Location on 5010</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCPCS code</td>
<td>J2794</td>
<td>Box 24D</td>
<td>Loop 2400, SV101-2</td>
</tr>
<tr>
<td>CPT* code</td>
<td>96372</td>
<td>Box 24D</td>
<td>Loop 2400, SV101-2</td>
</tr>
<tr>
<td>Units</td>
<td>25 (for 12.5-mg injection RISPERDAL® CONSTA®)</td>
<td>Box 24G</td>
<td>Loop 2400, SV104</td>
</tr>
<tr>
<td>ICD-9-CM/ICD-10-CM Code</td>
<td>296.05/F20.0</td>
<td>Box 21</td>
<td>Loop 2300, HI01-2</td>
</tr>
<tr>
<td>Reserved for Local Use</td>
<td>Payer requirements may vary</td>
<td>Box 19</td>
<td>Loop 2300, PWK01</td>
</tr>
</tbody>
</table>

Sample CMS-1500 Claim Form for Risperdal® Consta® (risperidone) long-acting injection

**Box 24G – Days or Units**
Enter the appropriate number of days or units.
Note: One unit of J2794 is equal to 0.5 mg. Enter 25 units for 12.5 mg, 50 units for 25 mg, 75 units for 37.5 mg, and 100 units for 50 mg.

**Box 24D – Procedures, Services, or Supplies**
Enter the appropriate HCPCS and CPT* codes. Example:
- J2794 (injection, risperidone, 0.5 mg)
- 96372 Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular.

**Box 21 – Diagnosis or Nature of Illness or Injury**
Enter the appropriate ICD code(s). Be sure to indicate the applicable ICD indicator (9 or 0) to identify which version of ICD codes is being reported.
Note: October 1, 2015 is the compliance date for healthcare providers to begin using the ICD-10-CM/PCS code sets. Claims for dates of service through September 30, 2015 should be reported using the ICD-9-CM code set.

Sample CMS-1450 (UB-04) Claim Form for Risperdal® Consta® (risperidone) long-acting injection

Field 66 – Diagnosis Code
Enter appropriate ICD diagnosis code.
Note: Enter the appropriate diagnosis as reflected in the patient’s medical record.

Field 46 – Service Units
Enter the appropriate number of units. When billing for Risperdal® Consta®, list the number of units based on the milligram dose of the pre-filled syringe used, unless otherwise indicated by the payer.
Note: One unit of J2794 is equal to 0.5 mg. Enter 25 units for 12.5 mg, 50 units for 25 mg, 75 units for 37.5 mg, and 100 units for 50 mg.

Fields 42-44: Revenue Code, Description, HCPCS
Enter the appropriate revenue code(s), and description relevant to the HCPCS code(s).
Revenue Code Example:
For Medicare, revenue code 0636 (drugs that require detailed coding) may be used. Non-Medicare payers may require revenue code 0510 (general pharmacy). Injection services may be reported with revenue code 0510 (clinical general service). Check with your local contractor for specific guidance.

HCPCS Drug Example:
For Medicare, HCPCS code J2794, injection, risperidone, 0.5 mg may be used.

HCPCS Procedure Example:
96372 Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular.

This document is provided for your guidance only.
Payment for INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable and RISPERDAL® CONSTA® (risperidone) long-acting injection

This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice, nor does it promise or guarantee coverage, levels of reimbursement, payment, or charge. Similarly, all CPT* and HCPCS codes are supplied for informational purposes only and represent no statement, promise, or guarantee by Janssen Pharmaceuticals, Inc., that these codes will be appropriate or that reimbursement will be made. The fact that a drug, device, procedure, or service is assigned an HCPCS code and a payment rate does not imply coverage by the Medicare and/or Medicaid program, but indicates only how the product, procedure, or service may be paid if covered by the program. Fiscal Intermediaries (FIs)/Medicare Administrative Contractors (MACs), and/or State Medicaid program administration determine whether a drug, device, procedure, or other service meets all program requirements for coverage.† It is not intended to increase or maximize reimbursement by any payer. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. We strongly recommend you consult the payer organization for its reimbursement policies.

Medicare Payment for INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable and RISPERDAL® CONSTA® (risperidone) long-acting injection

Manufacturers submit Average Sales Price (ASP) data to the Centers for Medicare & Medicaid Services (CMS) by specific deadlines following the end of each quarterly period. CMS uses this data to determine the Medicare reimbursement rate for the subsequent quarter. This results in a 2-quarter lag between the quarter in which the sales occur and the time when the sales are reflected in a revised reimbursement rate. For example, 1st quarter sales become the basis for 3rd quarter reimbursement. CMS publishes the most current ASP drug reimbursement data on its website. To identify the most current ASP pricing for J2426, INVEGA® SUSTENNA®, and J2794, RISPERDAL® CONSTA®, please visit the CMS website at [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2014ASPFiles.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2014ASPFiles.html) for information on the most current reimbursement rates.

Drug Administration Services

Medicare reimburses physicians and CMHCs for drug administration services based on the Medicare Physician Fee Schedule. For these services, payment includes the physician’s professional services as well as costs incurred in operating the office or clinic. The fee schedule is updated annually. Under Part B, Medicare typically pays 80% of the allowed amount and the patient is responsible for paying the remaining 20% of the allowed amount as part of the standard co-insurance.

