Addyi® REMS Program

Risk Evaluation and Mitigation Strategy

Website Screenshots
March 2019
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1. **Header**
   1. Header is included on every web page. To reduce the length of the document, the screenshot is included once.

   ![Addyi REMS Website Screenshots](image1)

2. **Footer**
   1. Footer is included on every web page. To reduce the length of the document, the screenshot is included once.

   ![Addyi REMS Website Screenshots](image2)
2. Home Page

Addyi Risk Evaluation and Mitigation Strategy (REMS)

What is the Addyi REMS Program?
A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure the benefits of a drug outweigh its risks. The purpose of the Addyi REMS Program is to inform prescribers, outpatient pharmacies, inpatient pharmacies, and patients about the increased risk of:

- Hypotension and Syncope due to an interaction with alcohol

Addyi REMS Program Requirements

### Prescribers
- To be able to prescribe Addyi, prescribers must be trained, successfully complete a knowledge assessment, and enroll to be certified in the Addyi REMS program.
- Before prescribing Addyi, prescribers must review and complete the Addyi REMS Patient-Provider Agreement Form with every patient.

### Outpatient Pharmacies
- To be able to dispense Addyi, the Authorized Representative of the outpatient pharmacy must be trained, successfully complete a knowledge assessment, and enroll their pharmacy to be certified in the Addyi REMS program.
- To be able to dispense Addyi, outpatient pharmacies must train all relevant pharmacy staff involved in dispensing.
- Before dispensing every prescription, pharmacies must counsel all patients on the need to avoid alcohol.

### Inpatient Pharmacies
- To be able to dispense Addyi, the Authorized Representative of the inpatient pharmacy must be trained, successfully complete a knowledge assessment, and enroll their pharmacy to be certified in the Addyi REMS program.
- To be able to dispense Addyi, inpatient pharmacies must train all relevant pharmacy staff involved in dispensing.
- Inpatient Pharmacies must not dispense Addyi for outpatient use.

Click on the appropriate button below to complete the certification process in 3 easy steps.

**Prescribers**

Click Here to Start the Addyi REMS Program Prescriber and Pharmacy Training

START

**Pharmacies**

Click Here to Start the Addyi REMS Program Prescriber and Pharmacy Training

START

Materials for Prescribers
- Addyi REMS Prescriber and Pharmacy Training Program (Including a Knowledge Assessment)
- Addyi REMS Prescriber Enrollment Form
- Addyi REMS Patient-Provider Agreement Form
- Prescribing Information
- Medication Guide

Materials for Pharmacies
- Addyi REMS Program Individual Location Outpatient Pharmacy Enrollment Form
- Addyi REMS Program Multiple Locations Outpatient Pharmacy Enrollment Form
- Addyi REMS Program Inpatient Pharmacy Enrollment Form
- Prescribing Information
- Medication Guide

Materials for Patients
- Addyi REMS Patient-Provider Agreement Form
- Prescribing Information
- Medication Guide
Indication:
Addyi is indicated for the treatment of premenopausal women with hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to:
- A co-existing medical or psychiatric condition.
- Problems within the relationship, or
- The effects of a medication or other drug substance.

Limitations of Use:
- Addyi is not indicated for the treatment of HSDD in postmenopausal women or in men.
- Addyi is not indicated to enhance sexual performance.

Search for a Certified Pharmacy near you
Enter your zip code to locate a certified pharmacy within 10 miles of your zip code.

Privacy Policy
Contact Us
ADDYI.com

You are encouraged to report side effects of prescription drugs to the FDA.
Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

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3. Prescriber Page

Prescriber Training, Enrollment, and Certification (3 Easy Steps)

The Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of Addyi® (flibanserin) outweigh the increased risk of hypotension and syncope due to an interaction with alcohol.

Prescribers and Pharmacies must be certified in the Addyi REMS Program to prescribe and dispense Addyi. For prescribers to successfully become certified they must complete the following 3 easy steps:

1. Read the Addyi REMS Program Prescriber and Pharmacy Training and Prescribing Information.
2. Review your knowledge by answering Knowledge Assessment questions.
3. Enroll by completing the enrollment process online or by faxing the appropriate enrollment form.

*For online enrollment first sign up by creating an account and providing all requested contact information

For prescribers the entire Addyi REMS Program certification process can be completed online or by downloading and following the directions in the Addyi REMS Program Prescriber and Pharmacy Training document, available on this website. You may also call the Addyi REMS Program Support Center (1-844-233-9415) to request that the requisite materials be sent to you.

PRESSRICERS: CLICK THE BUTTON BELOW TO INITIATE THE ENTIRE ADDYI REMS PROGRAM TRAINING, ENROLLMENT AND CERTIFICATION PROCESS. COMPLETION SHOULD TAKE LESS THAN 10 MINUTES.

PRESSRICERS

Click Here to Start
ADDYI REMS PROGRAM TRAINING, ENROLLMENT AND CERTIFICATION PROCESS

START
Search for a Certified Pharmacy near you
Enter your zip code to locate a certified pharmacy within 10 miles of your zip code.

Enter Your Zip Code

Search

Addyi REMS Program Support Center

- Hours of Operation:
  8:00 AM to 8:00 PM ET
- Email:
  AddyiREMSenroll@AddyiREMS.com
- Phone:
  1-844-233-5415
- Fax:
  1-844-694-3373

Sprout Customer Service

- Phone:
  1-844-746-5745

You are encouraged to report side effects of prescription drugs to the FDA.
Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.
4. Pharmacy Page

Pharmacy Training, Enrollment, and Certification (3 Easy Steps)

The Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of Addyi® (flibanserin) outweigh the increased risk of hypotension and syncope due to an interaction with alcohol.

Prescribers and Pharmacies must be certified in the Addyi REMS Program to prescribe and dispense Addyi. For pharmacies to successfully become certified they must complete the following 3 easy steps*:

1. Read the Addyi REMS Program Prescriber and Pharmacy Training and the Prescribing Information for Addyi. The Addyi REMS Program Prescriber and Pharmacy Training Program and Prescribing Information are available for download from this website (www.AddyiREMS.com) or they can be requested by calling the Addyi REMS Program Support Center 1-844-233-9415. You can also launch the Addyi REMS Program Prescriber and Pharmacy Training** (including the Knowledge Assessment) and enrollment process by clicking the appropriate button at the bottom of this webpage. (See Option 1: Online below for a description of the different pharmacies)

2. Review your knowledge by answering the questions contained within the Addyi REMS Program Knowledge Assessment.

3. Enroll in the Addyi REMS Program by completing the appropriate pharmacy enrollment process. Enrollment can be completed in 2 ways, online or fax.

* For online enrollment first sign-up by creating an account and providing all requested contact information.

Option 1: Online

Click on the appropriate button below to complete the Addyi REMS Program Prescriber and Pharmacy Training, knowledge assessment and enrollment online. Choose the button that best meets your needs.

---

Individual Location Outpatient Pharmacy Training Program, Certification and Enrollment
This is for individual or independent outpatient pharmacies to become certified to dispense Addyi. Clicking on this button will take the authorized representative through the entire training, enrollment and certification process.

Click Here

Multiple Locations Outpatient Pharmacy Training Program, Certification and Enrollment
This is for outpatient pharmacies with multiple locations (e.g., chains). A pharmacy headquarters must complete this process before individual outlets can be certified to dispense Addyi. Clicking this button will take the authorized representative through the entire training, enrollment and certification process.

Click Here

---

Materials for Prescribers

- Addyi REMS Prescriber and Pharmacy Training Program (Including a Knowledge Assessment)
- Addyi REMS Prescriber Enrollment Form
- Addyi REMS Patient-Provider Agreement Form
- Prescribing Information
- Medication Guide

Materials for Pharmacies

- Addyi REMS Program Individual Location Outpatient Pharmacy Enrollment Form
- Addyi REMS Program Multiple Locations Outpatient Pharmacy Enrollment Form
- Addyi REMS Program Inpatient Pharmacy Enrollment Form
- Addyi REMS Program Patient-Provider Agreement Form
- Prescribing Information
- Medication Guide

Materials for Patients

- Addyi REMS Patient-Provider Agreement Form
- Medication Guide
Inpatient Pharmacy Training Program, Certification and Enrollment
This is for facilities with inpatient pharmacies to become certified to dispense Addyi. Clicking on this button will take the authorized representative through the entire training, enrollment and certification process.

