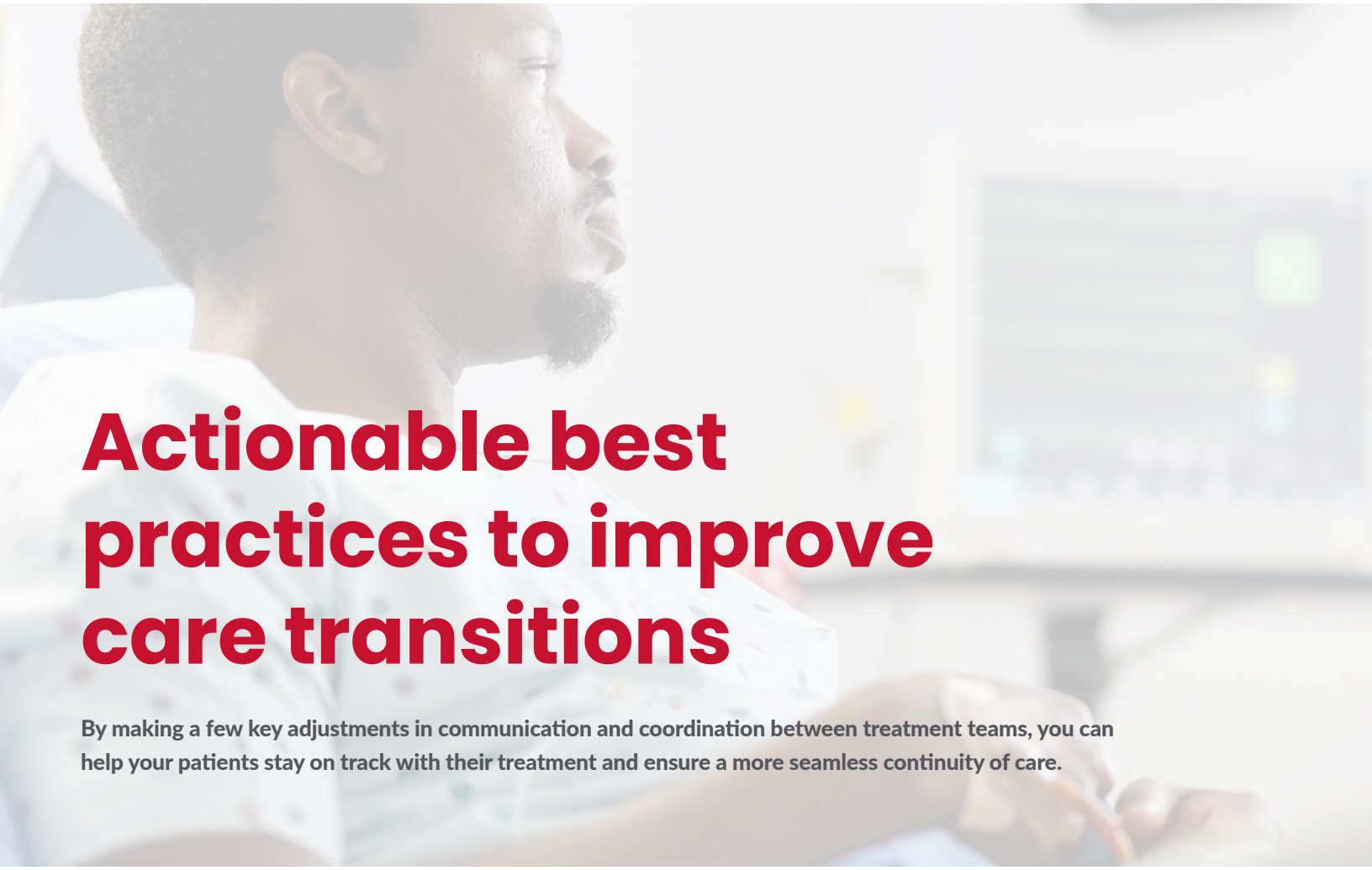
INVEGA SUSTENNA®
paliperidone palmitate extended-release injectable suspension
39mg, 78mg, 117mg, 156mg, 234mg

Improving treatment continuity during care transitions



Actionable best practices to improve care transitions

By making a few key adjustments in communication and coordination between treatment teams, you can help your patients stay on track with their treatment and ensure a more seamless continuity of care.

