



Pharmacy Staff Information

Name: _____

Job Title: _____

Knowledge Assessment: Module B

In-Depth Pharmacy Training for the XYWAV and XYREM REMS

1. Upon completion of formal training, a new pharmacist will perform which of the following assigned duties under the observation of a senior pharmacy mentor?
 - A. Execution of the XYWAV and XYREM REMS Patient Counseling Checklist with new patients (or their caregiver for pediatric patients) and patients (or their caregiver for pediatric patients) who have not received either XYWAV™ or XYREM® for 6 months or longer
 - B. Detailed monitoring, including completion of a XYWAV and XYREM REMS Risk Management Report (RMR)
 - C. Follow-up interactions with patients, caregivers (for pediatric patients), and prescribers
 - D. A, B, and C

(Answer: D)

2. The Central Pharmacy certified through the XYWAV and XYREM REMS will:
 - A. Limit the patient's first shipment of any oxybate-containing product within the XYWAV and XYREM REMS to a one-month supply and subsequent shipments to a three-month supply
 - B. Report potential adverse events to Jazz Pharmaceuticals
 - C. Notify prescribers when patients are taking sedative hypnotics, other CNS depressants, or other potentially interacting agents of which the prescriber is not already aware or there are signs of potential abuse or misuse
 - D. A, B, and C

(Answer: D)

3. The XYWAV and XYREM REMS Central Database will contain the following information that must be available for ongoing review to ensure XYWAV and XYREM are dispensed to enrolled patients only after completion and documentation of safe use conditions:
 - A. Complete patient and prescriber enrollment information
 - B. Patient information, including two additional identifiers, current and previous prescribers, comorbid conditions and concomitant medications reported by the patient or caregiver (for pediatric patients), and prescription history
 - C. Caregiver information (for pediatric patients)
 - D. Prescription information, including whether the prescription is for XYWAV or XYREM, date, dose, titration instructions, number of refills, and total quantity
 - E. RMRs, shipment information, and documentation of interactions with patients, caregivers, and prescribers
 - F. All of the above

(Answer: F)



4. XYWAV and XYREM contain the same amount of the active moiety, oxybate, per milliliter of solution.
- A. True
 - B. False
- (Answer: A)
5. Prior to shipment of XYWAV or XYREM, the XYWAV and XYREM REMS Patient Counseling Checklist must be completed as follows (not all possible scenarios triggering use of the Patient Counseling Checklist are noted):
- For initial prescriptions of XYWAV or XYREM and for patients restarting XYWAV or XYREM after not receiving either XYWAV or XYREM for 6 months or more, complete the entire checklist
 - For prescription renewals and refills, if the patient or caregiver indicates a change in the patient's health or medications, transfer the patient or caregiver to the pharmacist to determine if further counseling and prescriber outreach is required. Steps 1, 3, 4, and 5 of the XYWAV and XYREM REMS Patient Counseling Checklist must be completed if the patient or caregiver indicates that the patient is taking a new medication or has a new comorbid medical condition that is listed in Step 4 of the XYWAV and XYREM REMS Patient Counseling Checklist.
 - For new caregivers of already enrolled pediatric patients, complete the entire checklist
- A. True
 - B. False
- (Answer: A)
6. When the patient is transitioning from XYWAV to XYREM and is on a salt-restricted diet or has comorbidities such as high blood pressure, heart failure, or kidney problems, the certified pharmacy will have to counsel the patient utilizing the XYWAV and XYREM REMS Patient Counseling Checklist.
- A. True
 - B. False
- (Answer: A)
7. If patient use of a contraindicated medication (e.g. sedative hypnotics or alcohol) is confirmed and the prescriber has not indicated prior knowledge, the pharmacist will contact and consult the prescriber prior to shipping XYWAV or XYREM.
- A. True
 - B. False
- (Answer: A)
8. If there are any clinical usage clarifications needed for a prescription, the pharmacist will:
- A. Refuse to fill the prescription
 - B. Notify and consult the prescriber
 - C. Fill out an RMR
 - D. Disenroll the prescriber
- (Answer: B)
9. Which of the following is NOT true for the prescription refill process?
- A. Up to 5 refills are allowed on a XYWAV or XYREM prescription
 - B. Refill prescriptions can be submitted electronically
 - C. Refill orders are opened when the patient has approximately 10 days of therapy remaining from the previous prescription
 - D. All refills must be countersigned by the prescriber
- (Answer: D)



10. As part of processing a prescription refill, the pharmacist may discuss the following with the patient or caregiver (for pediatric patients) EXCEPT:

- A. Use of sedative hypnotics (e.g., diazepam, phenobarbital, or zolpidem)
- B. Use of alcohol
- C. History of sleep apnea
- D. Choice of prescriber
- E. History of asthma, COPD, or other conditions affecting breathing

(Answer: D)

11. If the pharmacist identifies that the patient is taking a potentially interacting agent that may present a risk to the patient, the pharmacist should consider which of the following actions before filling the prescription?

- A. Notifying law enforcement
- B. Taking no action
- C. Consulting the prescriber
- D. Consulting the insurance provider

(Answer: C)

12. In monitoring and assessing for signs of abuse, misuse, or diversion, a pharmacist must document risk management events in the Central Database by completing a Risk Management Report. Events that should generate an RMR include, but are not limited to (choose BEST answer):

- A. Early refill requests (excluding requests to accommodate shipment logistics)
- B. Lost, stolen, destroyed, or spilled drug
- C. Patient or caregiver claims that product was not delivered while carrier shows receipt of delivery
- D. Counterfeit or contaminated product
- E. All of the above

(Answer: E)

13. When is weight required on the prescription form?

- A. For all patients on every prescription form
- B. For all patients on initial and restart fills only
- C. For adult patients on every prescription form
- D. For adult patients on initial and restart fills only
- E. For pediatric patients on every prescription form
- F. For pediatric patients on initial and restart fills only

(Answer: F)