[CLICK HERE]

Pharmacy Staff Training Program for all pharmacy staff at Addyi REMS Program Certified Pharmacies.
Clicking on this button will take pharmacy staff through the appropriate training should they wish to take the Addyi REMS Program training online. After completion, pharmacy staff will be able to print a Certificate of Completion which an authorized representative can use as documentation of the training requirements of the Addyi REMS Program.

[CLICK HERE]

Option 2: Fax
Complete the appropriate enrollment form located on the right side of this page located under the heading Materials for Pharmacies and the Knowledge Assessment. Please fax all pages of the completed enrollment form and Knowledge Assessment to the Addyi REMS Program Support Center (1-844-694-3373) or scan and e-mail to AddyiREMSEnroll@AddyiREMS.com. You may also call the Addyi REMS Program Support Center (1-844-233-9415) to request the appropriate materials be sent to you.

** Note the training program is also available to pharmacy staff to meet the training requirements of the Addyi REMS Program.

addyi
(flibanserin)

Search for a Certified Pharmacy near you
Enter your zip code to locate a certified pharmacy within 10 miles of your zip code.

Enter Your Zip Code

Search

Addyi REMS Program Support Center

- Hours of Operation: 8:00 AM TO 8:00 PM ET
- Email: AddyiREMSEnroll@AddyiREMS.com
- Phone: 1-844-233-9415
- Fax: 1-844-694-3373

Sprout Customer Service

- Phone: 1-844-746-5745

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You are encouraged to report side effects of prescription drugs to the FDA.
Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.
5. **Certified Network Page**

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*Addyi Certified Network*

**Addyi Certified Pharmacy Network**

Search for a Certified Pharmacy near you

Enter your zip code to locate a certified pharmacy within 10 miles of your zip code.

Enter Your Zip Code  

Search

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Visit [www.FDA.gov/medwatch](http://www.FDA.gov/medwatch) or call 1-800-FDA-1088.

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Reference ID: 4413314
7. Stakeholder Identification Page

Addyi Stakeholder Identification

Please select one of the following stakeholder types to ensure you are directed to the process that is appropriate to your role:

- **Prescriber** - This is for individuals prescribing Addyi to their patients.
- **Individual Location Outpatient Pharmacy** - This is for individual or independent outpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- **Multiple Location Outpatient Pharmacy** - This is for outpatient pharmacies with multiple locations (e.g., chains). A pharmacy headquarters must complete this process before individual outlets can be certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- **Inpatient Pharmacy** - This is for facilities with inpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- **Pharmacy Staff** - Staff Pharmacists or Pharmacy Technicians who participate in dispensing of Addyi in the pharmacy. As a pharmacy staff member you represent yourself and are NOT Authorized to enroll a pharmacy location.

[Next]

---

8. Stakeholder Identification Confirmation Message – Prescriber

Addyi Stakeholder Identification

Please select one of the following stakeholder types to ensure you are directed to the process that is appropriate to your role:

- **Prescriber** - This is for individuals prescribing Addyi to their patients.
- **Individual Location Outpatient Pharmacy** - This is for individual or independent outpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- **Multiple Location Outpatient Pharmacy** - This is for outpatient pharmacies with multiple locations (e.g., chains). A pharmacy headquarters must complete this process before individual outlets can be certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- **Inpatient Pharmacy** - This is for facilities with inpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.
- **Pharmacy Staff** - Staff Pharmacists or Pharmacy Technicians who participate in dispensing of Addyi in the pharmacy. As a pharmacy staff member you represent yourself and are NOT Authorized to enroll a pharmacy location.

You have selected **Prescriber**. If this is correct, please choose **Next** to continue.

[Next]
9. Stakeholder Identification Confirmation Message – Individual Location Outpatient Pharmacy

Addyi Stakeholder Identification

Please select one of the following stakeholder types to ensure you are directed to the process that is appropriate to your role:

- **Prescriber** - This is for individuals prescribing Addyi to their patients.

- **Individual Location Outpatient Pharmacy** - This is for individual or independent outpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.

- **Multiple Location Outpatient Pharmacy** - This is for outpatient pharmacies with multiple locations (e.g., chains). A pharmacy headquarters must complete this process before individual outlets can be certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.

- **Inpatient Pharmacy** - This is for facilities with inpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.

- **Pharmacy Staff** - Staff Pharmacists or Pharmacy Technicians who participate in dispensing of Addyi in the pharmacy. As a pharmacy staff member you represent yourself and are NOT Authorized to enroll a pharmacy location.

You have selected *Individual Location Outpatient Pharmacy*. If this is correct, please choose **Next** to continue.
10. Stakeholder Identification Confirmation Message – Multiple Locations Outpatient Pharmacy

Addyi Stakeholder Identification

Please select one of the following stakeholder types to ensure you are directed to the process that is appropriate to your role:

- **Prescriber** - This is for individuals prescribing Addyi to their patients.

- **Individual Location Outpatient Pharmacy** - This is for individual or independent outpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.

- **Multiple Location Outpatient Pharmacy** - This is for outpatient pharmacies with multiple locations (e.g., chains). A pharmacy headquarters must complete this process before individual outlets can be certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.

- **Inpatient Pharmacy** - This is for facilities with inpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.

- **Pharmacy Staff** - Staff Pharmacists or Pharmacy Technicians who participate in dispensing of Addyi in the pharmacy. As a pharmacy staff member you represent yourself and are NOT Authorized to enroll a pharmacy location.

You have selected **Multiple Locations Outpatient Pharmacy**, if this is correct, please choose **Next** to continue.
11. **Stakeholder Identification Confirmation Message – Inpatient Pharmacy**

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**Addyi Stakeholder Identification**

Please select one of the following stakeholder types to ensure you are directed to the process that is appropriate to your role:

- **Prescriber** - This is for individuals prescribing Addyi to their patients.

- **Individual Location Outpatient Pharmacy** - This is for individual or independent outpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.

- **Multiple Location Outpatient Pharmacy** - This is for outpatient pharmacies with multiple locations (e.g., chains). A pharmacy headquarters must complete this process before individual outlets can be certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.

- **Inpatient Pharmacy** - This is for facilities with inpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.

- **Pharmacy Staff** - Staff Pharmacists or Pharmacy Technicians who participate in dispensing of Addyi in the pharmacy. As a pharmacy staff member you represent yourself and are NOT Authorized to enroll a pharmacy location.

You have selected *Inpatient Pharmacy*. If this is correct, please choose **Next** to continue.
12. Stakeholder Identification Confirmation Message – Pharmacy Staff

Addyi Stakeholder Identification

Please select one of the following stakeholder types to ensure you are directed to the process that is appropriate to your role:

- **Prescriber** - This is for individuals prescribing Addyi to their patients.

- **Individual Location Outpatient Pharmacy** - This is for individual or independent outpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.

- **Multiple Location Outpatient Pharmacy** - This is for outpatient pharmacies with multiple locations (e.g., chains). A pharmacy headquarters must complete this process before individual outlets can be certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.

- **Inpatient Pharmacy** - This is for facilities with inpatient pharmacies to become certified to dispense Addyi. Selecting this option will take the authorized representative through the entire training, enrollment and certification process.

- **Pharmacy Staff** - Staff Pharmacists or Pharmacy Technicians who participate in dispensing of Addyi in the pharmacy. As a pharmacy staff member you represent yourself and are NOT Authorized to enroll a pharmacy location.