Mental Health Treatment Limitation

Prior to January 2010, Medicare allowed for a limited reimbursement for Part B services in connection with treatment of mental psychoneurotic and personality disorders. The limitation is called the outpatient mental health treatment limitation. The outpatient mental health treatment limitation limits Medicare payment for outpatient mental health services to 62.5% of covered expenses incurred in any calendar year. The 62.5% limitation has been in place since the inception of the Medicare Part B program. The Mental Health Parity and Addiction Equity Act of 2008 required coverage and reimbursement parity with other diagnoses by 2010. As of January 1, 2014, the limitation has been phased out.15, 34

- January 1, 2010–December 31, 2011, the limitation percentage was 68.75%.
- January 1, 2012–December 31, 2012, the limitation percentage was 75%.
- January 1, 2013–December 31, 2013, the limitation percentage was 81.25%.
- January 1, 2014–onward, the limitation percentage is 100%.

* These are physician offices and CMHCs that are not Medicare-certified CMHCs.
Medicare Part D

If the patient obtains INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable or RISPERDAL® CONSTA® (risperidone) long-acting injection through Medicare Part D, the patient’s cost-sharing responsibilities will vary. The co-payment may vary depending on the tier in which INVEGA® SUSTENNA® or RISPERDAL® CONSTA® is placed and the plan structure. Also, some plans may have a deductible.

For patients who have Medicare Part D and are eligible for Medicare’s Low-Income Subsidy (LIS), their co-payments will vary depending on the level of the subsidy for which they qualify. The table below provides the co-payments, co-insurance, and deductibles for the different LIS levels.35

<table>
<thead>
<tr>
<th>Income</th>
<th>&lt;100% FPL*</th>
<th>&lt;135% FPL†</th>
<th>&lt;150% FPL*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deductible</td>
<td>None</td>
<td>None</td>
<td>$63</td>
</tr>
<tr>
<td>Patient Co-payment/Co-insurance</td>
<td>$1.20 generic/$3.60 other covered drugs</td>
<td>$2.55 generic/$6.35 other covered drugs</td>
<td>15% up to catastrophic limit</td>
</tr>
<tr>
<td>Catastrophic Coverage ($4,550)</td>
<td>No cost-sharing</td>
<td>No cost-sharing</td>
<td>$2.55 generic/$6.35 brand Co-pay above limit</td>
</tr>
</tbody>
</table>

Medicare Standard Benefit (2014)35

- Beneficiary pays the greater of 5% co-insurance or co-pays of $6.35 for brands and $2.55 for generics upon reaching catastrophic coverage (beneficiary has paid $4,550 out of pocket to reach catastrophic coverage).
- Beneficiary pays 47.5% (approximate max of $1,759.24) and manufacturers provide a 50% discount (approximate max of $1,845.76) on brand-name drugs through the donut hole. 100% of both contributions counts toward the $4,550 catastrophic limit.‡
- Beneficiary pays 25% co-insurance (max of $635).
- Beneficiary pays the $310 deductible.

* These are physician offices and CMHCs that are not Medicare-certified CMHCs.
† FPL – The federal poverty guidelines, more commonly referred to as the Federal Poverty Level (FPL), are issued each year by the U.S. Department of Health & Human Services (HHS).
‡ Patient cost sharing in the coverage gap is an estimate of costs for patients taking brand drugs. Patients cost share may vary depending on whether they are also taking generic drugs that are available at a 28% manufacturer discount.
Some dual eligibles—Medicare beneficiaries who also qualify for Medicaid coverage that supplements the costs of their Medicare Part B premiums and other cost shares—may be automatically enrolled by their states into LIS. Those who are automatically eligible for LIS include “full benefit” dual eligibles, who have no cost share since Medicaid pays all of their Part B costs; recipients of Supplemental Security Income (SSI) who also have Medicare; and those who participate in Medicare Savings Programs.13

Medicaid Payment
State Medicaid programs use a variety of methodologies to reimburse for physician and CMHC services. Reimbursement methodologies include payment based on fee schedules, discounted charges, or other predetermined rates. Drugs administered in the hospital outpatient setting may be reimbursed separately from professional services. Reimbursement for drugs may be based on the following:

- Wholesale Acquisition Cost (WAC)*
- Invoice cost
- A percentage of Average Sales Price (ASP)*

Actual reimbursement methodologies, payment amounts, and claim submission requirements vary according to each state. Physician offices and CMHCs should contact the Medicaid program for more information regarding state-specific coverage, payment, and billing requirements for INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable and RISPERDAL® CONSTA® (risperidone) long-acting injection.

Medicare/Medicaid: Dual-Eligibles Payment
With dual-eligible patients, services are paid first by Medicare, and the difference may be paid by Medicaid based on the patient’s status and the individual state’s requirement and payment limitations.12,14 For dual-eligible patients who access INVEGA® SUSTENNA® and RISPERDAL® CONSTA® through Medicare Part B, claims must be sent to Medicare first for processing, followed by Medicaid. For many payers including Medicaid, this process may be done automatically. Once Medicare has processed the claim, Medicare will automatically forward the claim to Medicaid for consideration of the remaining charges. However, in some states, the crossover process is not automatic. For these states, once Medicare has processed the claim, an Explanation of Benefits (EOB) is sent to the physician’s office or CMHC explaining how the claim was processed. The provider must then attach the EOB from the Medicare-processed claim to a new claim form to send to Medicaid. No additional action is needed from the physician or CMHC.

Please check with the individual state’s Medicaid program to determine how Medicaid processes claims sent first to a primary payer, such as Medicare.

* Please see Glossary for additional information on WAC and ASP.
For dual-eligible patients who access INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable and RISPERDAL® CONSTA® (risperidone) long-acting injection through Medicare Part B, Medicaid may consider paying all or a portion of the remaining co-insurance and deductible, but will always be the payer of last resort. Many Medicaid programs will only pay up to the Medicaid-allowed amount rather than the full Medicare Part B co-insurance. 12

**Private Payer Payment**

Private payers, also known as commercial insurance companies, reimburse healthcare providers based on individual contracts that are set up between the provider and the payer. Contracts vary in that some may automatically renew annually and others may have term lengths such as 3 years. Typically, healthcare providers have the option to renegotiate the terms and reimbursement of their individual managed care contracts. This differs from the payments offered by public payers (Medicare and Medicaid) where the terms are set by the government.

