PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

ADDYI
(flibanserin)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization ***Ref # 1288-C***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS
Addyi (flibanserin) 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.

Limitation of Use
Addyi (flibanserin) is not indicated for the treatment of HSDD in postmenopausal women or in men.
Addyi (flibanserin) is not indicated to enhance sexual performance.

COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:

- The patient is 18 years of age or older and premenopausal.

AND

- Patient has been receiving at least an 8 week supply of this medication as a paid claim through a pharmacy or medical benefit (excluding the use of samples or vouchers/coupons) AND has reported an improvement in the symptoms of hypoactive sexual desire disorder (HSDD)

  AND
- Hypoactive sexual desire disorder (HSDD) is NOT caused by a co-existing medical or psychiatric condition, problems within the relationship, or the effects of a medication or other drug substance.

  AND
- The patient does not require MORE than 30 tablets per month of Addyi (flibanserin)

  OR
- The patient has a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) that is appropriately documented (i.e., evaluated by a complete clinical assessment, using DSM-4, interviews/questionnaires).

  AND
- Hypoactive sexual desire disorder (HSDD) is NOT caused by a co-existing medical or psychiatric condition, problems within the relationship, or the effects of a medication or other drug substance.

Quantity Limits may apply.

RATIONALE
The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Addyi (flibanserin) is a mixed serotonin agonist and antagonist 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.[1] Acquired HSDD refers to HSDD that develops in patients who previously had no problems with sexual desire. Generalized HSDD refers to HSDD that occurs regardless of the type of stimulation, situation, or partner.

The efficacy of Addyi (flibanserin) in premenopausal women was established in three 24-week, randomized, double-blind, placebo-controlled trials. The three trials included premenopausal women of at least 18 years of age with HSDD diagnosed by Diagnostic and Statistical Manual of Mental Disorders fourth edition (DSM-IV) for at least 6 months in duration.[4-6] Addyi (flibanserin) is not indicated for the treatment of HSDD in postmenopausal women, in men or in pediatric patients.

DSM-IV defines HSDD as persistently or recurrently deficient sexual fantasies and desire for sexual activity that causes marked distress or interpersonal difficulty and is not better accounted for by another Axis I disorder and is not due exclusively to the direct physiologic effects of a substance or a general medical condition.[7] HSDD is no longer a stand-alone diagnosis in Diagnostic and Statistical Manual of Mental Disorders fifth edition (DSM-V). In DSM-V, HSDD has been merged with female sexual arousal disorder into a single category for female sexual interest/arousal disorder.[8]

Addyi (flibanserin) is available as a 100 mg oral tablet taken once daily at bedtime due to increased risk of central nervous system depression, hypotension, and syncope when administered during waking hours.

The prescribing information states that Addyi (flibanserin) should be discontinued if the patient does not report an improvement in symptoms after 8 weeks of therapy. HSDD should not be caused by a co-existing medical or psychiatric condition or by drug therapy.

REFERENCES

1. Addyi [package insert]. Raleigh, NC: Sprout Pharmaceuticals Inc; August 2015.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed December 2018.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed December 2018.
4. Thorp J, Simon J, Dattani D, et al. Treatment of Hypoactive Sexual Desire Disorder in premenopausal women: efficacy of flibanserin in the DAISY study. J Sex Med. 2012 Mar;9(3):793-804.
5. DeRogatis L, Komer L, Katz M, et al. Treatment of Hypoactive Sexual Desire Disorder in premenopausal women: efficacy of flibanserin in the VIOLET study. J Sex Med. 2012 Apr;9(4):1074-85.
6. Katz M, DeRogalis L, Ackerman R, Hedges P, et al. Efficacy of flibanserin in women with Hypoactive Sexual Desire Disorder: results from the BEGONIA trial. J Sex Med. 2013 Jul;10(7):1807-15.
7. American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorder, Fourth Edition, Text Revision. Washington DC: American Psychiatric Association; 2000.
8. American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorder, Fifth Edition, Arlington, VA: American Psychiatric Association; 2013.