This selection enables the healthcare professional to view the Addyi REMS Program Prescriber and Pharmacy Training. This training allows you to complete the Knowledge Assessment. If this is correct, please choose **Next** to continue.
## 13. Prescriber Intake Page

### Addyi REMS Program Prescriber Information Intake Form

Complete All Fields Below

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
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<tbody>
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<table>
<thead>
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<th>Telephone Number</th>
<th>Fax Number</th>
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</table>

<table>
<thead>
<tr>
<th>Email Address</th>
<th>Preferred Method of Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Email</td>
</tr>
<tr>
<td></td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>NPI</th>
<th>DEA</th>
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<table>
<thead>
<tr>
<th>Professional Designation</th>
<th>Your Clinical Specialty</th>
<th>Practice Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>MD</td>
<td>DO</td>
<td>PA</td>
</tr>
<tr>
<td>NP</td>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name of Practice/Clinic</th>
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</table>

<table>
<thead>
<tr>
<th>Address</th>
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</table>

<table>
<thead>
<tr>
<th>City</th>
<th>State</th>
<th>Zip Code</th>
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<td></td>
</tr>
</tbody>
</table>

Submit to Continue to Addyi REMS Program Prescriber and Pharmacy Training
14. Individual Location Outpatient Pharmacy Intake Form

Addyi REMS Program Individual Location Outpatient Pharmacy Information Intake Form (for Authorized Representative)

Complete All Fields Below

First Name

Last Name

Email

Phone Number

Fax Number

Title

Your Profession

Preferred Method of Contact

☐ R.Ph. ☐ PharmD ☐ Tech ☐ Other

☐ Email ☐ Fax

NPI

NCPDP

DEA

Pharmacy Name

Pharmacy Store # (optional)

Address 1

Address 2

City

State

Zip Code

Submit to Proceed to Addyi REMS Program Prescriber and Pharmacy Training
15. Multiple Locations Outpatient Pharmacy Intake Form

Addyi REMS Program Multiple Locations Outpatient Pharmacy Information Intake Form (for Authorized Representative)

Complete All Fields Below

- First Name
- Last Name
- Email
- Phone Number
- Fax Number
- Title
- Your Profession
- Preferred Method of Contact
- Chain ID
- Pharmacy Name
- Address 1
- Address 2
- City
- State
- Zip Code

Submit to Proceed to Addyi REMS Program Prescriber and Pharmacy Training
16. Inpatient Pharmacy Intake Form

Complete All Fields Below

First Name
Last Name
Email
Phone Number
Fax Number

Your Profession
- R.Ph.
- PharmD
- Tech
- Other

Preferred Method of Contact
- Email
- Fax

NPI
Pharmacy License Number
DEA

Facility Name
Address 1
Address 2
City
State
Zip Code

Submit to Proceed to Addyi REMS Program Pharmacy Training
ADDYI® (filbanserin) REMS Program Prescriber and Pharmacy Training

The Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of Addyi outweigh the increased risk of hypotension and syncope due to an interaction with alcohol.

Sprout Pharmaceuticals Inc.
4208 Six Forks Road, Ste 1010
Raleigh, NC 27609

You are encouraged to report side effects of prescription drugs to the FDA.

Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.
Addyi® REMS Program Overview

• The Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of Addyi outweigh the increased risk of hypotension and syncope due to an interaction with alcohol.

• Prescribers and Pharmacies must be certified in the Addyi REMS program to prescribe and dispense Addyi.

• Outpatient Pharmacies will only fill an Addyi prescription written by a certified prescriber. This is verified electronically when each Addyi prescription is processed through the pharmacy’s computer system or by calling the Addyi REMS Program Support Center.
19. Education Page 3

Addyi REMS Program Prescriber and Pharmacy Training

Addyi® REMS Program Prescriber and Pharmacy Training

• The information presented in this training program does not include a complete list of all risks and safety information on Addyi.

• Before prescribing or dispensing Addyi, please read the Addyi Prescribing Information and the Addyi Medication Guide available at www.AddyiREMS.com.

• Further information is also available at www.AddyiREMS.com.
Addyi® REMS Program Prescriber and Pharmacy Training

Addyi® REMS Program Certification Process

Complete the Addyi REMS Program Prescriber and Pharmacy Training in 3 easy steps*:

READ
Read the Addyi REMS Program Prescriber and Pharmacy Training and Prescribing Information

REVIEW
Review your knowledge by answering Knowledge Assessment questions

ENROLL
Enroll by completing the enrollment process online or by faxing the appropriate enrollment form

*For online enrollment first sign-up by creating an account and providing all requested contact information.

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You are encouraged to report side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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21. Education Page 5

Addyi® REMS Goal

The goal of the Addyi REMS is to mitigate the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol by:

- Ensuring prescribers and pharmacists are educated about the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol and the need to counsel patients about this risk.

- Informing patients of the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.
Addyi® is Indicated for HSDD

- Addyi is indicated for the treatment of premenopausal women with acquired generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to:
  - A co-existing medical or psychiatric condition,
  - Problems within the relationship, or
  - The effects of a medication or other drug substance.

Limitations of Use

- Addyi is not indicated for the treatment of HSDD in postmenopausal women or in men.
- Addyi is not indicated to enhance sexual performance.
23. Education Page 7

Addyi® and Alcohol:
Increased Risk of Hypotension and Syncope

- Dedicated alcohol interaction study with Addyi in 23 men and 2 premenopausal women.
- All subjects were co-administered Addyi 100 mg and the equivalent of two or four glasses of wine* consumed over 10 minutes in the morning.
- Severe hypotension was observed.
- Therapeutic intervention was needed in some cases.
- There were no events requiring therapeutic intervention when Addyi or alcohol was administered alone.

*Each glass of wine containing 12% alcohol content = one can of beer containing 5% alcohol = 1.5 ounce shot of 80-proof spirit in a 70 kg person.
Addyi® and Alcohol: 
Increased Risk of Hypotension and Syncope

- Four of 23 subjects (17%) co-administered Addyi 100 mg and the equivalent of two glasses of wine had events of hypotension or syncope.
  - Systolic blood pressure reductions from 28 to 54 mmHg
  - Diastolic blood pressure reductions from 24 to 46 mmHg
- Six of the 24 subjects (25%) co-administered Addyi 100 mg and the equivalent of four glasses of wine experienced orthostatic hypotension when standing from a sitting position.
  - Systolic blood pressure reductions from 22 to 48 mmHg
  - Diastolic blood pressure reductions from 0 to 27 mmHg
Addyi® Contraindications

- Alcohol
- Moderate or strong CYP3A4 inhibitors
- Hepatic impairment
26. Education Page 10

Addyi® and Alcohol

- Patients must not take Addyi unless they can abstain from alcohol use for the full duration of treatment.
- Prescribers need to evaluate a patient’s ability to abstain from using alcohol.
- Prescribers and Pharmacists must counsel their patients on the increased risk of hypotension and syncope with Addyi due to an interaction with alcohol and the need to abstain from alcohol.
- Pharmacists must counsel patients about the need to avoid alcohol with every prescription.
- The Addyi REMS Patient-Provider Agreement Form is an important and required tool for healthcare providers to use with patients.
Addyi® REMS Program Patient-Provider Agreement

- The Addyi REMS Program Patient-Provider Agreement Form must be used to counsel patients upon receiving their initial prescription for Addyi.
- After signing, this form should be kept in the patient's chart.
- The bottom portion can be torn off for the patient to take home.
- The digital Patient-Provider Agreement Form is available for the CareCloud EMR system.
- If the digital Patient-Provider Agreement Form is utilized, provide a copy for the patient.
- This form may also be used for pharmacy counseling.

Addyi® REMS Program Patient-Provider Agreement Form

You are encouraged to report side effects of prescription drugs to the FDA.
Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.
Patient-Provider Agreement: Patient Information

Patients taking Addyi® must express an understanding of the following:

- I understand I must not drink alcohol while taking Addyi (flibanserin).
- Drinking alcohol during treatment with Addyi has been shown to increase the risk of severe low blood pressure and fainting (loss of consciousness).
- If I feel lightheaded or dizzy, I will lie down right away and seek medical help if these symptoms do not go away.
- If I faint (lose consciousness), I will tell my healthcare provider as soon as possible.
- I understand that I should only take Addyi at bedtime.
- If I miss a dose, I will skip the missed dose. I will take my next dose the next day at bedtime.
29. Education Page 13

Completing the Addyi REMS Program Prescriber and Pharmacy Training

Confirm Understanding Through Knowledge Assessment

TRAINING COMPLETE
Confirm that you've read through and understand the Addyi REMS Program Prescriber and Pharmacy Training by completing the Knowledge Assessment and, if required, attestations.