Private payers may reimburse services and drugs and associated services in a variety of ways including:

- Fee schedules
- Usual and customary charges
- Percentage of WAC* or ASP*
- Other contracted or pre-negotiated rate
- Percent of billed charges

* Please see Glossary for additional information on WAC and ASP.
Medicare

Medicare reimburses for hospital inpatient stays according to a prospective payment system that uses Medicare Severity Diagnosis Related Groups (MS-DRGs) to determine payment levels. The MS-DRG payment system is based on the level of resources typically required to treat patients with similar diagnoses, and undergoing similar procedures, regardless of the length of stay. All services and supplies provided during the admission, including surgical procedures and medications, are included in the MS-DRG reimbursement rate. Hospitals will receive one global MS-DRG payment per patient encounter, and INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable or RISPERDAL® CONSTA® (risperidone) long-acting injection will not be reimbursed separately.

Hospitals may use ICD-9-CM procedure code 99.29 on Medicare claims with dates of service through September 30, 2015, and ICD-10-PCS procedure code 3E023GC on Medicare claims with dates of service on or after October 1, 2015, to report injections of INVEGA® SUSTENNA® and RISPERDAL® CONSTA®. Reimbursement for injections of INVEGA® SUSTENNA® and RISPERDAL® CONSTA® is included in the MS-DRG payment; no separate or additional payment will be made for the drug. While the use of this code to report INVEGA® SUSTENNA® and RISPERDAL® CONSTA® injections will not have an immediate effect on reimbursement, reporting additional procedures may influence future payment levels associated with specific MS-DRGs. MS-DRG payment amounts are recalibrated over time to account for changes in new technologies. Therefore, hospitals should document all procedures and supplies provided to the patient with appropriate codes on the claim form.

Although no single MS-DRG specifies the injection of INVEGA® SUSTENNA® or RISPERDAL® CONSTA®, the following shows the most common MS-DRG associated with schizophrenia and/or Bipolar I Disorder:

885, Psychoses

Inpatient Patient Financial Responsibility

For inpatient hospital stays, Medicare patients are responsible for a fixed co-insurance amount per benefit period. A benefit period lasts up to 90 days. Patients have an additional lifetime reserve of 60 days that can be used if they are in a hospital stay that exceeds 90 days. Patients may be responsible for more than one co-insurance payment per year depending on how often they are admitted for inpatient services and the reason for the inpatient stay. The 2013 patient cost-share amounts were:

- $1,216.00 – deductible per benefit period, up to a 60-day stay.
- $304.00 – co-insurance per day for the 61st through 90th day, per benefit period.
- $608.00 – co-insurance per lifetime reserve day, up to 60 days.

The patient is responsible for all costs beginning on day 91, unless they have their 60 excess days. Patients have and may utilize up to the 60 excess days in their lifetime. Once they have exhausted the 60 excess days, the patient is responsible for all hospital costs after day 91 of any hospital stay. Medicare beneficiaries who have less than 40 quarters of Social Security credits may pay a monthly premium for inpatient coverage.

Inpatient Psychiatric Facility Prospective Payment System (IPF PPS)

Under the Inpatient Psychiatric Facility Prospective Payment System (IPF PPS), there is a lifetime maximum of 190 days on inpatient psychiatric hospital services available to any beneficiary. Therefore, once an individual receives benefits for 190 days of care in a psychiatric hospital, no further benefits of that type are available to that individual. The psychiatric benefit application (190 days) applies to freestanding psychiatric hospitals and certain psychiatric-certified distinct part units.

Specialty Psychiatric Hospital Limitation

For those patients admitted to a specialty psychiatric hospital, Medicare helps pay up to 190 days of inpatient care in a Medicare-certified psychiatric facility, per lifetime. Medicare-certified psychiatric facilities are reimbursed according to actual costs rather than an MS-DRG like other types of hospitals. INVEGA® SUSTENNA® and RISPERDAL® CONSTA® should be reported separately in these facilities. Payment will be affected.
Medicaid

Medicaid law requires that each state pay for inpatient hospital and long-term care services. Medicaid payment for inpatient services rendered in general or psychiatric hospitals varies by state agency but is subject to maximum allowable cost-sharing limits for Medicaid patients. The states are required to set rates that are reasonable and adequate.

Institution for Mental Diseases (IMD)/Intermediate Care Facility for the Mentally Retarded (ICF/MR)

An IMD is a facility of more than 16 beds in which at least 50% of the residents have a primary diagnosis of a mental illness. An ICF/MR is a public or private facility whose primary purpose is to provide health or rehabilitative services to individuals with mental retardation or related conditions. These facilities are classified as medical institutions as defined by CMS and they are mandated to provide access to covered Part D drugs through their long-term care pharmacy network. Therefore, enrollees of IMDs and ICF/MRs who exhaust their Medicare Part A benefit should have the ability to access their Part D benefit while residing in these long-term care facilities.

In some states, licensing laws preclude facilities from obtaining prescription drugs and long-term care services for their residents from anyone but the facility’s in-house pharmacy. CMS clarifies that states may not be able to agree to certain standard clauses in some long-term care contracts. Based on each state’s criteria, there may be variance in how the facility is contracted with long-term care pharmacies. Each facility can be contacted to determine their long-term care pharmacy contract status.