Written by:	UM Development (DN/CT)
Date Written:	08/2015
Revised:	10/2015 (rephrased question 2 and rearranged questions), 06/2016, (JK) 05/2017; (DS) 12/2017 (no clinical changes), (ME) 12/2018
Reviewed:	Medical Affairs (LMS) 08/2015, 10/2015; (ME) 06/2016, (AN) 05/2017, (ME) 04/2019 External Review 09/2015, 08/2016, 08/2017, 04/2018, 04/2019

CRITERIA FOR APPROVAL

1	Is the patient 18 years of age or older AND premenopausal?	Yes	No
2	Has the patient received at least an 8 week supply of this medication as a paid claim through a pharmacy or medical benefit (excluding the use of samples or vouchers/coupons)? [If no, then skip to question 6.]	Yes	No
3	Has the patient reported an improvement in the symptoms of hypoactive sexual desire disorder (HSDD)?	Yes	No

4	Is the hypoactive sexual desire disorder (HSDD) caused by any of the following: A) A co-existing medical or psychiatric condition, B) Problems within the relationship, C) The effects of a medication or other drug substance?	Yes	No
5	Does the patient require more than the plan allowance of 30 tablets per month of Addyi (flibanserin)? [No further questions.] [RPh Note: If yes, then deny and enter a partial approval for 30 tablets per 25 days.]	Yes	No
6	Does the patient have the diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD)?	Yes	No
7	Has the diagnosis been appropriately documented (i.e., evaluated by a complete clinical assessment, using DSM-4, interviews/questionnaires)?	Yes	No
8	Is the hypoactive sexual desire disorder (HSDD) caused by any of the following: A) A co-existing medical or psychiatric condition, B) Problems within the relationship, C) The effects of a medication or other drug substance?	Yes	No
9	Does the patient require more than the plan allowance of 30 tablets per month of Addyi (flibanserin)? [RPh Note: If yes, then deny and enter a partial approval for 30 tablets per 25 days.]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you are 18 years of age or older and premenopausal. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
2.	Go to 3	Go to 6	
3.	Go to 4	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have all of the following: - You received at least an 8 week supply of this drug as a paid claim from a pharmacy or medical benefit (not by the use of samples or vouchers/coupons) - Your symptoms have improved Your request has been denied based on the information we have. [Short Description: Continuation of therapy, No response to treatment]
4.	Deny	Go to 5	You do not meet the requirements of your plan. Your plan covers this drug when your symptoms are not caused by any of the following: - A co-existing medical or psychiatric condition - Problems within the relationship - The effects of a medication or other drug substance Your request has been denied based on the information we have. [Short Description: Unapproved cause of diagnosis]
5.	Deny	Approve, 12 months, 30 tablets per 25	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 30 tablets/month of the requested drug and strength. You have been approved for the

		days	maximum quantity that your plan covers for a duration of 12 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]
6.	Go to 7	Deny	You do not meet the requirements of your plan. Your plan covers the requested drug when it is used for the FDA-approved use. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
7.	Go to 8	Deny	You do not meet the requirements of your plan. Your plan covers this drug when the diagnosis has been documented correctly. Your request has been denied based on the information we have. [Short Description: No documentation]
8.	Deny	Go to 9	You do not meet the requirements of your plan. Your plan covers this drug when your symptoms are not caused by any of the following: - A co-existing medical or psychiatric condition - Problems within the relationship - The effects of a medication or other drug substance Your request has been denied based on the information we have. [Short Description: Unapproved cause of diagnosis]
9.	Deny	Approve, 3 months, 30 tablets per 25 days	You have requested more than the maximum quantity allowed by your plan. Current plan approved criteria cover up to 30 tablets/month of the requested drug and strength. You have been approved for the maximum quantity that your plan covers for a duration of 12 months. Your request for additional quantities of the requested drug and strength has been denied. [Short Description: Over max quantity]