

Prior Authorization DRUG Guidelines

ADDYI (Flibanserin)

Effective Date: 4/26/16

Date Developed: 4/25/16 by Catherine Sanders, MD

Date Approved by P&T Committee: 4/26/16, 1/24/17,
1/23/18, 1/22/19, 2/18/20

Flibanserin exhibits agonist activity at 5-HT 1A and antagonist activity at 5-HT @A: moderate antagonist activity is seen at the 5-HT 2B, 5-HT 2C and dopamine D4 receptors. The mechanism of action in the treatment of premenopausal women with hypoactive sexual desire disorder is not known.

Pre-Authorization Criteria:

After review of the available literature, the reported benefit does not outweigh the potential risks. Therefore, the VCHCP P&T Committee has made a decision to designate this medication as not a covered benefit at this time. This will be re-reviewed as more research is available. This medication should reject at the retail pharmacy or ESI level.

As a requirement of the REMS program, access to the medication is restricted. Prescribers and pharmacies must be certified with the ADDYI REMS program; certified pharmacies may only dispense to patients pursuant to a prescription from a certified prescriber. More information, including a list of certified pharmacies, is available at www.AddyiREMS.com or 844-746-5745.

Medication Guide: An FDA-approved patient medication guide, which is available with the product information and as follows, must be dispensed with this medication:

Addyi: <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM459254.pdf>

Dosing: orally once daily at bedtime

Include any restrictions such as in kidney disease, liver disease.

Dosing Forms: tablet, oral: Addyi 100mg

US Boxed Warning:

Contraindicated with alcohol:

The use of flibanserin and alcohol increases the risk of severe hypotension and syncope. Therefore, alcohol use is contraindicated in patients taking flibanserin. Before prescribing flibanserin, assess the likelihood of the patient abstaining from alcohol, taking into account the patient's current and past drinking behavior, and other pertinent social and medical history. Counsel patients who are prescribed flibanserin about the importance of abstaining from alcohol use. Because of the increased risk of hypotension and syncope due to an interaction with alcohol, flibanserin is available only through a restricted program under Risk Evaluation and Mitigation Strategy (REMS) called the Addyi REMS program.

Contraindicated with strong or moderate CYP3A4 inhibitors:

The concomitant use of flibanserin and moderate or strong CYP3A4 inhibitors increases flibanserin concentrations, which can cause severe hypotension and syncope. Therefore, the use of moderate or strong CYP3A4 inhibitors is contraindicated in patients taking flibanserin.

Contraindicated in patients with hepatic impairment:

The use of flibanserin in patients with hepatic impairment increases flibanserin concentrations, which can cause severe hypotension and syncope. Therefore, flibanserin is contraindicated in patients with hepatic impairment.

Additional side effects: CNS depression, hypotension, syncope

References:

UpToDate Drug information: Flibanserin 2016

Addyi (flibanserin) [prescribing information]. Raleigh, NC: Sprout Pharmaceuticals; August 2015.

New England Journal of Medicine Journal Watch General Medicine October 1, 2015, Vol 35, No. 19

Revision History:

Date Approved by P&T Committee: 4/26/16

Date Reviewed/No Updates: 1/24/17 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/24/17

Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/23/18

Date Reviewed/No Updates: 1/22/19 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/22/19

Date Reviewed/No Updates: 2/18/20 by H. Taekman, MD; R. Sterling, MD

Date Approved by P&T Committee: 2/18/20

| Revision Date | Content Revised (Yes/No) | Contributors | Review/Revision Notes |
|---------------|--------------------------|--|-----------------------|
| 1/24/17 | No | Catherine Sanders, MD; Robert Sterling, MD | Annual review |
| 1/23/18 | No | Catherine Sanders, MD; Robert Sterling, MD | Annual review |
| 1/22/19 | No | Catherine Sanders, MD; Robert Sterling, MD | Annual review |
| 2/18/20 | No | Howard Taekman, MD; Robert Sterling, MD | Annual review |