INDICATION

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

- Schizophrenia in adults.

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 use in patients with dementia-related psychosis.

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

Please see additional Important Safety Information on the next page. Please click here to read the full Prescribing Information, including Boxed WARNING, for INVEGA SUSTENNA®.

Common problems faced by some patients resulting in discontinuity of care:

- Both **initiation doses** are not received as prescribed before discharge
- Long **wait times** for an appointment in the next care setting
- **Discharged without** maintenance prescription
- Injection delayed by waiting for **Prior Authorization,** if required
- Some commercial plans cover **INVEGA SUSTENNA®** under the medical benefit
- **Lack of support** from caregiver or other social support with treatment plan
- Have **transportation challenges** to appointments

Who should be informed?

Use the following key to ensure that the appropriate team members are educated on the topic:

Hospital Staff | Pharmacy Staff | Discharge Planner | Benefits Coordinator

IMPORTANT SAFETY INFORMATION (cont'd)

Cerebrovascular Adverse Reactions: Cerebrovascular adverse reactions (e.g., stroke, transient ischemic attacks), including fatalities, were reported at a higher incidence in elderly patients with dementia-related psychosis taking risperidone, aripiprazole, and olanzapine compared to placebo. No studies have been conducted with oral paliperidone, INVEGA SUSTENNA®, or the 3-month paliperidone palmitate extended-release injectable suspension in elderly patients with dementia. These medicines are not approved for the treatment of patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS): NMS, a potentially fatal symptom complex, has been reported in association with antipsychotic drugs, including paliperidone.

Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status including delirium, and autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure.

If NMS is suspected, immediately discontinue INVEGA SUSTENNA® and provide symptomatic treatment and monitoring.

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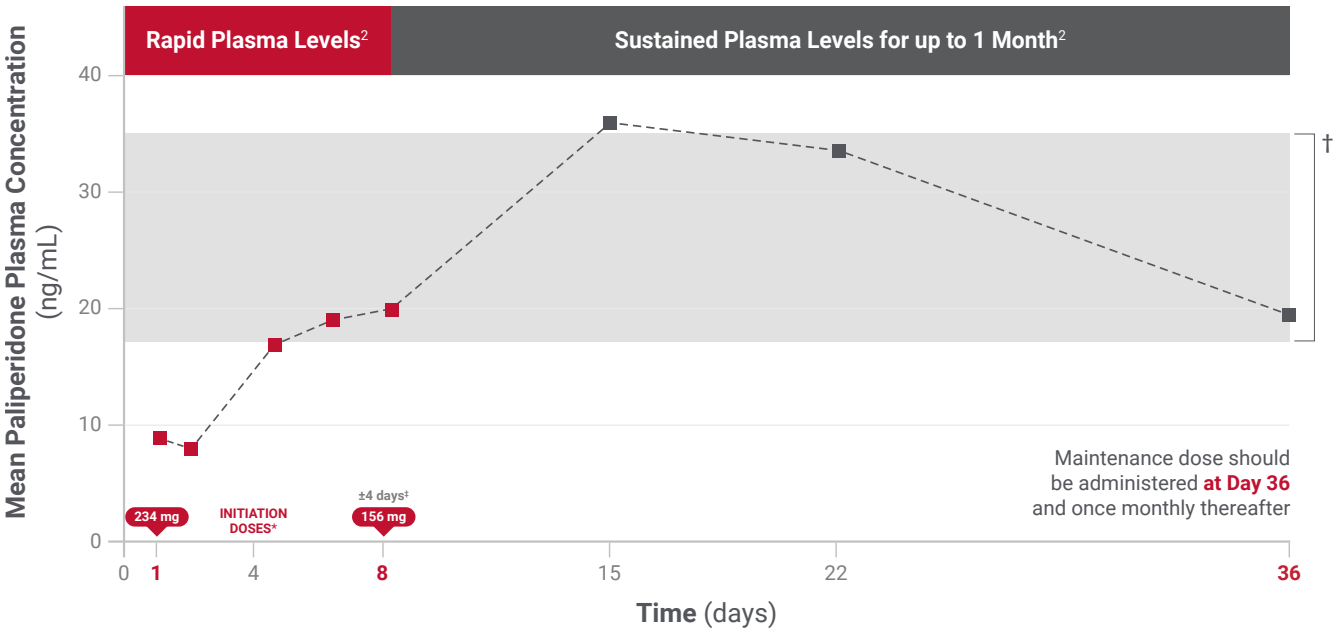
If patients are not receiving both initiation doses before discharge:

Administer both initiation doses while the patient is in your care, if the length of stay is appropriate, so that you can be confident patients will receive 1 month of medication[1]



- No oral supplementation required during initiation, including Day 1[1]
- Due to the difference in median pharmacokinetic profiles between INVEGA SUSTENNA® and oral paliperidone, use caution when directly comparing their pharmacokinetic properties[1]
- **Correlation to clinical effect has not been established**

*Both initiation doses must be administered in the deltoid muscle.[1]

†INVEGA SUSTENNA® initiation regimen allowed patients to stay in a median exposure window of 6-12 mg extended-release oral paliperidone.[2]

‡Utilizing the dosing window to help avoid missed doses should be considered the exception rather than the rule.

IMPORTANT SAFETY INFORMATION (cont'd)

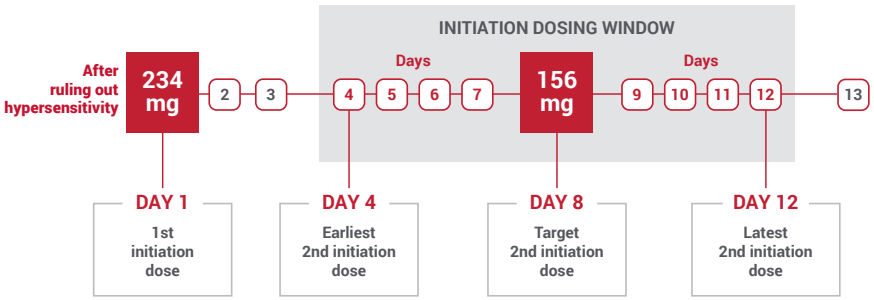
QT Prolongation: Paliperidone causes a modest increase in the corrected QT (QTc) interval. Avoid the use of drugs that also increase QTc interval and in patients with risk factors for prolonged QTc interval. Paliperidone should also be avoided in patients with congenital long QT syndrome and in patients 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.

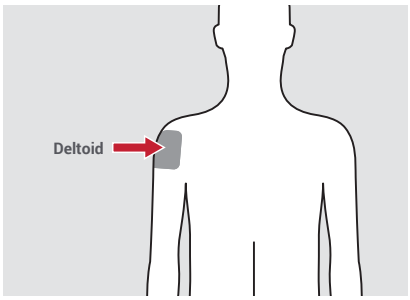
Tardive Dyskinesia (TD): TD, a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements, may develop in patients treated with antipsychotic drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to predict which patients will develop the syndrome. Whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown.

The risk of developing TD and the likelihood that it will become irreversible appear to increase with the duration of treatment and the cumulative dose. The syndrome can develop after relatively brief treatment periods, even at low doses. It may also occur after discontinuation. TD may remit, partially or completely, if antipsychotic treatment is discontinued. Antipsychotic treatment itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome, possibly masking the underlying process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown.

