UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 2074-5
Program	Prior Authorization/Medical Necessity
Medication	Addyi (flibanserin)
P&T Approval Date	9/2015, 3/2016, 5/2016, 4/2017, 5/2018
Effective Date	8/1/2018; Oxford only: 8/1/2018

1. Background:

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

2. Coverage Criteria:

A. Initial Authorization

1. Addyi will be approved based on **all** of the following criteria:

a. Diagnosis of one of the following:

(1) Acquired, generalized hypoactive sexual desire disorder (HSDD)

-OR-

(2) Female sexual interest/arousal disorder

-AND-

b. Symptoms of HSDD or female sexual interest/arousal disorder have persisted for at least 6 months

-AND-

c. Low sexual desire is NOT due to any of the following:

(1) A co-existing medical or psychiatric condition
(2) Problems within the relationship

(3) The effects of a medication or other drug substance

-AND-

d. Patient is female

-AND-

e. Patient is premenopausal

-AND-

f. Prescriber must be certified/enrolled in the Addyi REMS Program

-AND-

g. One of the following:

(1) Patient has no known history of alcohol abuse
(2) For a patient with a known history of alcohol abuse, patient has abstained from alcohol abuse for the past 6 months

-AND-

h. Patient will abstain from alcohol use during treatment with Addyi

-AND-

i. Patient does not have hepatic impairment (e.g., a Child-Pugh score of 6 points or greater)

-AND-

j. Patient is not concomitantly on moderate or strong CYP3A4 inhibitors (e.g., ciprofloxacin, clarithromycin, diltiazem, fluconazole, itraconazole, ketoconazole, ritonavir, verapamil)

-AND-

k. Prescriber attests to **all** of the following:

(1) The potential benefits of Addyi therapy outweigh the risks
(2) Both the prescriber and patient have completed the Addyi REMS Program Patient-Provider Agreement Form
(3) The information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a

routine audit and request the medical information necessary to verify the accuracy of the information provided

Initial authorization will be issued for 3 months

B. Reauthorization

1. **Addyi** will be approved based on **all** of the following criteria:

   a. Documentation of positive clinical response to Addyi therapy

   -AND-

   b. Patient continues to be premenopausal

   -AND-

   c. Patient continues to abstain from alcohol use during treatment with Addyi

   -AND-

   d. Patient does not have hepatic impairment (e.g., a Child-Pugh score of 6 points or greater)

   -AND-

   e. Patient is not concomitantly on moderate or strong CYP3A4 inhibitors (eg, ciprofloxacin, clarithromycin, diltiazem, fluconazole, itraconazole, ketoconazole, ritonavir, verapamil)

Reauthorization will be issued for 12 months

3. Additional Clinical Rules:

- Supply limits may be in place

4. References:

1. Addyi Prescribing Information. Sprout Pharmaceuticals, Inc, August 2015.
2. 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;9:793–804.
3. Katz M, DeRogatis LR, Ackerman R, et al. Efficacy of Flibanserin in Women with Hypoactive Sexual Desire Disorder: Results from the BEGONIA Trial. J Sex Med 2013;10:1807–1815.
4. DeRogatis LR, 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;9:1074–1085.
5. Sexual dysfunctions. In: Diagnostic and Statistical Manual of Mental Disorders, 5th ed., American Psychiatric Association, Arlington, Virginia 2013.
6. Sexual dysfunction in women: Management. UpToDate. Updated April 14, 2017. Last accessed April 6, 2018.
7. Addyi Risk Evaluation and Mitigation Stategy (REMS) Program information. https://www.addyirems.com/AddyiUI/rems/home.action. Last accessed April 6, 2018.

Program	Prior Authorization/Medical Necessity – Addyi
Change Control	
Date	Change
9/2015	New program.
3/2016	Addition of criteria that low sexual desire is not due to a co-existing condition, relationship problem, or the effects of a medication or drug substance. Changed reauthorization period from 6 to 12 months.
5/2016	Addition of criteria that requires provider attestation of benefits outweighing risk, completion of the REMS Program Patient-Provider Agreement and accuracy of the information provided.
4/2017	Minor formatting changes. Updated references.
5/2018	Annual review. Updated references.