

ZYPREXA[®]Relprevv[™]
*(olanzapine) For Extended Release
Injectable Suspension*

Please see Prescribing Information for full details about the risks of ZYPREXA RELPREVV, including Boxed Warnings.



Enclosed Registration Forms Include:

- ▶ **Prescriber Registration**
Enrolls the prescriber to treat patients with ZYPREXA RELPREW.
- ▶ **Pharmacy Service Providers**
 - **Pharmacy Registration**
Enrolls the pharmacy to order and dispense ZYPREXA RELPREW.
 - **Buy and Bill Pharmacy Service Provider Registration**
For prescribers who get product through standard buy and bill procedures, this form enrolls the prescriber as a Pharmacy Service Provider. **NOTE: Prescribers intending to buy and bill must complete both the Prescriber and Buy and Bill Pharmacy Service Provider Registration Forms.**
- ▶ **Patient Registration**
Enrolls the patient to receive treatment with ZYPREXA RELPREW.
- ▶ **Patient Registration Form – Patient Copy**
Provides patient or caregiver a copy of attestations from the Patient Registration Form.
- ▶ **Healthcare Facility Registration**
Enrolls the healthcare facility to administer ZYPREXA RELPREW injections and monitor patients after each injection.

ZYPREXA RELPREW Prescribing Information and Medication Guide Patient Injection and PDSS Reporting Forms

Single Patient Injection Form

- Used to collect the data for a single patient after treatment administration of ZYPREXA RELPREVV.
- This form is to be sent to the ZYPREXA RELPREVV Patient Care Program Coordinating Center **within 7 days after the patient's injection.**

Multiple Patient Injection Form

- Used when injections are administered to multiple patients on the same day at a given facility. This form is used to collect the data for multiple patients after treatment administration of ZYPREXA RELPREVV.
- This form is to be sent to the ZYPREXA RELPREVV Patient Care Program Coordinating Center **within 7 days after the patients' injections.**

Patient injection data should only be completed either via the Single Patient Injection Form or the Multiple Patient Injection Form. Do not use both forms for an individual injection; this will result in duplicate reporting.

Post-Injection Delirium/Sedation Syndrome (POSS) Form

- This form is used to collect the required data when a suspected PDSS event occurs after administration of ZYPREXA RELPREVV, either during the 3-hour observation period or any time thereafter. This form must be provided to the ZYPREXA RELPREVV Patient Care Program Coordinating Center within **24 hours** of becoming aware of a suspected PDSS event.

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Introduction to the ZYPREXA RELPREVV Patient Care Program

Patient Care Program Overview

ZYPREXA RELPREVV is the long-acting intramuscular formulation of olanzapine indicated for treatment of schizophrenia. The ZYPREXA RELPREVV Patient Care Program is a Risk Evaluation and Mitigation Strategy (REMS) program necessary to mitigate the risk of negative outcomes associated with ZYPREXA RELPREVV post-injection delirium/sedation syndrome (PDSS). In order to prescribe, dispense, receive, or administer ZYPREXA RELPREVV, healthcare professionals need to:

- Enroll in the ZYPREXA RELPREVV Patient Care Program
- Ensure the collection of information for each injection of ZYPREXA RELPREVV

Post-Injection Delirium/Sedation Syndrome:

ZYPREXA RELPREVV has been associated with a post-injection delirium/sedation syndrome characterized primarily by signs and symptoms consistent with olanzapine overdose. This syndrome does not apply to any other formulation of olanzapine, including ZYPREXA IntraMuscular (olanzapine for injection). The prescribing information for ZYPREXA RELPREVV includes the following BOXED WARNING.

