UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 2074-13
Program	Prior Authorization/Medical Necessity
Medication	Addyi™ (flibanserin)
P&T Approval Date	9/2015, 3/2016, 5/2016, 4/2017, 5/2018, 6/2019, 12/2019, 8/2021, 9/2022, 11/2023, 11/2024, 12/2025, 2/2026
Effective Date	5/1/2026

1. Background:

Addyi is indicated for the treatment of women less than 65 years of age 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 men and is not indicated to enhance sexual performance.

2. Coverage Criteria[a]:

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-

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d. Patient was female at birth

-AND-

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

-AND-

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

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

-AND-

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

Reauthorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Supply limits may be in place
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class

4. References:

1. Addyi [package insert]. Raleigh, NC: Sprout Pharmaceuticals, Inc; December 2025.
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.

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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. Overview of Sexual dysfunction in females: Management. UpToDate. Updated June 24, 2025. Last accessed October 13,2025.
7. Jasepers L, Feys, Frederik, Bramer, W, et al. Efficacy and Safety of Flibanserin for the Treatment of Hypoactive Sexual Desire Disorder in Women: A Systematic Review and Meta-analysis. *JAMA Intern Med*.2016;176(4):453-462.

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.
6/2019	Annual review. Changed criteria that member is female to member was female at birth. Updated references.
12/2019	Removed REMs and alcohol abstinence requirements due to updated labeling.
8/2021	Updated references.
9/2022	Annual review. Updated references. Added state mandate footnote.
11/2023	Annual review. Updated references.
11/2024	Annual review. Updated references.
12/2025	Annual review. Updated references.
2/2026	Updated based on new FDA approval for women ages 65 and less.

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