Private Payers

Payment methods used by private payers vary. Many private payers use a payment method in which most or all services, supplies, and medications are included in one global rate. Some commercial and managed care plans reimburse inpatient services based on case rates, “Usual, Customary, and Reasonable” (UCR) charges, discounted charges, or per diem rates. If a payer uses case rates, these are usually based on modified MS-DRGs, and there is no separate payment provided for drugs regardless of method of administration. However, some payers reimburse separately for drugs and other ancillary services provided in the hospital inpatient setting.
Medicare

Hospital Outpatient and Ambulatory Payment Classifications (APCs)

Under Medicare’s Hospital Outpatient Prospective Payment System (OPPS), most services are reimbursed based on groups of procedures known as Ambulatory Payment Classifications (APCs). The various procedures within an APC group are clinically similar and comparable in terms of resource consumption. Payment rates associated with each APC group are set on a prospective, or fixed, basis.44

INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable

In 2014, Medicare will reimburse INVEGA® SUSTENNA® separately based on Average Sales Price (ASP) + 6% when provided in the hospital outpatient setting.45 Because these rates can vary, it is important to consult with your local contractor regarding the most current reimbursement rate.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Maps to APC</th>
<th>Description</th>
<th>Status Indicator</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>96372</td>
<td>0436</td>
<td>Therapeutic, prophylactic or diagnostic injection; subcutaneous or intramuscular</td>
<td>S*</td>
<td>N/A</td>
</tr>
<tr>
<td>J2426</td>
<td>9255</td>
<td>INVEGA® SUSTENNA® Injection, paliperidone palmitate, extended release, 1 mg</td>
<td>K†</td>
<td>39 mg, 78 mg, 117 mg, 156 mg, 234 mg</td>
</tr>
</tbody>
</table>

* Status indicator “S” denotes an ancillary procedure that is reimbursed separately.
† Status indicator “K” denotes a “non pass through” drug or biologic that is reimbursed separately.
Note: Medicare allowables for the HCPCS codes listed above can be found using the CMS physician fee schedule RVU files.46

RISPERDAL® CONSTA® (risperidone) long-acting injection

In 2014, Medicare will reimburse RISPERDAL® CONSTA® separately based on Average Sales Price (ASP) + 6% when provided in the hospital outpatient setting.41 Manufacturers submit ASP data to CMS by specific deadlines following the end of each quarterly period. CMS uses this data to determine the Medicare reimbursement rate for the subsequent quarter. This results in a 2-quarter lag between the quarter in which the sales occur and the time when the sales are reflected in a revised reimbursement rate. For example, 1st-quarter sales become the basis for 3rd-quarter reimbursement.32

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Maps to APC</th>
<th>Description</th>
<th>Status Indicator</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>96372</td>
<td>0437</td>
<td>Therapeutic, prophylactic or diagnostic injection; subcutaneous or intramuscular</td>
<td>S*</td>
<td>N/A</td>
</tr>
<tr>
<td>J2794</td>
<td>9125</td>
<td>RISPERDAL® CONSTA® (risperidone), long-acting injection</td>
<td>K†</td>
<td>12.5 mg, 25 mg, 37.5 mg, 50 mg</td>
</tr>
</tbody>
</table>

* Status indicator “S” denotes an ancillary procedure that is reimbursed separately.
† Status indicator “K” denotes a “non pass through” drug or biologic that is reimbursed separately.
Note: Medicare allowables for the HCPCS codes listed above can be found using the CMS physician fee schedule RVU files.46
Partial Hospitalization Services\textsuperscript{47}

CMHC patients needing and receiving care through a Medicare-certified partial hospitalization program may be eligible for coverage under the partial hospitalization benefit. The following criteria for care are provided:

- Patients exhibit severe or disabling psychiatric condition.
- Level of treatment includes a program of partial hospitalization services not provided in a regular, outpatient setting.
- Coordinated, intensive, multidisciplinary treatment program.
- Individualized, comprehensive treatment plan established and reviewed every month.

Mental Health Treatment Limitation

Prior to January 2010, Medicare allowed for a limited reimbursement for Part B services in connection with treatment of mental psychoneurotic and personality disorders. The limitation is called the outpatient mental health treatment limitation. The 62.5% limitation has been in place since the inception of the Medicare Part B program. The Mental Health Parity and Addiction Equity Act of 2008 required coverage and reimbursement parity with other diagnoses by 2010. As of January 1, 2014, the limitation has been phased out.\textsuperscript{34}

- January 1, 2010–December 31, 2011, the limitation percentage was 68.75%.
- January 1, 2012–December 31, 2012, the limitation percentage was 75%.
- January 1, 2013–December 31, 2013, the limitation percentage was 81.25%.
- January 1, 2014–onward, the limitation percentage is 100%.

Outpatient Patient Financial Responsibility

Patient co-payments vary according to the number of procedures performed during a single visit, the types of services provided, and the actual hospital charge. The co-payment per APC cannot exceed the inpatient co-insurance amount of $1,216 per visit.\textsuperscript{38}

Medicare Part C (Medicare Advantage)

These Medicare managed care plans provide coverage for all of the Medicare beneficiary’s benefits in the hospital outpatient setting.
Medicaid

State Medicaid programs use a variety of methodologies to reimburse for hospital outpatient services, subject to maximum allowable cost-sharing limits. Payment methodologies include payment based on fee schedules, discounted charges, or other predetermined rates. Drugs administered in the hospital outpatient setting may be reimbursed separately from professional services. Reimbursement for drugs may be based on the following:

- Wholesale Acquisition Cost (WAC)*
- Invoice cost
- A percentage of Average Sales Price (ASP)*

Actual reimbursement methodologies, payment amounts, and claim submission requirements vary according to each state. Hospital outpatient facilities and CMHCs should contact the state Medicaid program for more information regarding state-specific coverage, payment, and billing requirements for INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable and RISPERDAL® CONSTA® (risperidone) long-acting injection.