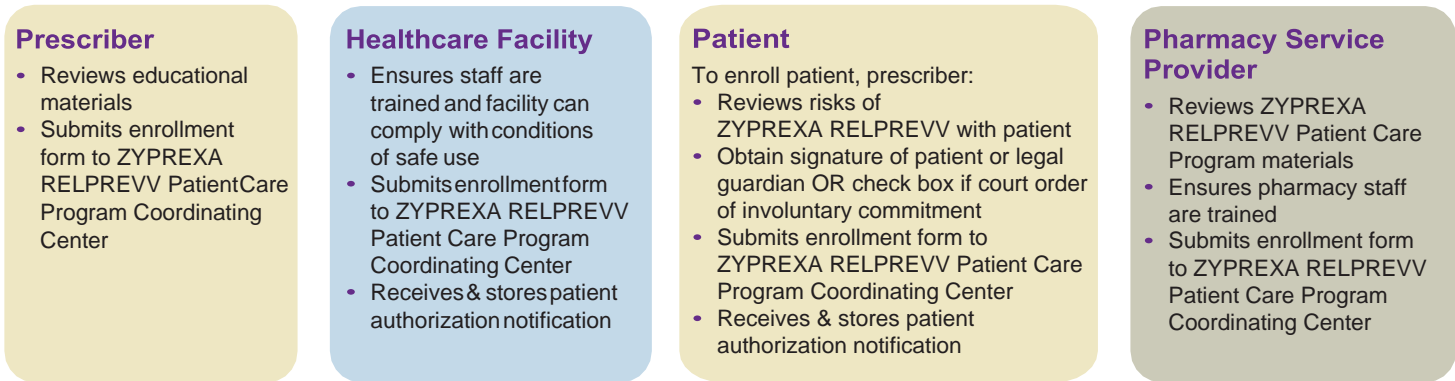
BOXED WARNING

See full prescribing information and the healthcare professional training for complete information on PDSS.

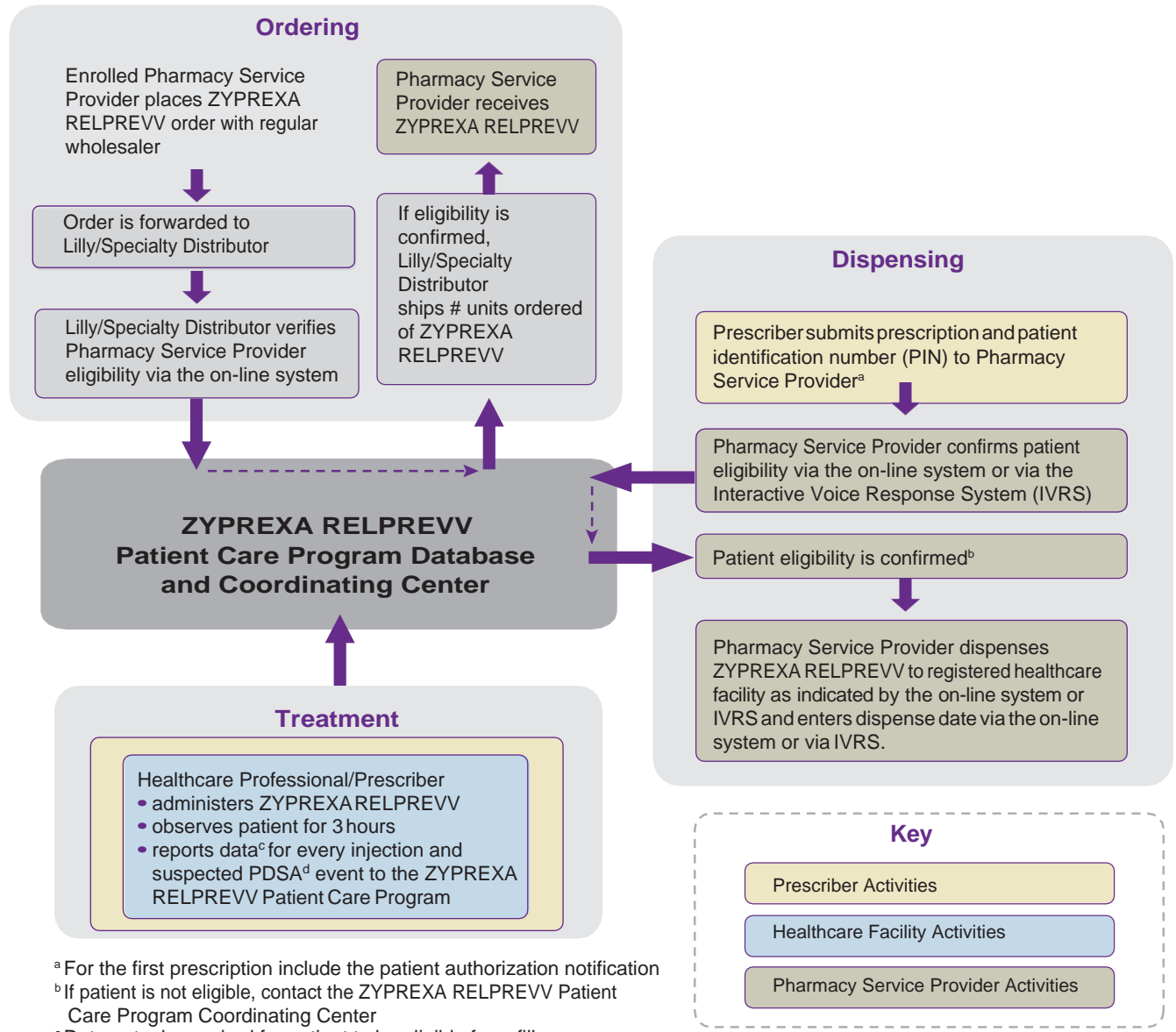
Post-Injection Delirium/Sedation Syndrome — Adverse events with signs and symptoms consistent with olanzapine overdose, in particular, sedation (including coma) and/or delirium, have been reported following injections of ZYPREXA RELPREVV. ZYPREXA RELPREVV must be administered in a registered healthcare facility with ready access to emergency response services. After each injection, patients must be observed at the healthcare facility by a healthcare professional for at least 3 hours. Because of this risk, ZYPREXA RELPREVV is available only through a restricted distribution program called ZYPREXA RELPREVV Patient Care Program and requires prescriber, healthcare facility, patient, and pharmacy enrollment.

