

# Xyrem Prescription and Distribution Process

*Video Script 2/2/01)*

<b>Audio</b>	<b>Video</b>	<b>Titles</b>
1. [Fade in music]	Graphic texture of oranges and yellows	Fade in first title/logo graphic.
[Up music.]	logo of Xyrem emerges	<b>Xyrem® (Sodium Oxybate) Oral Solution</b>
[Fade out music.]		Fade out first title/logo graphic. Fade in video title.
		<b>Prescription and Distribution Process</b>
2. Narcolepsy, it is a serious debilitating condition that diminishes the quality of life for approximately 125,000 Americans.	Fade to head-to chest shot of narrator.	
3. Xyrem is a promising new medication that, for some patients with narcolepsy, can significantly reduce the incidence of cataplexy, as well as improve symptoms of daytime sleepiness.	Fade to table-top shot of Xyrem box and a display of its contents.	
4. But, because Xyrem is a controlled substance, Orphan Medical wants to make certain that “only” patients for whom it is prescribed have ongoing access to this important treatment.	Fade back to shot of narrator sitting on desk.	

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| 5. Orphan Medical is committed to a distribution plan that is both safe and effective for patients and also protects the general public by minimizing opportunities for the diversion of Xyrem to unauthorized individuals.   | Fade to shot of Orphan representative making a presentation about success plans—perhaps pointing to a bullet point on an overhead screen.   |  |
| 6. To achieve that goal, Orphan Medical--after extensive consultation with law enforcement, prosecutors, field law enforcement personnel, pharmaceutical distribution experts, forensic experts, DEA consultants, and drug diversion experts-- has developed a comprehensive, restrictive distribution program. | Fade to build graphic that begins with shot of Xyrem box in center of screen.   | <p>Fade in titles as mentioned.</p> <ul style="list-style-type: none"> <li>• <b>law enforcement</b></li> <li>• <b>prosecutors</b></li> <li>• <b>field law enforcement personnel</b></li> <li>• <b>pharmaceutical distribution experts</b></li> <li>• <b>forensic experts</b></li> <li>• <b>DEA consultants</b></li> <li>• <b>drug diversion experts</b></li> </ul> |
| 7. In addition to thorough patient and physician education about Xyrem,   | Fade to shot of narrator holding up a variety of patient/physician education material and, then, setting it down on the desk.   |  |
| 8. As well as multiple security checks before, during and after prescription fulfillment.   | <p>Cut to split-screen shot showing</p> <ol style="list-style-type: none"> <li>a) pharmacist assistant verifying doctor's license</li> <li>b) pharmacist unlocking cabinet,</li> <li>c) patient signing for delivery by Federal Express.</li> </ol> |  |

9. The purpose of this video is to outline, step-by-step, all of the security measures that will occur whenever a prescription of Xyrem is written and filled.
- Cut back to narrator.
- 10.
- When Xyrem first becomes available, a select group of physicians with a documented history of prescribing medications for patients with narcolepsy will receive an educational module, in the mail, called the Physician Success Program.
- Begin action
- Fade to freeze-frame shot of a physician consulting with a patient.
- Fade in title with freeze frame.
- Notify A Select Group of Physicians about Xyrem®**
- Fade out title
11. This program will introduce these selected physicians to Xyrem and includes a videotape, Physician Success Program contact information, a patient education presentation, templates for medical records and patient contracts, and information about third-party payor reimbursement.
- Fade to table-top display of Physician Success Program materials.
- This mailing will be documented and no medication samples will ever be provided.
- Fade in titles when mentioned in narration.
- **Documented mailing**
  - **No physician samples**

12. Complementing this effort, a representative from Orphan Medical will visit each targeted physician and reinforce the information provided in the Physician Success Program.

Fade to shot of rep and physician meeting and discussing Physician Success Program materials.

The representative will ask the physician to sign a receipt if any additional Physician Success Program materials are left for the physician's office.

13.

Fade in title

A crucial component of the secure distribution of Xyrem is the use of a specialty pharmacy. The specialty pharmacy is a single, centrally-located facility that will have a variety of distribution, documentation, and security responsibilities.

Fade in narrator

**Specialty  
Pharmacy**

Fade out title.

