Pharmacist Managed: Olanzapine Long-Acting Injectable Clinic in a Community Mental Health Center

Innovative Practices Award Finalist

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Which of the following statements is CORRECT with regard to adherence to the Risk Evaluation and Mitigation Strategy (REMS) for Olanzapine Long Acting Injectable (OLAI)?

A. REMS is not a requirement from the FDA, they are recommendations for consideration by the prescriber.

B. REMS is a requirement from the FDA which requires the patient and prescriber to be registered prior to dispensing.

C. REMS is a requirement from the FDA which requires the patient, prescriber, and facility to be registered prior to dispensing.

D. REMS is a requirement from the FDA which requires the patient, prescriber, facility, and pharmacy to be registered prior to dispensing.

Per REMS, the patient MUST remain at the facility for at least 3 hours after receiving OLAI to mitigate the risk of Post-Injection Delirium/Sedation Syndrome (PDSS). What monitoring forms are provided to assist with assessing for PDSS?

A. No forms are provided.

B. Form 580b that is provided by the FDA.

C. A form provided by the manufacturer.

D. A site-specific form that is approved by the manufacturer.

Risk Evaluation and Mitigation Strategy (REMS)

1. Communication Plan
   - Letter sent to providers 60 days prior to being marketed
   - Explained enrollment into REMS via Patient Care Program to providers

2. Medication Guide

3. Elements to Assure Safe Use → Clinical Pharmacist Intervention
   - Registration of Facility
   - Registration of Prescribers
   - Registration of Patients
   - Registration of Pharmacy
   - Coordination of training & monitoring
   - Communication between Patient Care Program

4. Implementation System (manufacturer responsibility)
   - Maintains a secure database
   - Reviews distribution history
   - Monitors PDSS events
   - Assures safe use

Olanzapine Long Acting Injectable Clinic (OLAIC)

FDA approved December 2009

Boxed Warnings
- Appropriate Use
- Post-Injection Delirium/Sedation Syndrome (PDSS)

Risk Evaluation and Mitigation Strategy (REMS)
- Lessen the risk of negative outcomes from PDSS
- OLAI ONLY available through restricted distribution program
- Patient must be monitored in a facility with ready access to emergency response services
- Patient MUST be observed for at least 3 hours post injection

Olanzapine Long Acting Injectable (OLAI)

- FDA approved December 2009
- Boxed Warnings
  - Appropriate Use
  - Post-Injection Delirium/Sedation Syndrome (PDSS)
- Risk Evaluation and Mitigation Strategy (REMS)
  - Lessen the risk of negative outcomes from PDSS
  - OLAI ONLY available through restricted distribution program
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Patient Referral & Review Process

Prescriber identifies patient for OLAIC
Prescriber completes Prescriber Referral Form**
Referral form and chart reviewed by key pharmacists/psychiatrist
Verify prescriber and patient registration/consent
Pharmacist contacts patient and learn to review REMS

*Created by Pharmacist

Award Finalist Platform Presentation: Williams
Broadmoor Hall F
Pharmacist Responsibilities

- Ensures enrollment and consent
- Reviews adherence to REMS
- Educates patient and family/support system
- Identifies pharmacy, payer source, co-pay, and appropriate staff to pick up injection
- Schedules and communicates new starts to OLAIC team and administration
- Ensures appropriate labs are ordered and performed

Patient Flow: OLAIC

1. **Patient presents to OLAIC**
2. Nursing and pharmacy assess patient compliance
3. Injection administered/3 hour observation begins
4. Support staff uses monitoring form to assess for PDSS
5. Patient reassessed by nursing/pharmacy for PDSS
6. Pharmacist ensures patient transportation home
7. Patient schedule for next injection and assisted home

Clinic Outcomes

- Eleven patients enrolled
- Approximately 115 injections administered
- Most common dose: 300mg IM q 2 weeks
- All patients complied with REMS
- One possible PDSS occurring after OLAIC

Conclusions

- **Sustainability**
  - OLAIC LPN
  - RN manager

- **Essential Role of Clinical Pharmacist**
  - Assure safe and appropriate use
  - Supervise
  - Educate
  - Assist
  - Follow-through

- **Support of CMHC & Pharmacy Administration**
  - REMS
  - Outcomes
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