Please see additional Important Safety Information on the next page. Please click here to read the full Prescribing Information, including Boxed WARNING, for INVEGA SUSTENNA®.

If patients are not receiving both initiation doses before discharge (cont'd):





- Administer both initiation doses of INVEGA SUSTENNA® while the patient is under your care, if the length of stay is appropriate[1]
  - Fully initiate INVEGA SUSTENNA® for schizophrenia in 7 days with 2 initiation doses—with no oral supplementation
  - Both initiation doses must be given in the deltoid muscle
  - Previous oral antipsychotics can be discontinued at the time of initiation of treatment with INVEGA SUSTENNA®
  - To avoid a missed dose, administer the second initiation dose within a ±4-day flexible window
  - **Utilizing the dosing window to help avoid missed doses should be considered the exception rather than the rule**
  - If transitioning from a long-acting injectable (LAI) antipsychotic to INVEGA SUSTENNA®, initiate INVEGA SUSTENNA® in place of the next scheduled injection.
  - No second initiation dose is required when transitioning from another LAI antipsychotic
- Prepare patients for future care by keeping detailed records for colleagues
- Set up flags or pop-ups in your electronic health records (EHRs):
  - Ensure that the patient has received both initiation doses of INVEGA SUSTENNA® before discharge
  - Order the second dose of INVEGA SUSTENNA® when the first dose is ordered
- If the patient's stay is not long enough to receive both initiation doses, coordinate injection services with their next care setting

Click to learn more about INVEGA SUSTENNA® dosing

Click to learn more about dosing for patients with renal impairment

IMPORTANT SAFETY INFORMATION (cont'd)

Tardive Dyskinesia (TD) (cont'd): If signs and symptoms of TD appear in a patient on INVEGA SUSTENNA®, drug discontinuation should be considered. However, some patients may require treatment with INVEGA SUSTENNA® despite the presence of the syndrome. In patients who do require chronic treatment, use the lowest dose and the shortest duration of treatment producing a satisfactory clinical response. Periodically reassess the need for continued treatment.

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.

Please see additional Important Safety Information on the next page. Please click here to read the full Prescribing Information, including Boxed WARNING, for INVEGA SUSTENNA®.

If the wait time for an outpatient appointment is longer than the maintenance dosing window:

- Help patients identify an alternate site of care where they can receive the next injection by visiting JanssenConnectLocator.com

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If patients are being discharged without a maintenance prescription:

- Educate the hospital staff and the discharge planning team on the maintenance dosing window and that a prescription for the maintenance dose should be written as part of discharge planning
- Confirm the date and the location of the first maintenance dose appointment to facilitate coordination of additional support, transportation assistance, or appointment reminder needs for the patient

IMPORTANT SAFETY INFORMATION (cont'd)

Metabolic Changes (cont'd):

Hyperglycemia and Diabetes Mellitus: Hyperglycemia and diabetes mellitus, in some cases extreme 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 antidiabetic treatment despite discontinuation of the suspect drug.

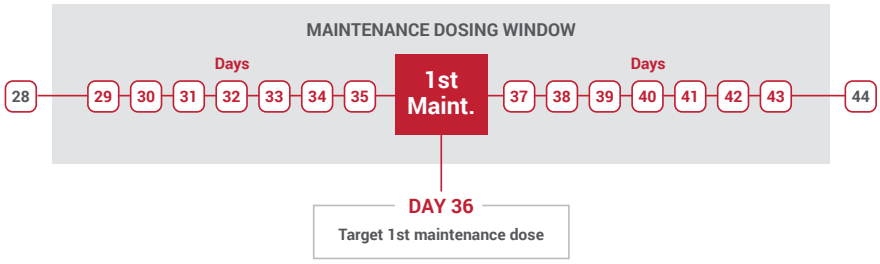
Dyslipidemia: Undesirable alterations have been observed in patients treated with atypical antipsychotics.