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 seventeen 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. ZYPREXA RELPREVV is not approved for the treatment of patients with dementia-related psychosis.

ZYPREXA RELPREVV Patient Care Program Enrollment



ZYPREXA RELPREVV Patient Care Program Process Flow



^a For the first prescription include the patient authorization notification
^b If patient is not eligible, contact the ZYPREXA RELPREVV Patient Care Program Coordinating Center
^c Data entry is required for patient to be eligible for refill
^d PDSS = post-injection delirium/sedation syndrome

ZYPREXA RELPREVV Patient Care Program Coordinating Center Contact Information

For questions regarding the Patient Care Program or to enroll, please contact the Patient Care Program Coordinating Center:

Via Telephone: 1-877-772-9390
Monday – Friday: 8:00am – 8:00pm ET

Via Mail: ZYPREXA RELPREVV Patient Care Program
P.O. Box 4649
Star City, WV 26504-4649

Via Fax: 1-877-772-9391

Via Internet: www.zyprexarelprevvprogram.com

Prescriber Information

Prescribers must enroll in the ZYPREXA RELPREVV Patient Care Program in order to prescribe ZYPREXA RELPREVV.

Three Steps to Prescriber Enrollment:

1. Review:

Attend a training or review the following educational materials:

- ZYPREXA RELPREVV Patient Care Program Instructions Brochure (this document)
- Healthcare Professional Training Slide Presentation with text notes or Recorded Presentation with participant guide, available at www.zyprexarelprevvprogram.com

2. Complete/Sign:

Complete the Prescriber Registration Form on-line, or print and sign.

3. Submit:

Submit on-line or via fax or mail to the Patient Care Program Coordinating Center.

Prescribers must repeat the enrollment process every 3 years. You will be notified by fax or email 60 days prior to your reenrollment date.

Enrolling in the ZYPREXA RELPREVV Patient Care Program will allow prescribers to securely and easily view data for all of the patients they have enrolled in the program, along with the patients' next expected injection dates and injection histories.