14. A staff of dedicated pharmacists, reimbursement specialists, and customer service representatives will provide a closed-loop distribution system that will not only serve patients and prescribers, but will also be able to generate data, recording prescribers, patients and dosing that could provide information for any possible investigations and prosecutions for state and federal authorities.

Fade to shot of pharmacist

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| 15. This distribution system begins with a secure holding warehouse area where an inventory of Xyrem is kept, according to scheduling requirements by federal and state laws and checked several times a day.  | Fade to shot of pharmacy employee unlocking holding warehouse to reveal Xyrem supply.  | Fade in benefit title.          |
| 16. On a regular basis, a small supply of Xyrem is moved from the gated and locked warehouse to a gated and locked area within the same pharmacy. Only qualified pharmacists and pharmacy technicians, dedicated to the Xyrem Program will be allowed access or will handle Xyrem. | Cut to shot of pharmacy employees transferring inventory.  | <b>Secure inventory storage</b> |
| 17. Both Orphan and the pharmacy acknowledge and document every time any inventory is moved.   | Slow fades shot of<br>a) pharmacy personnel signing some transaction documentation<br>b) Orphan personnel at computer screen documenting the same. |                                 |
| 18. Now, let's take a step-by-step look at how the specialty pharmacy provides verification and documentation of both the prescription and the prescribing physician before preceding to fill any requests for Xyrem.  | Fade to shot of narrator.  |                                 |
| 19. When a physician determines that Xyrem is an appropriate medication for a patient,   | Fade to shot of physician in the office using Orphan Medical's materials to educate a patient about Xyrem.   |                                 |
| 20. The prescription is faxed or mailed, depending on each states pharmacy board regulations, directly to the specialty pharmacy.  | Fade to shot of physician faxing prescription.   |                                 |

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| <p>21. Upon receipt of the prescription, the specialty pharmacy first verifies if the prescribing physician is on Orphan Medical's list of targeted physicians and has active DEA and State License. Additionally, the pharmacy checks data from the physician's home State Board of Health to determine if there are any pending or previous actions against the physician.</p> | <p>Cut to shot of pharmacy employee picking up prescription fax and sitting down at a computer to verify physician's eligibility.</p> | <p>Fade in title with freeze frame.</p>                              |
| <p>22. Next, the pharmacy calls the physician's office to verify the origin of the prescription.</p>   | <p>Fade to split-screen shot of pharmacist and physician on the phone.</p>  | <p>Fade in title with freeze frames.</p>                             |
| <p>23. If it is the physician's first time prescribing Xyrem, the specialty pharmacy will ship a Xyrem Physician Success Program to the Physician's office to ensure that the physician is given every opportunity to become thoroughly familiar with a prescriber's responsibilities regarding Xyrem.</p>   | <p>Fade to table-top display of the Physician Success Program components.</p>   | <p><b>Physician verification</b></p>                                 |
| <p>24. Another important benefit of using a single, specialty pharmacy for the distribution of Xyrem is that it's possible to keep all the data about inventory, physicians, reimbursement, patients, and delivery in one efficient and quickly-accessible location.</p>   | <p>Fade to shot of narrator.</p>  | <p>Fade in benefit title.</p> <p><b>All data in one location</b></p> |

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| <p>25. Some of the data available include prescriptions by physician specialty, prescriptions by patient name, prescriptions by volume or frequency, and prescriptions by dose.</p>  | <p>Fade to build title graphic.</p>   | <p>Fade in title.</p>   |
|  |   | <p><b>Data Available</b></p>  |
|  |   | <p>Fade in bullet points when mentioned.</p>  |
|  |   | <ul style="list-style-type: none"> <li>• <b>Prescriptions by physician specialty</b></li> <li>• <b>Prescriptions by patient name</b></li> <li>• <b>Prescriptions by volume (frequency)</b></li> <li>• <b>Prescriptions by dose</b></li> </ul> |
| <p>26. The specialty pharmacy will also be responsible for contacting the patient's third-party payor to research benefits, file claims, appeal denials, and collect reimbursement.</p>  | <p>Cut to shot of pharmacy employee on phone with insurance company.</p>            |   |
| <p>27. The specialty pharmacy will also follow specific procedures for communicating with the patient both before and after the Xyrem is shipped.</p>  | <p>Fade to shot of narrator.</p>  |   |
| <p>28. First, the specialty pharmacy will contact the patient directly to make specific arrangements for the patient or the patient's authorized designee to personally receive the package containing the Xyrem and to discuss or verify third-party payor reimbursement.</p> | <p>Slow fades of patient and pharmacist discussing arrangements over the phone.</p> | <p>Fade in title.</p>   |
|  |   | <p><b>Patient communication</b></p>   |