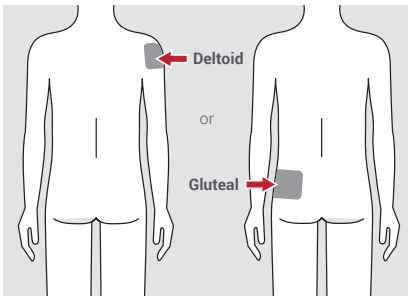
Weight Gain: Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Orthostatic Hypotension and Syncope: INVEGA SUSTENNA® may induce orthostatic hypotension in some patients due to its alpha-adrenergic 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.

Please see additional Important Safety Information on the next page. Please click here to read the full Prescribing Information, including Boxed WARNING, for INVEGA SUSTENNA®.

Maintaining INVEGA SUSTENNA®[1]





- The first monthly maintenance dose* should be administered 5 weeks after the first injection regardless of when the second injection was administered
- To avoid a missed dose, monthly maintenance doses may be given within a ±7-day flexible window
  - **Utilizing the dosing window to help avoid missed doses should be considered the exception rather than the rule**

Click to learn more about INVEGA SUSTENNA® dosing

*The recommended maintenance dose for the treatment of schizophrenia is 117 mg. Patients may benefit from flexible maintenance dosing options within the available strengths.

IMPORTANT SAFETY INFORMATION (cont'd)

Falls: Somnolence, postural hypotension, motor and sensory instability have been reported with the use of antipsychotics, including INVEGA SUSTENNA®, which may lead to falls and, consequently, fractures or other fall-related injuries. For patients, particularly the elderly, with diseases, conditions, or medications that could exacerbate these effects, assess the risk of falls when initiating antipsychotic treatment and recurrently for patients on long-term antipsychotic therapy.

Leukopenia, Neutropenia and Agranulocytosis have been reported with antipsychotics, including INVEGA SUSTENNA®. In patients with a history of clinically significant low white blood cell count (WBC)/absolute neutrophil count (ANC) or drug-induced leukopenia/neutropenia, perform a complete blood count frequently during the first few months of therapy. Consider discontinuing INVEGA SUSTENNA® at the first sign of a clinically significant decline in WBC in the absence of other causative factors. Monitor patients with clinically significant neutropenia for fever or other symptoms or signs of infection and treat promptly if such symptoms or signs occur. Discontinue INVEGA SUSTENNA® in patients with severe neutropenia (absolute neutrophil count <1000/mm^3) and follow their WBC until recovery.

Hyperprolactinemia: As with other drugs that antagonize dopamine D_2 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.

Please see additional Important Safety Information on the next page. Please click here to read the full Prescribing Information, including Boxed WARNING, for INVEGA SUSTENNA®.

If injection is delayed by waiting for Prior Authorization (PA):

- While the patient is still in the inpatient setting, verify the patient's insurance benefits for drug coverage in the outpatient setting
- Ensure that the benefits coordinator is informed about plan-specific information for the patient, including PA requirements, and that they will be able to complete missing or incomplete forms
- Make sure that the PA process is completed before the maintenance dose appointment. This will help ensure that the patient can receive their treatment as scheduled

covermymeds®

Prior Authorization Support* for INVEGA SUSTENNA®

Johnson & Johnson can provide prior authorization (PA) support through CoverMyMeds to help your patients get started on their prescribed medicine by Johnson & Johnson.

Providers can access this functionality on CoverMyMeds.com

For information on CoverMyMeds, call 866-452-5017, Monday-Friday 8:00 AM-11:00 PM ET and Saturday 8:00 AM-6:00 PM ET or visit CoverMyMeds.com

*CoverMyMeds does not fill out any information that requires the medical judgment of the prescriber, and only the prescriber can determine whether to submit a prior authorization for a determination.

IMPORTANT SAFETY INFORMATION (cont'd)

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 using only the needles provided in the INVEGA SUSTENNA® kit. Care should be taken to avoid inadvertent injection into a blood vessel.