Take the Knowledge Assessment

Addyi REMS Program Prescriber and Pharmacy Training

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You are encouraged to report side effects of prescription drugs to the FDA.
Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.
30. Knowledge Assessment Landing Page

Completing the Addyi REMS Program Prescriber and Pharmacy Training

Confirm Understanding Through Knowledge Assessment

TRAINING COMPLETE
Confirm that you've read through and understand the Addyi REMS Program Prescriber and Pharmacy Training by completing the Knowledge Assessment and, if required, attestations.

Take the Knowledge Assessment
31. Knowledge Assessment

Addyi REMS Program Knowledge Assessment

Confirm that you've read through and understand the Addyi REMS Program Prescriber and Pharmacy Training by completing the Knowledge Assessment questions.

1. Why is alcohol contraindicated with Addyi?
   - Hepatotoxicity
   - Teratogenicity
   - Hypotension and syncope
   - Hypersensitivity

2. What is the purpose of the Addyi REMS Patient-Provider Agreement Form?
   - For prescribers to counsel patients at the office visit
   - For patient charting
   - For the patient to take home the important safety messages
   - For pharmacy counseling
   - All of the above

3. How often must pharmacists counsel patients about the need to avoid alcohol?
   - Never
   - Only if the patient asks about alcohol use
   - With the first prescription only
   - With every prescription

4. What is the primary counseling message for the patient?
   - Do not drink alcohol while taking Addyi until you know how alcohol affects you
   - Limit your alcohol use while taking Addyi
   - You must not drink alcohol while taking Addyi
   - Do not drink alcohol at night when you take your daily Addyi

Click to Submit and Continue Enrollment
Addyi REMS Program Knowledge Assessment

You have completed the Addyi REMS Program Prescriber and Pharmacy Training and Knowledge Assessment. Your results are below.

Your Score: 4 out of 4 correct.

PROCEED TO PRESCRIBER ATTESTATION

1. Why is alcohol contraindicated with Addyi?
   Answer Provided: Hypotension and syncope

2. What is the purpose of the Addyi REMS Patient-Provider Agreement Form?
   Answer Provided: All of the Above

3. How often must pharmacists counsel patients about the need to avoid alcohol?
   Answer Provided: With every prescription

4. What is the primary counseling message for the patient?
   Answer Provided: You must not drink alcohol while taking Addyi
33. Knowledge Assessment – Success Page for Individual Location Outpatient Pharmacy

Addyi REMS Program Knowledge Assessment

You have completed the Addyi REMS Program Prescriber and Pharmacy Training and Knowledge Assessment. Your results are below.

Your Score: 4 out of 4 correct.

PROCEED TO INDIVIDUAL LOCATION OUTPATIENT PHARMACY ATTESTATIONS

1. Why is alcohol contraindicated with Addyi?
   Answer Provided: Hypotension and syncope

2. What is the purpose of the Addyi REMS Patient-Provider Agreement Form?
   Answer Provided: All of the Above

3. How often must pharmacists counsel patients about the need to avoid alcohol?
   Answer Provided: With every prescription

4. What is the primary counseling message for the patient?
   Answer Provided: You must not drink alcohol while taking Addyi
34. Knowledge Assessment – Success Page for Multiple Locations
Outpatient Pharmacy

Addyi REMS Program Knowledge Assessment

You have completed the Addyi REMS Program Prescriber and Pharmacy Training and Knowledge Assessment. Your results are below.

Your Score: 4 out of 4 correct.

PROCEED TO MULTIPLE LOCATIONS OUTPATIENT PHARMACY ATTESTATIONS

1. Why is alcohol contraindicated with Addyi?
   Answer Provided: Hypotension and syncope

2. What is the purpose of the Addyi REMS Patient-Provider Agreement Form?
   Answer Provided: All of the Above

3. How often must pharmacists counsel patients about the need to avoid alcohol?
   Answer Provided: With every prescription

4. What is the primary counseling message for the patient?
   Answer Provided: You must not drink alcohol while taking Addyi
35. Knowledge Assessment – Success Page for Inpatient Pharmacy

Addyi REMS Program Knowledge Assessment

You have completed the Addyi REMS Program Prescriber and Pharmacy Training and Knowledge Assessment. Your results are below.

Your Score: 4 out of 4 correct.

PROCEED TO INPATIENT PHARMACY ATTESTATIONS

1. Why is alcohol contraindicated with Addyi?
   Answer Provided: Hypotension and syncope

2. What is the purpose of the Addyi REMS Patient-Provider Agreement Form?
   Answer Provided: All of the Above

3. How often must pharmacists counsel patients about the need to avoid alcohol?
   Answer Provided: With every prescription

4. What is the primary counseling message for the patient?
   Answer Provided: You must not drink alcohol while taking Addyi
36. Knowledge Assessment – Success Page for Pharmacy Staff

Addyi REMS Program Knowledge Assessment

You have completed the Addyi REMS Program Prescriber and Pharmacy Training and Knowledge Assessment. Your results are below.

Your Score: 4 out of 4 correct.

[CLICK TO COMPLETE TRAINING]

1. Why is alcohol contraindicated with Addyi?
   Answer Provided: Hypotension and syncope

2. What is the purpose of the Addyi REMS Patient-Provider Agreement Form?
   Answer Provided: All of the Above

3. How often must pharmacists counsel patients about the need to avoid alcohol?
   Answer Provided: With every prescription

4. What is the primary counseling message for the patient?
   Answer Provided: You must not drink alcohol while taking Addyi
37. Knowledge Assessment – Failure Attempt Page

Addyi REMS Program Knowledge Assessment

You have completed the Addyi REMS Program Prescriber and Pharmacy Training and Knowledge Assessment. Your results are below.

Your Score: 3 out of 4 correct.

- Incorrect Result(s) Below:
  1. Why is alcohol contraindicated with Addyi?
     - Answer Provided: Hyperosensitivity

- Correct Result(s) Below:
  2. What is the purpose of the Addyi REMS Patient-Provider Agreement Form?
     - Answer Provided: All of the Above
  3. How often must pharmacists counsel patients about the need to avoid alcohol?
     - Answer Provided: With every prescription
  4. What is the primary counseling message for the patient?
     - Answer Provided: You must not drink alcohol while taking Addyi
38. Prescriber Attestation

Prescriber Attestations

Please click to attest to each of the following statements:

- I understand that Addyi is only available through prescribers and pharmacies that are certified by the Addyi REMS Program and that I must comply with the program requirements to prescribe Addyi.
- I understand that there is an increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.
- I have reviewed the Addyi Prescribing Information.
- I have reviewed the Addyi REMS Program Prescriber and Pharmacy Training and successfully completed the Addyi REMS Program Knowledge Assessment.
- I will counsel my patients about the increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol, using the Addyi REMS Program Patient-Provider Agreement Form.
- I will maintain the completed Addyi REMS Program Patient-Provider Agreement Form in the patient's records and provide the patient with the form. If the form is not utilized, a copy will be provided for the patient.
- I understand that the Addyi REMS Program may contact me via phone, mail, or email to survey me on the effectiveness of the REMS Program requirements.
- I will report any adverse events of hypotension or syncope where an interaction with alcohol cannot be ruled out to Sprout Pharmaceuticals at 1-844-233-6415.