Upon registration, the prescriber will be sent a username and password, which allows secured access to the on-line Patient Care Program system. The prescriber is responsible for entering required Patient Care Program data for any PDSS event that occurs.

Prescribers who obtain ZYPREXA RELPREVV through a pharmacy: Provide a prescription to a registered pharmacy.

Prescribers who order and dispense ZYPREXA RELPREVV through buy and bill procedures: Enroll as a Buy and Bill Pharmacy Service Provider as described on pages 9 and 10 of this brochure.

The facility/practice where injections are administered or patients are monitored must be enrolled in the ZYPREXA RELPREVV Patient Care Program as a healthcare facility as described on page 7. The Prescriber will receive an email or fax notification once the healthcare facility(s) become enrolled. The healthcare facility(s) are required to enter data following each patient injection.

Prescriber Information

To report SUSPECTED ADVERSE REACTIONS other than PDSS, contact Eli Lilly and Company at 1-800-LILLYRX (1-800-545-5979) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

The prescriber is responsible for enrolling the **patient** in the ZYPREXA RELPREVV Patient Care Program prior to writing a prescription for that patient.

Three Steps to Patient Enrollment:

1. Confirm:

- Both the prescriber and the healthcare facility where the patient will receive the injection are enrolled in the ZYPREXA RELPREVV Patient Care Program.
- Patient has been provided with a Medication Guide and informed about the risks associated with the administration of ZYPREXA RELPREVV.
- Patient has been informed about the Patient Care Program guidelines.

2. Complete/Sign:

Complete a Patient Registration Form and have the patient or legal guardian sign the form, or check the box relating to the presence of a court order. If the court order box is checked, provide the expiration date of the court order. Provide the Patient Registration Form-Patient Copy version to the patient or legal guardian.

3. Submit:

Submit on-line or via fax or mail to the Patient Care Program Coordinating Center.

After enrollment is complete, a unique Patient Identification Number (PIN) and a healthcare facility unique identifier will be provided to the prescriber via a patient authorization notification fax or email.

The prescriber should provide the patient's PIN and healthcare facility unique identifier with the first prescription to assist the pharmacy service provider in completing its ZYPREXA RELPREVV Patient Care Program responsibilities.

For any changes in patient care setting, changes in prescriber, or to discontinue or reactivate a patient, call the Coordinating Center (1-877-772-9390).

Patient Care Program Data Entry

All suspected cases of PDSS should be reported to the ZYPREXA RELPREVV Patient Care Program within **24 hours of awareness of the event**. The ZYPREXA RELPREVV Patient Care Program may need to contact you to obtain additional information to further characterize the PDSS event.

For each suspected PDSS event, the prescriber can record and submit data to the Patient Care Program in one of the following ways:

Via Telephone: 1-877-772-9390

Via Fax: 1-877-772-9391

Via Internet: www.zyprexarelprevvprogram.com

Steps for On-line Data Entry

1. With the assigned username and password, log in to the ZYPREXA RELPREVV Patient Care Program system through the website.
2. Upon logging into the Patient Care Program system, the prescriber will see only their associated patients and the option to enroll new patients.
3. Select:
 - The appropriate patient for whom he/she is entering data.
 - Or the option to enroll a new patient.
4. The system will prompt the prescriber to enter enrollment data for a new patient, or PDSS data for an already enrolled patient.

Healthcare Facility Information

A healthcare facility must be enrolled in the ZYPREXA RELPREVV Patient Care Program to: ensure each patient is enrolled in the Patient Care Program prior to administering an injection, to administer ZYPREXA RELPREVV and/or to monitor patients who have been administered ZYPREXA RELPREVV and to enter data for each injection administered to a patient.

Authorized Healthcare Facility Representative

The authorized healthcare facility representative must ensure that all appropriate staff responsible for administering ZYPREXA RELPREVV and for monitoring patients are educated on ZYPREXA RELPREVV injection techniques, signs and symptoms of PDSS, and patient monitoring requirements following

injection. Additionally, the authorized healthcare facility representative is responsible to ensure systems are in place to report all PDSS events to the prescriber and to identify all appropriate staff as delegates who will be responsible for entering data following each injection.