Drug Interactions: Strong CYP3A4/P-glycoprotein (P-gp) inducers: Avoid using a strong inducer of CYP3A4 and/or P-gp (e.g., carbamazepine, rifampin, St. John's Wort) during a dosing interval for INVEGA SUSTENNA®. If administering a strong inducer is necessary, consider managing the patient using paliperidone extended-release tablets.

Please see additional Important Safety Information on the next page. Please click here to read the full Prescribing Information, including Boxed WARNING, for INVEGA SUSTENNA®.

If a patient has a commercial plan that covers INVEGA SUSTENNA® as a medical benefit, staff should:

- While the patient is still in the inpatient setting, verify the patient's insurance benefits for drug coverage in the outpatient setting
- Explain to the pharmacy that they would need to explore an Assignment of Benefits request to determine eligibility for reimbursement
- Involve all the appropriate members of the team in the discharge process

If patients lack caregiver or other social support in their treatment plans, staff should:

- Use the "Starting Patients on INVEGA SUSTENNA®" brochure to educate patients on the importance of staying on treatment
  - Ask your Johnson & Johnson representative for copies you can share with your patients starting on INVEGA SUSTENNA®
- Explain to patients how LAI antipsychotics can help with their treatment goals to help them see the value and importance of continuing treatment
- Remind patients that they should continue their treatment even if their symptoms have subsided
- When possible, include any family members or caregivers in the discharge planning process

If a patient does not have transportation to their next appointment, staff should:

- Coordinate transportation for the patient to the next care setting and ensure that the outpatient locations are convenient and accessible to the patient as needed
- Every Medicaid beneficiary is entitled to free transportation to their behavioral health appointments[3]
- To help patients find an injection site, please visit JanssenConnectLocator.com

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IMPORTANT SAFETY INFORMATION (cont'd)

Pregnancy/Nursing: INVEGA SUSTENNA® may cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure. Advise patients to notify their healthcare professional if they become pregnant or intend to become pregnant during treatment with INVEGA SUSTENNA®. Patients should be advised that there is a pregnancy registry that monitors outcomes in women exposed to INVEGA SUSTENNA® during pregnancy. INVEGA SUSTENNA® can pass into human breast milk. The benefits of breastfeeding should be considered along with the mother's clinical need for INVEGA SUSTENNA® and any potential adverse effects on the breastfed infant from INVEGA SUSTENNA® or the mother's underlying condition.

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IMPORTANT SAFETY INFORMATION (cont'd)

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.

Please click here to read the full Prescribing Information, including Boxed WARNING, for INVEGA SUSTENNA®.

cp-64200v3

INDICATION

INVEGA® (paliperidone) extended-release tablets are indicated for the treatment of schizophrenia.

IMPORTANT SAFETY INFORMATION FOR INVEGA® (paliperidone)

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® is not approved for use in patients with dementia-related psychosis.

Commonly Observed Adverse Reactions: The most commonly observed adverse reactions in clinical trials occurring at an incidence of ≥5% and at least 2 times placebo in the treatment of adults with schizophrenia were extrapyramidal symptoms, tachycardia, and akathisia.

Please click here to read the full Prescribing Information, including Boxed WARNING, for INVEGA®.

References:

1. INVEGA SUSTENNA® [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc. **2.** Samtani MN, Gopal S, Gassmann-Mayer C, et al. Dosing and switching strategies for paliperidone palmitate. *CNS Drugs*. 2011;25(10):829-845. **3.** Medicaid Program; Rescission of School-Based Administration/Transportation Final Rule, Outpatient Hospital Services Final Rule, and Partial Rescission of Case Management Interim Final Rule. *Fed Regist*. 2009;78(124):31183-31196. Accessed October 29, 2024. To be codified at 42 CFR §431, 433, 440, 441. https://www.govinfo.gov/content/pkg/FR-2009-06-30/pdf/E9-15345.pdf

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