Dual Eligibles

For dual-eligible patients who access INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable and RISPERDAL® CONSTA® (risperidone) long-acting injection through Medicare Part B, Medicaid will consider paying all or a portion of the remaining co-insurance and deductible, but will always be the payer of last resort. Many Medicaid programs will only pay up to the Medicaid-allowed amount rather than the full Medicare Part B co-insurance. Actual coverage, reimbursement methodologies, payment amounts, and claim submission requirements vary according to each state. CMHCs and physician offices should contact the Medicaid program for more information regarding state-specific billing requirements for INVEGA® SUSTENNA® and RISPERDAL® CONSTA®.

Private Payers

Private payers may reimburse services and drugs provided in the hospital outpatient and partial hospitalization settings in a variety of ways including:

- Fee schedules
- Usual and customary charges
- Percentage of WAC* or ASP*
- Other prenegotiated rate

* Please see Glossary for additional information on WAC and ASP.
Reimbursement Tools
The following tools may be of assistance for filing claims for INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable and RISPERDAL® CONSTA® (risperidone) long-acting injection.

**Benefit Verification and Prior Authorization Checklist**

This worksheet lists the key questions physicians and CMHCs may consider asking to conduct their own benefit verification and to determine if prior authorization is required for INVEGA® SUSTENNA® or RISPERDAL® CONSTA® and the guidelines for prior authorization.

**Sample Prior Authorization Request Letter**

Payers may require prior authorizations and written requests for treatment. This letter provides a sample of a prior authorization request letter. It should be customized for each patient.

**Sample Letter of Medical Necessity**

Instead of prior authorization, some payers may require the physician or CMHC to submit a Letter of Medical Necessity. The Letter of Medical Necessity explains the patient’s condition and history, and provides medical justification for initiating therapy. This letter should be customized for each patient.

**Appeals Checklist**

This list provides several key questions physicians and CMHCs may ask if a claim for INVEGA® SUSTENNA® or RISPERDAL® CONSTA® is denied by the payer. Understanding the reasons the payer denied the claim is critical for filing a successful appeal.

**Sample Letter of Appeal**

Payers may require a written request to reconsider a claim. This letter should be customized for each patient.
The following tips will assist you with verifying benefits and navigating prior authorization successfully for INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable and RISPERDAL® CONSTA® (risperidone) long-acting injection:

When calling a payer to verify benefits and inquire about prior authorization, the following key questions should be considered:

- Is INVEGA® SUSTENNA® or RISPERDAL® CONSTA® covered as a medical or pharmacy benefit?
- If covered as a pharmacy benefit, is there a Pharmacy Benefit Manager (PBM)?
- What is the PBM’s phone number and address?
- Are there any special distribution requirements (e.g., specialty pharmacy, purchase/billing, physician purchase/bill only, pharmacy purchase/bill only)?
- What is the patient’s deductible?
- Has the deductible been met? If not, what amount has been applied to date?
- What is the patient’s co-payment or co-insurance for the drug?
- Does the patient have an out-of-pocket maximum?
- Has the out-of-pocket maximum been met? If not, what amount has been applied to date?
- Does the patient have an annual or lifetime benefit maximum?
- Has the benefit maximum been met? If not, what amount has been applied to date?
- What are the coding and claim submission requirements for INVEGA® SUSTENNA® and RISPERDAL® CONSTA®?
  - Code to report INVEGA® SUSTENNA®
  - Code to report RISPERDAL® CONSTA®
  - Claims phone number and address
  - Claims completion instructions
  - Required documentation (Letter of Medical Necessity, Prescribing Information)
- What is the reimbursement amount for INVEGA® SUSTENNA® or RISPERDAL® CONSTA®?
- What is the reimbursement amount for the administration procedure?
- Does the patient have other insurance benefits that will need to be coordinated?
- Is prior authorization required?
  - What is the prior authorization process (special form, Letter of Medical Necessity)?
  - What is the phone number or fax number for the authorization department?
  - How long will it take?
  - What information is required?
Many payers may require prior authorization for mental health services. Prior authorization allows the payer to review the reason for the requested therapy to determine medical appropriateness. Some payers allow the provider to call to request the prior authorization. However, for therapies that are new or expensive, payers may require a written request for treatment. Payers may have specific forms that must be completed in order to request prior authorization. The following letter provides an example of a letter requesting prior authorization:

[Date]
[Contact] (Usually someone within the Prior Authorization Department)
[Title]
[Name of Health Insurance Company]
[Address]
[City, State, Zip Code]
Insured: [Name]
Policy Number: [Number]
Group Number: [Number]

Dear [Insert appropriate contact name or department]:

I am writing on behalf of my patient, [Name of patient], to request prior authorization for INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable. The patient will be treated with INVEGA® SUSTENNA® for [Patient’s diagnosis].

INVEGA® SUSTENNA® is indicated for the treatment of schizophrenia and/or schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers or antidepressants.

Below, this letter outlines [Insert patient’s name]’s medical history, prognosis, and treatment rationale.

Summary of Patient History [You may want to include]:

[Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient’s medical condition].

• Patient’s diagnosis, condition, and history.
• Previous therapies the patient has undergone for the symptoms associated with [schizophrenia and/or schizoaffective disorder].
• Patient’s response to these therapies.
• Brief description of the patient’s recent symptoms and conditions.

Summary of your professional opinion of the patient’s likely prognosis or disease progression without treatment with INVEGA® SUSTENNA®.

[Provide a brief discussion of patient’s symptoms and therapy to date].