Patient Care Program Data Entry

The authorized healthcare facility representative may assign the Patient Care Program responsibilities to a delegate(s). Upon registration, the delegate(s) will be sent a username and password, which allows secured access to the on-line Patient Care Program system. After registration, additional delegates may be assigned by calling the Coordinating Center (1-877-772-9390).

Three Steps to Healthcare Facility Enrollment:

1. Review:

Staff involved with ZYPREXA RELPREVV patients review the educational materials listed below. Materials are available on-line, through an on-line order form, or by calling the ZYPREXA RELPREVV Patient Care Program Coordinating Center.

- Required for nurse or other individuals giving injections:
 - ZYPREXA RELPREVV Patient Care Program Instructions Brochure (this document)
 - Healthcare Professional Training Slide Presentation with text notes or Recorded Presentation with participant guide, available at www.zyprexarelprevvprogram.com
 - Reconstitution & Administration Training Video and Poster

- Required for staff working with patients post-injection:
 - Healthcare Professional Training Slide Presentation with text notes or Recorded Presentation
 - ZYPREXA RELPREVV Patient Care Program Instructions Brochure (this document)

2. Complete/Sign:

Healthcare facility representative completes the Healthcare Registration Form on-line or print and sign.

3. Submit:

Submit on-line or via fax or mail to the ZYPREXA RELPREVV Patient Care Program Coordinating Center.

Healthcare facilities must repeat the enrollment process every 3 years. You will be notified by fax or email 60 days prior to your reenrollment date.

Healthcare Facility Information

After a patient associated with your facility is enrolled by a prescriber, a unique Patient Identification Number (PIN) will be assigned to the patient and provided to the facility via a patient authorization notification fax or email, which should be filed in the patient's chart.

Prior to each injection, verify that the patient is enrolled in the Zyprexa Relprevv Patient Care Program registry by accessing the system.

Following the injection, patients are to be monitored continuously for at least 3 hours. Report required Patient Care Program injection data (see Injection Form) **within 7 days of injection administration.**

Injection data may be submitted individually for each patient by using the Single Patient Injection Form or for multiple patients by using the Multiple Patient Injection Form.

For each injection, record and submit injection data to the Patient Care Program in one of the following ways:

Via Telephone: 1-877-772-9390

Via Fax: 1-877-772-9391

Via Internet: www.zyprexarelprevvprogram.com

Steps for On-line Data Entry

1. With the assigned username and password, log in to the ZYPREXA RELPREVV Patient Care Program system through the website.
2. Upon logging into the Patient Care Program system, the delegate will see only their associated patients.
3. Select the appropriate patient and dispense date to enter injection data.
4. The system will prompt the delegate to enter injection data for an enrolled patient.

Product Replacement

If, during the course of reconstitution or administration of ZYPREXA RELPREVV, the medication becomes unusable (e.g., aspiration of blood or a broken vial), call the Coordinating Center.

Pharmacy Service Provider Information

A pharmacy service provider must be enrolled in the ZYPREXA RELPREVV Patient Care Program to order and dispense ZYPREXA RELPREVV. Pharmacy service providers include any retail pharmacy, hospital pharmacy, physician or healthcare facility that can order and dispense ZYPREXA RELPREVV.

Three Steps to Pharmacy Service Provider Enrollment:

1. Review:

Pharmacy staff should review the training and education material within this document before dispensing the medication.

2. Complete:

Representative for the pharmacy service provider completes a registration form, depending upon the type of pharmacy operation.

- Pharmacy Registration Form: Enrolls a pharmacy to allow ordering and dispensing of ZYPREXA RELPREVV. To be completed by the pharmacist in charge.
- Buy and Bill Pharmacy Service Provider Registration Form: Enrolls a prescriber organization that wishes to order and dispense ZYPREXA RELPREVV to patients through buy and bill procedures.