29. Throughout this entire process of verification and documentation, if any of the data or behavior suggests the possibility that Xyrem may be used inappropriately, the specialty pharmacy is empowered to contact the appropriate authorities. Pharmacy finds a doctors that does not verify.
30. The patient's medication will be shipped overnight by Federal Express utilizing a tracking system designed specifically for the specialty pharmacy. Fade to shot of pharmacy employee putting Xyrem in Fed Ex packaging. Fade in title. **Overnight delivery**
31. And, if it is the patient's first time receiving Xyrem, the specialty pharmacy will also include the Patient Success Program in the package. Cut to close-up shot of pharmacy employee adding the Patient Success Program to the Fed Ex packaging.
32. This program will introduce the patient to their responsibilities pertaining to Xyrem and includes a videotape, Patient Success Program contact information, advice for safe in-home storage and disposal, advice for traveling with Xyrem, and information about third-party payor reimbursement. Fade to table-top display of Patient Success Program materials.
33. Shipments of Xyrem can only be left with the patient or the patient's authorized designee. Therefore, if the patient or the patient's designee is not available to receive or sign for the Xyrem, the package will be returned to the specialty pharmacy. Fade to shot of Fed Ex employee with package knocking on a patient's door. Patient—answers the door and they have a brief conversation. The Fed Ex employee shakes his head and gets signature. At the same time, the person closes the front door.
- Also, if the package is somehow lost, the specialty pharmacy will initiate an immediate investigation.

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| 34. Because the specialty pharmacy provides next-day, follow up through their in-house FedEx computer stations, they will telephone the patient within 24 hours after receiving the shipment of Xyrem.  | Fade to shot of specialty pharmacy employee working at an in-house FedEx computer station.   | Fade in title.<br><b>Real-time tracking</b> |
| 35. During this call, the specialty pharmacy will confirm receipt of the Xyrem prescription and the Patient Success program,  | Cut to split-screen shot of pharmacy employee and patient on the phone. Patient has all the Xyrem materials spread out on a table. |   |
| 36. counsel the patient about Xyrem dosing and compliance,  | Cut to close-up shot of patient removing contents of the Xyrem box.  |   |
| 37. and ensure the patient's understanding of the Patient Success Program as well as the patient's legal responsibilities and liabilities relating to the bifercated scheduling of Xyrem.   | Cut to slow fades of pharmacy employee and patient on the phone. Patient is holding and reading a patient education brochure.      |   |
| 38. The specialty pharmacy also keeps track of expected prescription refill dates and will contact the patient ahead of time. Patients who request a refill before their refill date will be flagged and their physician contacted. The physician verification process is repeated before every refill is sent. | Pharmacy finds a patient that does not verify on getting a refill  |   |
| 39. As you can see, the Xyrem prescription and distribution process is a comprehensive program that ensures the responsible distribution of this important medication.  | Fade to shot of narrator.  |   |

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| 40. Both physicians and patients will receive a thorough education about the use and safe handling of Xyrem.  | Fade to shot of physician and patient in the office reviewing patient education materials.                                   | Fade in title.<br><b>Thorough physician and patient education</b> |
| 41. Strict adherence to security and verification protocols will minimize diversion of the medication to unauthorized individuals.  | Fade to shot of Fed Ex employee at patient's door. Patient is signing the Fed Ex receipt and receiving the package of Xyrem. | Fade in title.<br><b>Helps prevent diversion</b>                  |
| 42. A staff of dedicated specialists provide a closed-loop distribution system that will not only serve patients and prescribers, but will also have information to support any possible investigations and prosecutions. | Fade to shot of pharmacy employee entering data on a PC.   | Fade in title.<br><b>Prosecution assistance</b>                   |
| 43. And, most importantly, the Xyrem prescription and distribution process will ensure that this life-changing medication will be available to the thousands of patients who so desperately need it.                      | Fade to shot of happy patient after talking on phone at home with the success program.                                       |   |
| [Fade in music.]  |  |   |
| 44. [Up music.]   | Fade to black.   | Roll credits, disclaimers, contact information, copyright, etc.   |