Based on the above facts, I am confident you will agree that INVEGA® SUSTENNA® is indicated and medically necessary for this patient. If you have any further questions, please feel free to call me at [Physician’s telephone number, including area code] to discuss.

Thank you in advance for your immediate attention to this request.

Sincerely,

[Physician’s name]
[Physician’s practice name]
[Physician’s practice address]
Many payers may require prior authorization for mental health services. Prior authorization allows the payer to review the reason for the requested therapy to determine medical appropriateness. Some payers allow the provider to call to request the prior authorization. However, for therapies that are new or expensive, payers may require a written request for treatment. Payers may have specific forms that must be completed in order to request prior authorization. The following letter provides an example of a letter requesting prior authorization:

[Date]
[Contact] (Usually someone within the Prior Authorization Department)
[Title]
[Name of Health Insurance Company]
[Address]
[City, State, Zip Code]
Insured: [Name]
Policy Number: [Number]
Group Number: [Number]

Dear [Insert appropriate contact name or department]:

I am writing on behalf of my patient, [Name of patient], to request prior authorization for RISPERDAL® CONSTA® (risperidone) long-acting injection. The patient will be treated with RISPERDAL® CONSTA® for [Patient’s diagnosis]. RISPERDAL® CONSTA® long-acting injection is indicated for the treatment of schizophrenia and for the maintenance treatment of Bipolar I Disorder.

Below, this letter outlines [Insert patient’s name]’s medical history, prognosis, and treatment rationale.

Summary of Patient History [You may want to include]:

• Patient’s diagnosis, condition, and history.
• Previous therapies the patient has undergone for the symptoms associated with [Insert indicated disease state].
• Patient’s response to these therapies.
• Brief description of the patient’s recent symptoms and conditions.

Summary of your professional opinion of the patient’s likely prognosis or disease progression without treatment with RISPERDAL® CONSTA®.

[Provide a brief discussion of patient’s symptoms and therapy to date].

Based on the above facts, I am confident you will agree that RISPERDAL® CONSTA® long-acting injection is indicated and medically necessary for this patient. If you have any further questions, please feel free to call me at [Physician’s telephone number, including area code] to discuss.

Thank you in advance for your immediate attention to this request.

Sincerely,

[Physician’s name]
[Physician’s practice name]
[Physician’s practice address]
Sample Letter of Medical Necessity for INVEGA® SUSTENNA® (paliperidone palmitate)

Once the patient’s diagnosis has been established, providers will need to determine the course of treatment. As a treatment option for patients diagnosed with schizophrenia and/or schizoaffective disorder, providers may need to submit a Letter of Medical Necessity with the claim form to support coverage of INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable. The Letter of Medical Necessity explains why the drug or procedure was provided. Manually submitted claims for INVEGA® SUSTENNA® may include medical necessity documentation, along with other supporting documentation (eg, medical records, peer-reviewed literature).

[Date]
[Contact] (Usually the Medical Director)
[Title]
[Name of Health Insurance Company]
[Address]
[City, State, Zip Code]
Insured: [Name]
Policy Number: [Number]
Group Number: [Number]

Dear Dr. [Medical Director’s name]:
I am writing on behalf of my patient, [Name of patient], to request that [Name of health insurance company] approve coverage and appropriate payment associated with [Name of patient]’s treatment. The patient will be treated with INVEGA® SUSTENNA® (paliperidone palmitate) for [Patient’s diagnosis]. INVEGA® SUSTENNA® extended-release injectable is indicated for the treatment of schizophrenia and/or schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers or antidepressants.

Below, this letter outlines [Insert patient’s name]’s medical history, prognosis, and treatment rationale.

Summary of Patient History [You may want to include]:
- Patient’s diagnosis, condition, and history.
- Previous therapies the patient has undergone for the symptoms associated with [schizophrenia and/or schizoaffective disorder].
- Patient’s response to these therapies.
- Brief description of the patient’s recent symptoms and conditions.
- Summary of your professional opinion of the patient’s likely prognosis or disease progression without treatment with INVEGA® SUSTENNA®.

[Provide a brief discussion of patient’s symptoms and therapy to date]. Based on the above facts, I am confident you will agree that INVEGA® SUSTENNA® (paliperidone palmitate) is indicated and medically necessary for this patient. If you have any further questions, please feel free to call me at [Physician’s telephone number, including area code] to discuss.

Thank you in advance for your immediate attention to this request.

Sincerely,
[Physician’s name]
[Physician’s practice name]
[Physician’s practice address]
Once the patient’s diagnosis has been established, providers will need to determine the course of treatment. As a treatment option for patients diagnosed with schizophrenia or Bipolar I Disorder, providers may need to submit a Letter of Medical Necessity with the claim form to support coverage of RISPERDAL® CONSTA® (risperidone) long-acting injection. The Letter of Medical Necessity explains why the drug or procedure was provided. Manually submitted claims for RISPERDAL® CONSTA® may include medical necessity documentation, along with other supporting documentation (eg, medical records, peer-reviewed literature).

[Date]
[Contact] (Usually the Medical Director)
[Title]
[Name of Health Insurance Company]
[Address]
[City, State, Zip Code]
Insured: [Name]
Policy Number: [Number]
Group Number: [Number]

Dear [Medical Director’s name]:

I am writing on behalf of my patient, [Name of patient], to request that [Name of health insurance company] approve coverage and appropriate payment associated with [Name of patient]’s treatment. The patient will be treated with RISPERDAL® CONSTA® (risperidone) long-acting injection for [Patient’s diagnosis]. RISPERDAL® CONSTA® long-acting injection is indicated for the treatment of schizophrenia and for the maintenance treatment of Bipolar I Disorder.