Submit Attestations

You are encouraged to report side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch or call 1-800-FDA-1088.
## 39. Individual Location Outpatient Pharmacy Attestation

<table>
<thead>
<tr>
<th>Prescriber Training, Enrollment, and Certification (3 Easy Steps)</th>
<th>Pharmacy Training, Enrollment, and Certification (3 Easy Steps)</th>
<th>Addyi Certified Pharmacy Network</th>
</tr>
</thead>
</table>

Please click to attest to each of the following statements:

1. I have reviewed the Addyi REMS Program Prescriber and Pharmacy Training, the Addyi Medication Guide, and the Prescribing Information and successfully completed the Addyi REMS Program Knowledge Assessment.

2. I understand that there is an increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.

3. My certified pharmacy must complete training of pharmacists and staff involved with the dispensing of Addyi using the Addyi REMS Program Prescriber and Pharmacy Training and must comply with the REMS requirements. This training will be documented and is subject to audit.

4. I will ensure my certified pharmacy counsels patients to abstain from alcohol use with Addyi prior to dispensing.

5. My certified pharmacy will refrain from reselling, loaning, or transferring Addyi to another pharmacy, institution, distributor, or prescriber.

6. I will ensure that all relevant staff involved in the dispensing of Addyi understand the importance of reporting any adverse event of hypotension and syncope where an interaction with alcohol cannot be ruled out to either Sprout Pharmaceuticals (1-844-746-5745) or MedWatch (1-800-FDA-1088).

7. I understand that recertification in the Addyi REMS Program must be completed if the pharmacy designates a new authorized representative to maintain certification to order and dispense Addyi.

8. I will maintain appropriate documentation that all processes and procedures are in place and are being followed for the Addyi REMS Program and provide upon request to Sprout Pharmaceuticals, FDA, or a third party.

9. I will comply with audits by Sprout Pharmaceuticals or a designated third party and inspections by FDA to ensure that all processes and procedures are in place and are being followed for the Addyi REMS Program.

10. I understand Addyi REMS Program personnel may contact pharmacists at certified outpatient pharmacies to gather information, resolve discrepancies, or to provide other information related to the Addyi REMS Program.

11. I will oversee compliance with the Addyi REMS Program requirements.

12. I understand that my certified outpatient pharmacy must verify the prescriber is certified in the Addyi REMS Program prior to dispensing Addyi and will ensure verification through the following option (Click either Option A or B and indicate the NCPDP# as noted on the next page).

Click to Submit Attestations and Select Your Verification Option
# 40. Multiple Locations Outpatient Pharmacy Attestation

## Multiple Locations Outpatient Pharmacy Attestations (for Authorized Representative)

Please click to attest to each of the following statements:

<table>
<thead>
<tr>
<th>Statement</th>
<th>Attest</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I have reviewed the Addyi REMS Program Prescriber and Pharmacy Training Program, the Addyi Medication Guide, and the Prescribing Information and have successfully completed the Addyi REMS Program Knowledge Assessment.</td>
<td>☐</td>
</tr>
<tr>
<td>2. I understand that there is an increased risk of hypotension and syncope associated with Addyi due to an interaction with alcohol.</td>
<td>☐</td>
</tr>
<tr>
<td>3. I will establish processes and procedures for all my certified outpatient pharmacy dispensing locations to ensure compliance with the requirements of the Addyi REMS Program before dispensing Addyi, including the following: (A) All certified outpatient pharmacy dispensing locations will complete training of pharmacists and staff involved with the dispensing of Addyi using the Addyi REMS Program Prescriber and Pharmacy Training Program and will comply with the REMS requirements. This training will be documented and is subject to audit. (B) All certified outpatient pharmacy dispensing locations will verify the prescriber is certified in the Addyi REMS Program prior to dispensing Addyi. (C) All certified outpatient dispensing locations will counsel patients prior to dispensing the drug to abstain from alcohol consumption while undergoing treatment with Addyi. (D) All certified outpatient pharmacy dispensing locations will refrain from reselling, loaning, or transferring Addyi to another pharmacy, institution, distributor, or prescriber.</td>
<td>☐</td>
</tr>
<tr>
<td>4. I will ensure that all relevant staff involved in the dispensing of Addyi understand the importance of reporting any adverse event of hypotension and syncope where an interaction with alcohol cannot be ruled out to either Sprout Pharmaceuticals (1-844-746-5745) or MedWatch (1-800-FDA-1088).</td>
<td>☐</td>
</tr>
<tr>
<td>5. I understand that recertification in the Addyi REMS Program must be completed if the pharmacy designates a new authorized representative to maintain certification to order and dispense Addyi.</td>
<td>☐</td>
</tr>
<tr>
<td>6. I will maintain such documentation that all processes and procedures are in place and are being followed for the Addyi REMS Program and provide upon request to Sprout Pharmaceuticals, FDA, or a third party.</td>
<td>☐</td>
</tr>
<tr>
<td>7. I will comply with the audits by Sprout Pharmaceuticals or a designated third party and inspections by FDA to ensure that all processes and procedures are in place and are being followed for the Addyi REMS Program.</td>
<td>☐</td>
</tr>
<tr>
<td>8. I understand Addyi REMS Program personnel may contact pharmacists at certified outpatient pharmacies to gather information, resolve discrepancies, or to provide other information related to the Addyi REMS Program.</td>
<td>☐</td>
</tr>
<tr>
<td>9. I will oversee compliance with the Addyi REMS Program requirements.</td>
<td>☐</td>
</tr>
<tr>
<td>10. I will ensure the following Pharmacy Management System requirements will be in place for all certified outpatient pharmacy dispensing locations: (A) The Pharmacy Management System configuration and/or updates will be in place and verified with the Addyi REMS Program Support Center to ensure that Addyi prescriptions are submitted in accordance with the program requirements. (B) The Pharmacy Management System configuration and/or updates will be in place to ensure alerts are in place to notify pharmacists of the need to counsel patients to abstain from alcohol consumption with every dispensed prescription. (C) The Pharmacy Management System configuration must process all Addyi prescriptions, regardless of the method of payment, through our pharmacy management system and “pharmacy claims routing switch” for Addyi REMS verification of prescriber certification prior to dispensing every prescription.</td>
<td>☐</td>
</tr>
<tr>
<td>11. Proper authorization or provision of data rights to my switch provider are in place to meet Addyi REMS Program requirements.</td>
<td>☐</td>
</tr>
</tbody>
</table>

Complete Addyi REMS Program Prescriber and Pharmacy Training
# 41. Inpatient Pharmacy Attestation

Inpatient Pharmacy Attestations (for Authorized Representative)

Please click to attest to each of the following statements:

<table>
<thead>
<tr>
<th>Attest</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>I have read the Addyi REMS Program Prescriber and Pharmacy Training,</td>
<td></td>
</tr>
<tr>
<td>the Addyi Medication Guide and the full prescribing information and</td>
<td></td>
</tr>
<tr>
<td>have successfully completed the Addyi REMS Program Knowledge</td>
<td></td>
</tr>
<tr>
<td>Assessment.</td>
<td></td>
</tr>
<tr>
<td>I understand that there is an increased risk of syncope and</td>
<td></td>
</tr>
<tr>
<td>hypotension associated with Addyi due to an interaction with</td>
<td></td>
</tr>
<tr>
<td>alcohol.</td>
<td></td>
</tr>
<tr>
<td>I will ensure that my inpatient pharmacy does not dispense Addyi for</td>
<td></td>
</tr>
<tr>
<td>outpatient use.</td>
<td></td>
</tr>
<tr>
<td>I understand that pharmacies within or associated with my healthcare</td>
<td></td>
</tr>
<tr>
<td>facility that dispense drugs to outpatients must be separately</td>
<td></td>
</tr>
<tr>
<td>certified as a certified outpatient pharmacy and comply with the</td>
<td></td>
</tr>
<tr>
<td>Addyi REMS Program requirements to dispense Addyi to</td>
<td></td>
</tr>
<tr>
<td>outpatients.</td>
<td></td>
</tr>
<tr>
<td>I understand that a prescriber who wants to discharge a patient</td>
<td></td>
</tr>
<tr>
<td>with an Addyi prescription, intended to be dispensed by an outpatient</td>
<td></td>
</tr>
<tr>
<td>pharmacy, will be required to enroll in the Addyi REMS Program.</td>
<td></td>
</tr>
<tr>
<td>My certified pharmacy will refrain from reselling, loaning, or</td>
<td></td>
</tr>
<tr>
<td>transferring Addyi to another pharmacy, institution, distributor, or</td>
<td></td>
</tr>
<tr>
<td>prescriber.</td>
<td></td>
</tr>
<tr>
<td>I will ensure all relevant staff involved in the dispensing of Addyi</td>
<td></td>
</tr>
<tr>
<td>understand the importance of reporting any adverse events of</td>
<td></td>
</tr>
<tr>
<td>hypotension or syncope where an interaction with alcohol cannot</td>
<td></td>
</tr>
<tr>
<td>be ruled out to Sprout Pharmaceuticals (1-844-746-5745) or MedWatch</td>
<td></td>
</tr>
<tr>
<td>(1-800-FDA-1088).</td>
<td></td>
</tr>
<tr>
<td>I understand that recertification in the Addyi REMS Program must be</td>
<td></td>
</tr>
<tr>
<td>completed if the pharmacy designates a new authorized representative.</td>
<td></td>
</tr>
<tr>
<td>I will maintain such documentation that all processes and procedures</td>
<td></td>
</tr>
<tr>
<td>are in place and are being followed for the Addyi REMS Program and</td>
<td></td>
</tr>
<tr>
<td>provide upon request to Sprout Pharmaceuticals, FDA, or a third</td>
<td></td>
</tr>
<tr>
<td>party.</td>
<td></td>
</tr>
<tr>
<td>I will comply with audits by Sprout Pharmaceuticals or a designated</td>
<td></td>
</tr>
<tr>
<td>third party and inspections by FDA to ensure that all processes and</td>
<td></td>
</tr>
<tr>
<td>procedures are in place and are being followed for the Addyi REMS</td>
<td></td>
</tr>
<tr>
<td>Program.</td>
<td></td>
</tr>
<tr>
<td>I understand Addyi REMS Program personnel may contact pharmacists at</td>
<td></td>
</tr>
<tr>
<td>certified inpatient hospital pharmacies to gather information, solve</td>
<td></td>
</tr>
<tr>
<td>discrepancies, or to provide other information related to the Addyi</td>
<td></td>
</tr>
<tr>
<td>REMS Program.</td>
<td></td>
</tr>
<tr>
<td>I will oversee compliance with the Addyi REMS Program</td>
<td></td>
</tr>
</tbody>
</table>

Submit Attestations
42. Individual Location Outpatient Pharmacy Verification Options

<table>
<thead>
<tr>
<th>Prescriber Training, Enrollment, and Certification (3 Easy Steps)</th>
<th>Pharmacy Training, Enrollment, and Certification (3 Easy Steps)</th>
<th>Addyi Certified Pharmacy Network</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Select the option that best matches your Pharmacy Management System (A or B)

**OPTION A**

0113388

My pharmacy utilizes a Pharmacy Management System (PMS) to transmit prescriptions electronically and will utilize this technology to verify prescriber certification.

I will ensure the following Pharmacy Management System requirements will be in place for my pharmacy:

1. The pharmacy management system configuration and/or updates will be in place and verified with the Addyi REMS Program Support Center to ensure that Addyi prescriptions are submitted in accordance with the program requirements.
2. The pharmacy management system configuration and/or updates will be in place to ensure alerts are in place to notify pharmacists of the need to counsel patients to abstain from alcohol with every dispensed prescription.
3. The pharmacy management system configuration must process all Addyi prescriptions, regardless of the method of payment, through the pharmacy management system and “pharmacy routing switch” for Addyi REMS verification of prescriber certification prior to dispensing every prescription.
4. I acknowledge that prior to Addyi REMS pharmacy certification, the Addyi REMS Program Support Center will contact me if an agreement is needed to permit the switch provider to use prescription data from this pharmacy to conduct the REMS.

**OPTION B**

0113388

My pharmacy does not utilize a Pharmacy Management System (PMS) to transmit prescriptions electronically and will verify prescriber certification through the Addyi REMS Program website or the Addyi REMS Program Support Center.

I will ensure my pharmacy staff will access the Addyi REMS Program website at www.AddyiREMS.com or call the Addyi REMS Program Support Center (1-844-233-9415) to confirm the authorizing prescriber is certified (as outlined in attestation 12) before dispensing each Addyi prescription. A complete authorization requires the pharmacist to identify a unique patient, provide dispense information, and provide the prescriber’s NPI or DEA.

Complete Addyi REMS Program Provider and Pharmacy Training
43. Individual Location Outpatient Pharmacy Verification Options – With Option Selected

Select the option that best matches your Pharmacy Management System (A or B)

**OPTION A**

0113588

My pharmacy utilizes a Pharmacy Management System (PMS) to transmit prescriptions electronically and will utilize this technology to verify prescriber certification.

I will ensure the following Pharmacy Management System requirements will be in place for my pharmacy:

1. The pharmacy management system configuration and/or updates will be in place and verified with the Addyi REMS Program Support Center to ensure that Addyi prescriptions are submitted in accordance with the program requirements.
2. The pharmacy management system configuration and/or updates will be in place to ensure alerts are in place to notify pharmacists of the need to counsel patients to abstain from alcohol with every dispensed prescription.
3. The pharmacy management system configuration must process all Addyi prescriptions, regardless of the method of payment, through the pharmacy management system and “pharmacy routing switch” for Addyi REMS verification of prescriber certification prior to dispensing every prescription.
4. I acknowledge that prior to Addyi REMS pharmacy certification, the Addyi REMS Program Support Center will contact me if an agreement is needed to permit the switch provider to use prescription data from this pharmacy to conduct the REMS.

**OPTION B**

0113588

My pharmacy does not utilize a Pharmacy Management System (PMS) to transmit prescriptions electronically and will verify prescriber certification through the Addyi REMS Program website or the Addyi REMS Program Support Center.

I will ensure my pharmacy staff will access the Addyi REMS Program website at www.AddyiREMS.com or call the Addyi REMS Program Support Center (1-844-233-9415) to confirm the authorizing prescriber is certified (as outlined in attestation 12) before dispensing each Addyi prescription. A complete authorization requires the pharmacist to identify a unique patient, provide dispense information, and provide the prescriber’s NPI or DEA.
44. Prescriber Enrollment Confirmation

Addyi REMS Program
Prescriber and Pharmacy Training, Enrollment and Certification Complete.

(addyi
(flibanserin)

Congratulations!
You've completed the certification process.
Thank you for completing the Addyi REMS Program certification process!

Certification ID: PRS0766683184
Addyi REMS Program Support Center
1-844-233-9415

Return to Addyi Rems Home
45. Individual Location Outpatient Pharmacy Enrollment Confirmation

Addyi REMS Program
Prescriber and Pharmacy Training, Enrollment and Certification Complete.

Congratulations!
You've completed the certification process. Please see the directions below for the remaining steps.

Once your submission is successfully processed, you will receive a fax or email with instructions on how to submit test transaction(s) to the Addyi REMS Program to ensure that your pharmacy management system has been successfully configured/updated to communicate with the Addyi REMS Program. Upon successful verification of connectivity, you will be provided with the Terms & Conditions to become certified. Once this process is complete your pharmacy will receive a confirmation from the Addyi REMS Support Center and you will be considered certified and permitted to order, receive, and dispense Addyi.

Certification ID: PHY0766682260

If you have any questions or require additional information, please contact the Addyi REMS Program Support Center at 1-844-233-9415.

Return to Addyi REMS Home
46. **Multiple Location Outpatient Pharmacy Enrollment Confirmation**

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Addyi REMS Program Prescriber and Pharmacy Training, Enrollment and Certification Complete.

