MEDICAL MUTUAL®

Drug Policy

Policy:	Addyi (flibanserin)	Annual Review Date: 03/21/2024 Last Revised Date: 03/21/2024

OVERVIEW

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.

POLICY STATEMENT

This policy involves the use of Addyi. Prior authorization is recommended for pharmacy benefit coverage of Addyi. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Addyi is recommended in those who meet the following criteria:

1. **Acquired, Generalized Hypoactive Sexual Desire Disorder (HSDD)/Female Sexual Interest/Arousal Disorder (FSIAD), initial therapy**
   Criteria. *Patient must meet the following criteria*
   - **A.** The patient is a premenopausal woman; AND
   - **B.** The patient has a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD)/female sexual interest/arousal disorder (FSIAD) consistent with the current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM) [documentation required]; AND
   - **C.** The patient has had normal sexual desire in the past, prior to the diagnosis of HSDD/FSIAD; AND
   - **D.** Patient's low sexual desire is NOT caused by any of the following:
     - **a.** Co-existing medical or psychiatric condition
     - **b.** Problems within the relationship
     - **c.** The effects of medication (e.g. antidepressants) or other drug substances
     - **d.** Drug abuse; AND
   - **E.** Addyi is not being used to enhance sexual performance; AND

F. The prescriber has counseled the patient regarding the interaction of Addyi with alcohol and the increased risk of hypotension and syncope; AND
G. Patient does not have hepatic impairment; AND
H. Patient will not use Addyi concurrently with CYP3A4 inhibitors (e.g. ketoconazole, clarithromycin); AND
I. Patient will not exceed maximum recommended dose of 100 mg taken once daily at bedtime; AND
J. Patient is not currently pregnant or breastfeeding

2. **Acquired, Generalized Hypoactive Sexual Desire Disorder (HSDD)/Female Sexual Interest/Arousal Disorder (FSIAD), Continuation of Therapy**
Criteria. *Patient must meet the following criteria*

A. The patient continues to meet all criteria for new starts above; AND
B. Patient has been evaluated and has seen improvement on Addyi defined by an increase in satisfying sexual events, and/or improvement in sexual desire, as determined by the prescriber; AND
C. The patient has not reported any serious or concerning adverse events (e.g. hypotension, syncope, dizziness) while using Addyi

Initial Approval/ Extended Approval.
A) *Initial Approval:* 2 months (60 days)
B) *Extended Approval:* 1 year (365 days)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Addyi has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Hypoactive Sexual Desire Disorder (HSDD)/Female Sexual Interest/Arousal Disorder (FSIAD) in Postmenopausal Patients.** Two published Phase III trials assessed the efficacy of Addyi in postmenopausal women with HSDD. In the SNOWDROP trial though there was statistical significance in the primary endpoints (number of satisfying sexual events over 28 days and increase in desire score), the treatment difference between Addyi and placebo was very minimal. The PLUMERIA study was discontinued early by the study sponsor for commercial reasons; however, published data are available for up to Week 16. The improvement from baseline to Week 16 in the Female Sexual Function Index desire domain was significantly greater with Addyi compared with placebo, but the other co-primary endpoint of sexually satisfying events was not significantly different between Addyi and placebo. Addyi is currently not approved for use in postmenopausal women with HSDD/FSIAD symptoms.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Addy tablets [prescribing information]. Raleigh, NC: Sprout Pharmaceuticals, Inc.; September 2021.
2. Food and Drug Administration. Addyi initial Risk Evaluation and Mitigation Strategy (REMS) approval. August 18, 2015. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022526REMS.pdf
3. Goldstein I, Kim NN, Clayton AH et al. Hypoactive Sexual Desire Disorder: International Society for the Study of Women's Sexual Health (ISSWSH) Expert Consensus Panel Review. Mayo Clin Proc. 2017 Jan;92(1):114-128. doi: 10.1016/j.mayocp.2016.09.018. Epub 2016 Dec 1.
4. Flibanserin. In: DRUGDEX [online database]. Truven Health Analytics. Greenwood Village, CO. Last updated 14 March 2024. Accessed 19 March 2024.
5. Portman DJ, Brown L, Yuan J, et al. Flibanserin in postmenopausal women with hypoactive sexual desire disorder: results of the PLUMERIA study. *J Sex Med.* 2017;14:834-842.
6. Simon JA, Kingsberg SA, Shumel B, et al. Efficacy and safety of flibanserin in postmenopausal women with hypoactive sexual desire disorder: results of the SNOWDROP trial. *Menopause.* 2014;21:633-640.
7. Female Sexual Dysfunction. *ACOG Practice Bulletin.* Clinical Management Guidelines for Obstetrician-Gynecologists. Number 213; July 2019. Available at: https://www.acog.org/. Accessed on December 6, 2022.