Below, this letter outlines [Insert patient’s name]’s medical history, prognosis, and treatment rationale.

Summary of Patient History [You may want to include]:

- Patient’s diagnosis, condition, and history.
- Previous therapies the patient has undergone for the symptoms associated with [Insert indicated disease state].
- Patient’s response to these therapies.
- Brief description of the patient’s recent symptoms and conditions.
- Summary of your professional opinion of the patient’s likely prognosis or disease progression without treatment with RISPERDAL® CONSTA®.

[Provide a brief discussion of patient’s symptoms and therapy to date]. Based on the above facts, I am confident you will agree that RISPERDAL® CONSTA® is indicated and medically necessary for this patient. If you have any further questions, please feel free to call me at [Physician’s telephone number, including area code] to discuss.

Thank you in advance for your immediate attention to this request.

Sincerely,
[Physician’s name]
[Physician’s practice name]
[Physician’s practice address]
If a claim for INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable or RISPERDAL® CONSTA® (risperidone) long-acting injection is improperly reimbursed or denied, you may consider submitting an appeal. The most common reasons for denied claims include:

- Use of incorrect codes
- Incorrect units
- Omission of Letter of Medical Necessity

The following provides some tips for appealing denied claims:

- Review the Explanation of Benefits (EOB) to determine the reason for the denial.
- If additional information is requested, submit the necessary documentation immediately.
- Submit a corrected claim if the denial was due to a technical billing error (eg, incorrect patient identification number, missing diagnosis):
  - Has it been met? If not, what amount has been applied to date?
- Verify appeals process with payer:
  - Is there a particular form that must be completed?
  - Can the appeal be conducted over the phone or must it be in writing?
  - To whom should the appeal be directed?
  - What information must be included with the appeal (eg, copy of original claim, explanation of benefits, supporting documentation)?
  - How long does the appeals process usually take?
  - How will the payer communicate the appeal decision?
- Review appeal request for accuracy including patient identification numbers, coding, and requested information.
- Request that a psychiatrist or other specialist who is familiar with INVEGA® SUSTENNA® or RISPERDAL® CONSTA® reviews the claim for medical necessity. It is preferable to have the claim reviewed by a specialist who is presently treating patients with INVEGA® SUSTENNA® or RISPERDAL® CONSTA®.
- File claims appeal as soon as possible and within filing time limits.
- Reconcile claims appeal responses promptly and thoroughly to ensure appeals have been processed appropriately.
- Record appeals result (eg, payment amount or if further action is required).

If you receive a claim denial due to a payer policy excluding INVEGA® SUSTENNA® or RISPERDAL® CONSTA® from coverage, resubmit the claim with additional documentation supporting medical necessity.

- If you have not previously submitted a detailed Letter of Medical Necessity, it is strongly recommended to include one in the appeal packet. Please see the sample Letter of Medical Necessity for examples of the type of information that should be included.
- If you have already submitted a Letter of Medical Necessity, you should include a Letter of Appeal indicating why the agent should be covered and paid by the payer.
- Additionally, you should include a copy of the original claim and denial notification, the patient’s complete medical history, the physician’s plan for continuing treatment, and relevant journal articles supporting the use of INVEGA® SUSTENNA® or RISPERDAL® CONSTA®.

If this second claim submission is denied, it may be necessary to contact the payer’s medical or claims director. Often a claim denial is reversed upon a director’s review of an accurate and complete denial appeal request.
Key Points for Appealing Denied Claims

- File claims and appeals within required time limits.
- Use designated appeal forms, if required.
- Send supporting medical information with appeals.
- Request that a psychiatrist who is treating patients with INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable or RISPERDAL® CONSTA® (risperidone) long-acting injection review the claim.
Sample Letter of Appeal for INVEGA® SUSTENNA® (paliperidone palmitate)

In some cases, a claim denial may be overturned after a phone call to the payer. However, payers will often require a formal Letter of Appeal. The following is a sample Letter of Appeal for INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable.

[Date]
[Contact]
[Title]
[Name of Health Insurance Company]
[Address]
[City, State, Zip Code]
Insured: [Patient’s name]
Policy Number: [Policy number]
Group Number: [Group number]
Diagnosis: [Diagnosis and ICD-9-CM or ICD-10-CM code]

Dear [Name of Contact]:

This letter serves as a request for reconsideration of a claim representing charges for INVEGA® SUSTENNA® (paliperidone palmitate) administered to [Patient’s name] on [Date of service]. [Patient’s name] has been under my treatment for [his/her] diagnosis of [diagnosis]. You have indicated that INVEGA® SUSTENNA® is not covered by [Insurance name] for this patient because [Reason for denial].

INVEGA® SUSTENNA® is indicated for the treatment of schizophrenia and/or schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers or antidepressants. Because of (Insert relevant patient information—history, diagnosis, etc.), I have administered INVEGA® SUSTENNA® as a medically necessary part of this patient’s treatment and we would appreciate your reconsideration of the [Date of service] claim for [Patient’s name]. Please contact me at [Physician’s telephone number, including area code] if you require additional information.

Thank you in advance for your immediate attention to this request.

Sincerely,

[Physician’s name]
[Physician’s practice name]
[Physician’s practice address]

Attachments [original claim form, denial/EOB, additional supporting documents]
In some cases, a claim denial may be overturned after a phone call to the payer. However, payers will often require a formal Letter of Appeal. The following is a sample Letter of Appeal for RISPERDAL® CONSTA® (risperidone) long-acting injection.

