VENTURA COUNTY
HEALTH CARE PLAN

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; 8/3/21; 2/1/22; 1/31/23; 2/13/24, 2/18/25

Flibanserin exhibits agonist activity at 5-HT 1A and antagonist activity at 5-HT 2A: 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:

Hypoactive Sexual Desire Disorder (HSDD)/Female Sexual Interest/Arousal Disorder (FSIAD). Approve for the duration noted if the patient meets ONE of the following (A or B):

A) **Initial Therapy**. Approve for 8 weeks if the patient meets the following (i, ii, iii, iv, v, and vi):
Patient is premenopausal; AND
Patient's symptoms of HSDD/FSIAD have persisted for a minimum of 6 months; AND
Patient has had normal sexual desire in the past, prior to the diagnosis of HSDD/FSIAD; AND
Patient does not have a diagnosis of depression; AND
Other known causes of HSDD/FSIAD, such as co-existing medical or psychiatric conditions, problems within a relationship, effects of medications (e.g., antidepressants), or drug abuse have been ruled out by the prescriber; AND
The prescriber has counseled the patient regarding the interaction with alcohol and Addyi, and the increased risk of hypotension and syncope.

B) **Continuation of therapy.** Patient is Currently Receiving Addyi. Approve for 6 months if the patient meets the following (i, ii, and iii):
Patient is premenopausal; AND
The prescriber confirms that since initiating Addyi therapy, the patient reports a significant improvement in sexual desire and/or a decrease in sexual distress; AND

Patient has not reported any serious or concerning adverse events (e.g., hypotension, syncope, dizziness) while taking Addyi.

NOTE: Addyi is currently not approved for use in postmenopausal women with HSDD/FSIAD symptoms

NOTE: 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.

Dosing: orally once daily at bedtime
Include any restrictions such as kidney disease, liver disease.

Dosing Forms: tablet, oral: Addyi 100mg

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

US Boxed Warning:

Contraindicated with alcohol:
The use of flibanserin and alcohol increases the risk of severe hypotension and syncope. Women should discontinue drinking alcohol at least two hours before taking Addyi at bedtime or to skip the Addyi dose that evening. Women should not consume alcohol at least until the morning after taking Addyi at bedtime. The boxed warning, REMS program, and contraindication about alcohol still remain in the product labeling.

References:

UpToDate Drug information: Flibanserin 2016

Addyi (flibanserin) [prescribing information]. Raleigh, NC: Sprout Pharmaceuticals; September 2021.

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Derogatis LR, Komer L, Katz M, et al; VIOLET Trial Investigators. Treatment of hypoactive sexual desire disorder in premenopausal women: efficacy of flibanserin in the VIOLET Study. J Sex Med. 2012;9(4):1074-1085.

Simon JA, Thorp J, Millheiser L. Flibanserin for premenopausal hypoactive sexual desire disorder: pooled analysis of clinical trials. J Womens Health (Larchmt). 2019;28(6):769-777. doi:10.1089/jwh.2018.

Thorp J, Simon J, Dattani D, et al; DAISY trial investigators. Treatment of hypoactive sexual desire disorder in premenopausal women: efficacy of flibanserin in the DAISY study. J Sex Med. 2012;9(3):793-804.

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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
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2/18/20	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
8/3/21	Yes	Howard Taekman, MD; Robert Sterling, MD	Contraindicated with alcohol: NOTE: This restriction removed by FDA in 2019 and modified to 2 hours before a bedtime dose]
2/1/22	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
1/31/23	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/13/24	No	Howard Taekman, MD; Robert Sterling, MD	Annual review
2/18/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Updated Pre-authorization criteria, removed Medication Guide and US Boxed warning sections