3. Submit:

Submit on-line or via fax or mail to the ZYPREXA RELPREVV Patient Care Program Coordinating Center.

Pharmacy Service Providers must repeat the enrollment process every 3 years. You will be notified by fax or email 60 days prior to your reenrollment date.

Once the ZYPREXA RELPREVV Patient Care Program Coordinating Center receives the completed registration form, the pharmacy service provider will be sent a username and password, which allows secured access to the on-line Patient Care Program system and interactive voice response system (IVRS).

Ordering ZYPREXA RELPREVV

ZYPREXA RELPREVV will be shipped through a controlled distribution system. Following the pharmacy service provider registration, the Patient Care Program Coordinating Center will notify distributors that the pharmacy is enrolled. The pharmacy will then be able to submit orders for ZYPREXA RELPREVV to their regular wholesaler.

Patient Care Program requirements must be followed for the pharmacy to maintain an active registration status and to have continued access to ZYPREXA RELPREVV.

Dispensing ZYPREXA RELPREVV

It is the responsibility of the pharmacy service provider to verify the ongoing eligibility of the patient prior to dispensing each prescription and entering the date of each dispensing. The pharmacist will ensure prescription verification (including patient eligibility check and recording the dispense date) is completed on the date of dispense, **prior to** the vial kit leaving the pharmacy. This is accomplished by contacting the Patient Care Program in one of the following ways:

Via Telephone/IVRS: 1-877-772-9390

Via Internet: www.zyprexarelprevvprogram.com

Prior to dispensing ZYPREXA RELPREVV, the pharmacy service provider must confirm that the prescriber, healthcare facility, and patient are enrolled in the ZYPREXA RELPREVV Patient Care Program and that the patient is eligible to receive ZYPREXA RELPREVV via the process outlined below. **The pharmacy service provider must only dispense ZYPREXA RELPREVV to registered healthcare facilities or a healthcare professional, not directly to a patient.**

A patient identification number (PIN) and healthcare facility unique identifier should be provided by the prescriber with the first prescription. Through the on-line Patient Care Program system, the PIN will quickly identify the patient and prescriber as enrolled in the Patient Care Program. The healthcare facility unique identifier will allow confirmation of healthcare facility registration. The system will indicate the patient's eligibility to receive a dispensing of ZYPREXA RELPREVV.

Pharmacy Service Provider Information

Patient eligibility is determined by enrollment in the Patient Care Program and entry of required injection data into the Patient Care Program system by the healthcare facility.

Steps to Dispense:

1. Order the product from a distributor.
2. Receive ZYPREXA RELPREVV from distributor and maintain a supply of product at the pharmacy.
3. Receive a valid prescription, patient identification number (PIN), and healthcare facility unique identifier.
4. Maintain the PIN and healthcare facility unique identifier in the patient record within the pharmacy system to access when refilling a prescription.
5. With the assigned username and password, access the ZYPREXA RELPREVV Patient Care Program system in one of three ways: access the website or call the Coordinating Center (1-877-772-9390) and chose either the Interactive Voice Response System (IVRS) option or speak to a Patient Care Program representative.

Web based – www.zyprexarelprevvprogram.com

- Enter the PIN (If the PIN is not provided, call the Coordinating Center and provide patient's first and last name, patient's date of birth and prescriber's name).
- System displays prescriber and patient name
- Confirm both names match prescription
- System displays healthcare facility number and name
- Confirm healthcare facility name/unique identifier matches patient authorization notification
- The system will indicate the patient's eligibility to receive ZYPREXA RELPREVV.

- If eligible, the pharmacist will enter the date of dispensing (**prior to** the vial kit leaving the pharmacy) into the Patient Care Program system and dispense only to the healthcare facility (representative) associated with that patient. Do NOT dispense directly to a patient.
- If ineligible, do NOT dispense product. Contact the Patient Care Program Coordinating Center for resolution.