*(flibanserin)*

**Congratulations!**

You've completed the certification process. Upon receipt of all enrollment materials, you will receive a fax or email with instructions on how to submit test transaction(s) to the Addyi REMS Program to ensure that your pharmacy management system has been successfully configured/updated to communicate with the Addyi REMS Program. After successful completion of test transaction(s) you will receive a multiple pharmacy enrollment confirmation via fax and/or email from the Addyi REMS Support Center. Your multiple pharmacy entity will be considered certified and your retail chain dispensing locations will be eligible to complete their certification procedures.

Certification ID: CHQ0666883776

If you have any questions or require additional information, please contact the Addyi REMS Program Support Center at 1-844-235-9413.

Return to Addyi Rems Home
47. Inpatient Pharmacy Enrollment Confirmation

Addyi REMS Program Prescriber and Pharmacy Training, Enrollment and Certification Complete.

(FLIBANSERIN) Congratulations!

You've completed the certification process. Upon receipt the Addyi REMS Program Support Center will contact you to complete the certification process.

Certification ID: HF0766681447

If you have any questions or require additional information, please contact the Addyi REMS Program Support Center at 1-844-233-9415 or visit www.AddyiREMS.com.

Return to Addyi Rems Home
48. Pharmacy Staff Enrollment Confirmation

Addyi REMS Program
Prescriber and Pharmacy Training, Enrollment and Certification Complete.

addyi
(flibanserin)

John Doe
03/10/2016

Congratulations!
You've completed the Addyi REMS Program Prescriber and Pharmacy Training and Knowledge Assessment.

Click here to print

Return to Addyi Rems Home
49. Pre-dispensing Authorization Intake

To determine if the safe use conditions have been met for your patient to receive Addyi, please complete the Predispose Authorization information below and submit. All fields are required unless otherwise indicated.

First Name  

Last Name  

Prescriber Identifier Information  

Prescriber DEA  

Prescriber NPI  

Cancel  

Submit
50. Pre-dispensing Authorization Confirmation

You are now authorized to dispense Addyi. Please counsel the patient and provide a medication guide.

Pre-dispense Authorization Code: XXXXXXXXXXX

NPI: XXXXXXXXX

DEA: XXXXXXXXX

Close
51. Contact Us

Addyi REMS Program Support Center
- Hours of Operation: 8:00 AM – 8:00 PM ET
- Phone: 1-844-233-9415
- Fax: 1-844-694-3373
- Email: AddyiREMS@AddyiREMS.com

For questions or requests pertaining to the Addyi REMS Program, please contact the Addyi REMS Support Center.

Sprout Pharmaceuticals, Inc. Customer Service
- Phone: 1-844-746-5745
- Email: AddyiREMS@sproutpharma.com
- Mailing Address:
  4205 Six Forks Road, Ste 1010
  Raleigh, NC 27609

You are encouraged to report side effects of prescription drugs to the FDA.
Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

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Indication and Important Safety Information

Indication

- Addyi is indicated for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to:
  - A co-existing medical or psychiatric condition,
  - Problems within the relationship, or
  - The effects of a medication or other drug substance.

Acquired HSDD refers to HSDD that develops in a patient who previously had no problems with sexual desire. Generalized HSDD refers to HSDD that occurs regardless of the type of stimulation, situation or partner.

Limitations of Use

- Addyi is not indicated for the treatment of HSDD in postmenopausal women or in men.
- Addyi is not indicated to enhance sexual performance.

Important Safety Information

WARNING: HYPOTENSION AND SYNCOPE IN CERTAIN SETTINGS
See full prescribing information for complete boxed warning.

- Use of Addyi and alcohol increases the risk of severe hypotension and syncope; therefore alcohol use is contraindicated. Before prescribing Addyi, assess the likelihood of the patient abstaining from alcohol. Counsel patients prescribed Addyi about the importance of abstaining from alcohol.
- Addyi is available only through a restricted program called the Addyi REMS Program.
- Severe hypotension and syncope can occur when Addyi is used with moderate or strong CYP3A4 inhibitors or in patients with hepatic impairment; therefore, Addyi use in these settings is contraindicated.

Contraindications

Addyi is contraindicated:

- With use of alcohol.
- With concomitant use with moderate or strong CYP3A4 inhibitors.
- In patients with hepatic impairment.

Summary of Warnings and Precautions

- Hypotension and Syncope due to an Interaction with Alcohol. An interaction between Addyi and alcohol increases the risk of severe hypotension and syncope. Alcohol use is contraindicated. Before prescribing Addyi, the healthcare provider should assess the likelihood of the patient abstaining from alcohol use.
- Addyi Risk Evaluation and Mitigation Strategy (REMS) Program. Addyi is available only through a restricted program called the Addyi REMS Program, because of the increased risk of severe hypotension and syncope due to an interaction between Addyi and alcohol. The Addyi REMS requires that prescribers are certified by enrolling and completing training, and, pharmacies are certified and will not dispense Addyi unless it is prescribed by a certified prescriber. More information is available at www.AddyiREMS.com.
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- **Hypotension and Syncope with CYP3A4 Inhibitors.**
  - Moderate and strong CYP3A4 inhibitors significantly increase Addyi concentrations, which can lead to hypotension and syncope. Concomitant use of Addyi with a moderate or strong CYP3A4 inhibitor is contraindicated.
  - Concomitant use of multiple weak CYP3A4 inhibitors that may include herbal supplements (e.g., ginkgo, resveratrol) or non-prescription drugs (e.g., cimetine) could also lead to clinically relevant increases in flibanserin concentrations that may increase the risk of hypotension and syncope.

- **Central Nervous System Depression.** Addyi can cause CNS depression (e.g., somnolence, sedation). In five 24-week, randomized, placebo-controlled, double blind trials of premenopausal women with HSDD the incidence of somnolence, sedation or fatigue was 21% and 8% in patients treated with 100 mg of Addyi at bedtime and placebo, respectively. The risk of CNS depression is increased if Addyi is taken during waking hours, or if Addyi is taken with alcohol or other CNS depressants, or with medications that increase flibanserin concentrations.

Patients should not drive or engage in other activities requiring full alertness until at least 6 hours after taking Addyi and until they know how Addyi affects them.

- **Hypotension and Syncope with Addyi Alone.** The use of Addyi – without other concomitant medications known to cause hypotension or syncope – can cause hypotension and syncope. In five 24-week, randomized, placebo-controlled, double-blind trials of premenopausal women with HSDD, hypotension was reported in 0.2% and <0.1% of Addyi-treated patients and placebo-treated patients, respectively; syncope was reported in 0.4% and 0.2% of Addyi-treated patients and placebo-treated patients, respectively. The risk of hypotension and syncope is increased if Addyi is taken during waking hours. Consider the benefits of Addyi and the risks of hypotension and syncope in patients with pre-existing conditions that predispose to hypotension. Patients who experience pre-syncope should immediately lie supine and promptly seek medical help if the symptoms do not resolve. Prompt medical attention should also be obtained for patients who experience syncope.

- **Syncope and Hypotension in Patients with Hepatic Impairment.** Any degree of hepatic impairment significantly increases flibanserin concentrations, which can lead to hypotension, syncope, and CNS depression. Therefore, Addyi is contraindicated in patients with hepatic impairment.

**Most Common Adverse Reactions**

- The most common adverse reactions among patients treated with Addyi were dizziness (Addyi 11.4%; Placebo 2.2%), somnolence (Addyi 11.2%; Placebo 2.9%), nausea (Addyi 10.4%; Placebo 3.9%), fatigue (Addyi 9.2%; Placebo 5.5%), insomnia (Addyi 4.9%; Placebo 2.8%) and dry mouth (Addyi 2.4%; Placebo 1.0%).