[Date]
[Contact]
[Title]
[Name of Health Insurance Company]
[Address]
[City, State, Zip Code]
Insured: [Patient’s name]
Policy Number: [Policy number]
Group Number: [Group number]
Diagnosis: [Diagnosis and ICD-9-CM or ICD-10-CM code]

Dear [Name of Contact]:

This letter serves as a request for reconsideration of a claim representing charges for RISPERDAL® CONSTA® (risperidone) long-acting injection administered to [Patient’s name] on [Date of service]. [Patient’s name] has been under my treatment for [his/her] diagnosis of [diagnosis]. You have indicated that RISPERDAL® CONSTA® is not covered by [Insurance name] for this patient because [Reason for denial].

RISPERDAL® CONSTA® is indicated for the treatment of schizophrenia and for the maintenance treatment of Bipolar I Disorder. Because of [Insert relevant patient information—history, diagnosis, etc.], I have administered RISPERDAL® CONSTA® as a medically necessary part of this patient’s treatment and we would appreciate your reconsideration of the [Date of service] claim for [Patient’s name]. Please contact me at [Physician’s telephone number, including area code] if you require additional information.

Thank you in advance for your immediate attention to this request.

Sincerely,

[Physician’s name]
[Physician’s practice name]
[Physician’s practice address]

Attachments [original claim form, denial/EOB, additional supporting documents]
References
References

1. 42 USC § 426.
2. 42 CFR §§ 410.10(b) & 410.29 & 42 USC § 1395w-3.
3. 42 USC § 1396d(a).
5. Ibid.
6. 42 USC §§ 1395d & 1395x.
8. 42 USC §§ 1395k & 1395x.
11. 42 USC § 1395w-102.
14. 42 CFR § 423.34.
15. 42 CFR § 410.155.
Glossary
Assignment of Benefits (AOB)\textsuperscript{43}
Occurs when the beneficiary authorizes the health plan to pay benefits directly to the medical provider.

Ambulatory Payment Classification (APC)\textsuperscript{44}
Medicare reimbursement methodology for hospital outpatient facilities and CMHCs that provides partial hospitalization services. Medicare assigns a fixed payment to group procedures that are comparable clinically and in terms of resource costs.

Average Sales Price (ASP)\textsuperscript{45}
Medicare reimbursement methodology for Part B covered drugs. ASP is the sum of gross sales less certain discounts, drawbacks, and rebates divided by the total number of units sold in the United States. Manufacturers submit ASP data to CMS by specific deadlines following the end of each quarterly period.

Buy-and-Bill
A method of submitting claims for drugs and supplies purchased by a physician and commonly administered in an office setting under direct physician supervision.

Co-insurance\textsuperscript{49}
A beneficiary cost-sharing amount that begins after the deductible is paid and is typically based on a percentage of the cost of services and varies by health plan.

Coordination of Benefits (COB)\textsuperscript{43}
A contractual provision designed to prevent a beneficiary from receiving duplicate benefits under more than one health plan so that the beneficiary’s benefits from all sources do not exceed allowable medical expenses or eliminate appropriate patient incentives to contain costs.

Co-payment (Co-pay)\textsuperscript{49}
The flat fee a beneficiary pays each time he or she receives medical care. The co-payment may be in addition to other out-of-pocket costs such as deductibles and co-insurance and varies by benefit structure.

Dual Eligibles\textsuperscript{12}
Dual eligibles are individuals who are entitled to Medicare Part A and/or Part B and are eligible for some form of Medicaid benefit.

Explanation of Benefits (EOB)\textsuperscript{43}
A document sent to the beneficiary when the health plan handles a claim. The document explains how reimbursement was made, or why the claim was not paid, and if any additional information is needed.

Fee Schedule\textsuperscript{43}
Maximum dollar or unit allowances for health services that apply under a specific contract.

Marketplace
Also known as the health insurance exchange, this is a combination of state and federally run health insurance exchanges that are set up to facilitate the purchase of health insurance in accordance with the Affordable Care Act.

Medicaid\textsuperscript{49}
A Federal program administered by the states to provide health care for eligible poor and low-income individuals and families.

Medicare\textsuperscript{1}
A Federal insurance program that provides healthcare coverage to individuals 65 years of age and older, certain disabled individuals under age 65, and individuals of any age with end-stage renal disease.
Glossary

Medicare Part B
The Medicare benefit that covers doctors’ services, outpatient hospital care, and some other medical services that Medicare Part A doesn’t cover.

Medicare Part D
A prescription drug option under Medicare that is run by private insurance companies contracted with Medicare.

Modifier
Two-digit numeric or alpha code used with another code to indicate that a service or procedure has been altered, but is not changed in its definition or code.

National Drug Code (NDC)
A unique identifier assigned to individual drugs by the Food and Drug Administration (FDA) and the manufacturer.

National Provider Identifier (NPI)
The NPI is a unique identification number for a healthcare provider that is used by all health plans. The NPI is a 10-digit numeric identifier.

Prior Authorization
Also referred to as a pre-authorization, a prior authorization is a request for a payer to review services or supplies for medical necessity prior to the services or supplies being provided. Prior authorization may be obtained via fax, phone, or written request as outlined by the payer.

Usual, Customary, and Reasonable (UCR)
Charges of healthcare providers that are consistent with charges from similar providers for identical or similar services in a given locale.

Wholesale Acquisition Cost (WAC)
The manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications.
For more information on INVEGA® SUSTENNA® (paliperidone palmitate) extended-release injectable, click here for the full Prescribing Information, including Boxed WARNING.

For more information on RISPERDAL® CONSTA® (risperidone) long-acting injection, click here for the full Prescribing Information, including Boxed WARNING.

For additional reimbursement and billing questions, please contact:

JANSSEN® CONNECT® 1-877-JC-HELP9 (1-877-524-3579)
Monday–Friday, 7:00 AM–7:00 PM CT

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