Interactive Voice Response System – call 1-877-772-9390

- Enter the PIN (If the PIN is not provided, call the Coordinating Center and provide patient's first and last name, patient's date of birth and prescriber's name).
- IVRS provides first 5 letters of prescriber and patient last name
- Confirm both names match prescription
- IVRS provides healthcare facility unique identifier
- Confirm unique identifier/healthcare facility name matches patient authorization notification
- The system will indicate the patient's eligibility to receive ZYPREXA RELPREVV.
- If eligible, the pharmacist will enter the date of dispensing (**prior to** the vial kit leaving the pharmacy) into the Patient Care Program system and dispense only to the healthcare facility (representative) associated with that patient. Do NOT dispense directly to a patient.
- If ineligible, do NOT dispense product. Contact the Patient Care Program Coordinating Center for resolution.

Pharmacy Service Provider Information

Call the Coordinating Center Help Desk 1-877-772-9390

- Provide the PIN (If the PIN is not available, provide patient's first and last name, patient's date of birth and prescriber's name).
- Patient Care Program representative will ask pharmacy provider questions and provides verification of patient eligibility to receive ZYPREXA RELPREVV.
 - If eligible, Patient Care Program representative will enter the date of dispensing **prior to** the vial kit leaving the pharmacy.
 - Pharmacy Service Provider agrees to dispense only to the healthcare facility (representative) associated with that patient and not directly to a patient.
 - If ineligible, Do NOT dispense product. The Coordinating Center will work to resolve.

Product Replacement

If, during the course of administering a ZYPREXA RELPREVV injection to a patient, an accident occurs that causes the ZYPREXA RELPREVV vial to be broken or to become unusable (e.g., aspiration of blood), call the Coordinating Center.

Reconciliation

Shipping records will be monitored against dispensing data by the Patient Care Program. If dispensing data are not provided, the pharmacy service provider will be contacted to obtain the information. Unreconciled discrepancies may lead to removal of the pharmacy from the approved list of pharmacies for ZYPREXA RELPREVV.

Glossary of Terms

Healthcare Facility

A healthcare facility administering and/or monitoring injections of ZYPREXA RELPREVV.

Interactive Voice Response System (IVRS)

System that allows a pharmacy service provider to confirm patient and prescriber eligibility and provide dispensing data via telephone rather than the on-line system.

Patient Authorization Notification

Provided to the prescriber and healthcare facility upon registration and includes the PIN and healthcare facility unique identifier. To be provided to the pharmacy service provider with the first prescription for each patient.

Patient Identification Numbers (PIN)

Unique numbers assigned to patients, which are used by the pharmacy service provider to confirm enrollment in the ZYPREXA RELPREVV Patient Care Program.

Pharmacy Service Provider

Any retail pharmacy, hospital pharmacy, physician, or properly licensed healthcare facility that can order for and deliver ZYPREXA RELPREVV to a healthcare professional in accordance with their agreement to implement all relevant requirements of the ZYPREXA RELPREVV Patient Care Program.

- Pharmacy - Retail and hospital pharmacies
- Buy & Bill Pharmacy Service Provider – a licensed healthcare provider that purchases pharmaceuticals through a licensed distributor for its own use in the treatment of a patient and then includes the cost of the pharmaceutical in its billing of patients and third-party payers.

Post-Injection Delirium/Sedation Syndrome (PDSS)

During premarketing clinical studies, adverse events that presented with signs and symptoms consistent with olanzapine overdose, in particular, sedation (including coma) and/or delirium, were reported in patients following an injection of ZYPREXA RELPREVV. Sedation ranged from mild in severity to coma and delirium included confusion, disorientation, agitation, anxiety, and other cognitive impairment. Other symptoms noted include extrapyramidal symptoms, dysarthria, ataxia, aggression, dizziness, weakness, hypertension, and convulsion. The potential for onset of the event is greatest within the first hour. The majority of cases have occurred within the first 3 hours after injection; however, the event has occurred after 3 hours.

Prescriber

A healthcare professional writing prescriptions for ZYPREXA RELPREVV. Prescribers are responsible for ensuring that all patients receiving ZYPREXA RELPREVV are enrolled in the program.