**Summary of Drug Interactions**

- Addyi is primarily metabolized by CYP3A4 and, to a lesser extent, by CYP2C19.
- Addyi is contraindicated in women taking a moderate (e.g., fluconazole) or strong (e.g., ketoconazole) CYP3A4 inhibitor.
- Patients using Addyi with combined oral contraceptives or with weak CYP3A4 inhibitors may experience a higher incidence of adverse reactions.
- CYP2C19 inhibitors (e.g. proton pump inhibitors, selective serotonin reuptake inhibitors, benzodiazepines, antifungals) may increase Addyi exposure, which may increase the risk of hypotension, syncope, and CNS depression.
- Do not use Addyi with strong CYP3A4 inducers (e.g., rifampin, St. John’s Wort) as this will substantially reduce the concentration of Addyi.
- Addyi inhibits P-glycoprotein (P-gp). Monitoring of drug concentrations of any narrow therapeutic index drugs that are substrates for P-gp (e.g., digoxin) should be increased if co-administered with Addyi. The concomitant use of Addyi with digoxin, a drug that is transported by P-gp, increases the digoxin concentration. This may lead to digoxin toxicity.
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Children; Parental Consent Policy
The Children's Online Privacy Protection Act imposes certain requirements on websites directed toward children under 13 that collect information on these children, or on websites that know they are collecting Personal Information from children under the age of 13. The Sites are not intended for children under the age of 13, and it currently is our policy not to collect Personal Information from any person under 13, and we request that children under the age of 13 not submit any Personal Information to us via the Sites. If we learn that we have inadvertently gathered Personal Information from children under 13, we will use reasonable efforts to notify such child's parent or guardian and erase such information from our records, unless the child's parent or guardian consents to our maintaining such information.

Use of Information Obtained by Company
Information collected automatically when you access the Sites is used to administer the Sites and to analyze trends and gather statistical information for aggregate use. We may disclose any such information for our legitimate business purposes.

In general, Personal Information you provide to us is used to respond to requests that you make (for example, we may use your Personal Information to process your Addyi REMS certification). Company may also send you service-related announcements from time to time through the general operation of the Sites. Generally, you may opt out of such communications, although Company reserves the right to send you service-related notices even if you opt out of all voluntary notifications.

Policy on Use of Social Security Numbers
Note to Healthcare Professionals and Business Partners
If you have a business or professional relationship with Company, we may use your Personal Information, including Personal Information we may collect about you from other sources, to develop our business relationship with you and your organization.

Sharing Your Information with Third Parties
You may choose to provide information about you and your company or organization to other users and to the public by providing such information on public areas of the Sites ("Public Information"). Public Information does not include information you submit to us but do not post on areas of the Sites accessible by other users or the public ("Non-Public Information"). Non-Public Information may include Personal Information.

We share your Non-Public Information with third parties only in limited circumstances, such as the information required to successfully complete Addyi REMS certification, where we believe such sharing is reasonably necessary to operate the Sites, legally required or, permitted by you. For example:

- We may share your Non-Public Information with a parent company, any subsidiaries, joint ventures, or other companies under common control with Company now or in the future (collectively, "Affiliates"). In such case we will require our Affiliates to honor this Privacy Policy with respect to such shared information.
- We may provide Non-Public Information to service providers who help us bring you the services we offer, such as hosting the service at a co-location facility, sending email updates about Company, removing repetitive information from our user lists, or to provide search results or links. In connection with these offerings and business operations, our service providers may have access to your Non-Public Information for use for a limited time in connection with these business activities.
- We utilize third parties for the processing of any of your Non-Public Information, we implement reasonable contractual protections limiting the use of that Non-Public Information to the provision of services to Company.
- We may provide to your company or organization or a third party on our behalf.
- We may also share your Non-Public Information if you request such a disclosure, to enforce an agreement we have with you, or to comply with the terms of an agreement with a product-related co-promotion partner. If the ownership of all or substantially all of the Company business, or individual business units or assets owned by Company that are related to the Sites, were to change, your Non-Public Information may be transferred to the new owner. In such event, Company will notify you by posting such notice on one or more of the Sites before information about you is transferred and becomes subject to a different privacy policy in order to give you a reasonable opportunity to opt out of such different privacy policy, provided however. In the event Company fails to notify you, your Personal Information will still be transferred but subject to this Privacy Policy.
- Account or other Non-Public Information (i) pursuant to lawful requests, such as subpoenas or court orders, or in compliance with applicable laws, or (ii) when we believe it is necessary to comply with law, to protect our interests or property, including, but not limited to, in the context of a legal dispute, to protect the rights, property or safety of our employees or others, to prevent fraud or other illegal activity perpetrated through the Sites or using the Company name, or to prevent imminent harm. This may include sharing Non-Public Information with other companies, lawyers, agents or government agencies where needed, for corporate audits or to investigate or respond to a complaint or security threat.

Note: We do not share any of your Personal Information with third parties for their own direct marketing purposes unless you explicitly give us permission to do so. This information is shared for the purpose of Addyi REMS certification.

Third Party Links
Company Sites may contain links to other websites which may collect information directly from you. Each of the websites linked to the Sites may have separate privacy and data collection practices. Independent of Company. Once you link to another site from ours, you are subject to the Privacy Policy and Terms of Use of the new site, and Company has no responsibility or liability for these independent policies or actions and is not responsible for the privacy practices or the content of such websites, nor does Company endorse or make any warranties or representations about the contents, products or services offered on such websites or the security of any information you provide to them. If you have any questions about how these other sites use your information, you should contact them directly. This Privacy Policy applies solely to information collected by Company via the Sites.

Security
Although we use reasonable efforts to safeguard the security of your Personal Information, transmissions made on or through the Internet are inherently vulnerable to attack and cannot be guaranteed to be secure. Consequently, we cannot and do not guarantee that unauthorized access, hacking, data loss, or other breaches will never occur. In addition, submissions made via email are not protected by encryption and are vulnerable to interception during transmission. You are solely responsible for safeguarding and maintaining the security of your Personal Information. Please be careful and responsible whenever you are online. We urge you to take steps to keep your Personal Information safe. Our hosting provider's computer systems employ software to monitor network traffic in order to identify unauthorized attempts to upload or change information, or otherwise cause damage. Unauthorized attempts to upload or change information on the Sites are strictly prohibited and may be punishable under the Computer Fraud and Abuse Act of 1986 and the National Information Infrastructure Protection Act.
Protecting Yourself: Updating Your Information
You can learn more about internet privacy from government websites such as www.ftc.gov/privacy. In addition, it is important to keep us updated with your most current contact information. You can review and make changes to the information we have on file about you by emailing us your updated information. To the extent we maintain your email address or other information about you, you may ask us via email at compliance@company.com to have such information deleted, updated or corrected, and/or to request us to cease collecting Personal Information about you in the future.

Changing Your Preferences; Opt-Out of Receiving Communications
When you provide us with your Personal information, you may be given some choices about how we use that Personal information. You may change these preferences later. For example, if you sign up for an e-mail newsletter, you may opt out of receiving future e-mail newsletters at any time. If you opt in to receive communications from Company, we will always provide you with one or more of the following ways to opt out: (i) by following any opt-out instructions contained in communications you receive from Company, (ii) by un-subscribing at specific areas of the Sites where you registered, if available, or (iii) by sending a written request to the Company contact address immediately below.

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This Privacy Policy is effective with respect to any information collected on or after the date below. Company reserves the right to modify or supplement this Privacy Policy at any time. If we make any changes, we will update the Sites and Privacy Policy to include such change and notice thereof. Please review this Privacy Policy often to review any changes that may affect your use of the Sites. Your continued use of the Sites once the revised Privacy Policy has been posted on any of the Sites with the updated date affirms your agreement to such changes. If you do not agree to abide by this Privacy Policy, do not use or access (or continue to use or access) the Sites.

Contacting Company
If you have any questions about this Privacy Policy or Company's privacy practices in general, or if you need help accessing your Personal Information or changing your preferences, please contact us at:

Phone: 919-882-0850
Fax: 919-882-0855
Email: info@sproutpharma.com

You may also contact us by mail at Sprout Pharmaceuticals, Inc., 4206 Six Forks Road, Ste 1010 Raleigh, NC 27605. Or, you can visit our Contact Us section at www.sproutpharma.com/contact-us for more information.

Make sure to provide the name of the Site(s) applicable to your request, and your name and contact information. If you do not provide us with this information, we may not be able to respond.

You are encouraged to report side effects of prescription drugs to the FDA.

Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

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