PRIOR AUTHORIZATION POLICY

POLICY: Hypoactive Sexual Desire Disorder – Addyi Prior Authorization Policy
- Addyi™ (flibanserin tablets – Sprout)

REVIEW DATE: 01/03/2024

OVERVIEW

Addyi is indicated for the **treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD)** that is 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] Addyi is not indicated for the treatment of HSDD in postmenopausal women or in men. It is also not indicated to enhance sexual performance. The prescribing information notes that Addyi should be discontinued after 8 weeks if the patient does not report any improvement in HSDD symptoms.[1] In the Addyi clinical studies, one of the coprimary efficacy endpoints was assessed by the median increase in the number of satisfying sexual events standardized over a 28-day period.

Safety

Addyi contains a Boxed Warning regarding the use of alcohol and the increase in risk of severe hypotension and syncope.[1] Patients should be counseled to wait at least two hours after consuming one or two standard alcoholic drinks before taking Addyi or skip the dose if they have consumed three or more standard alcoholic drinks that evening.

Guidelines

The American College of Obstetricians and Gynecologists guideline on Female Sexual Dysfunction (2019) notes the importance of recognizing if the loss of sexual interest is due to a co-morbid or undiagnosed condition, or medication.[4] The guidelines note that Addyi was approved in 2015 by the FDA to treatment hypoactive sexual desire disorder in premenopausal women without depression. Addyi is noted as a treatment option for HSDD in premenopausal women without depression who are appropriately counseled about the risk of alcohol use during treatment.[4] The guidelines also discuss that systemic review and meta-analysis of existing studies with Addyi show that although the studies were randomized, their overall quality of evidence for efficacy and safety was very low.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Addyi. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **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):
     - **i.** Patient is premenopausal; AND
     - **ii.** Patient's symptoms of HSDD/FSIAD have persisted for a minimum of 6 months; AND
     - **iii.** Patient has had normal sexual desire in the past, prior to the diagnosis of HSDD/FSIAD; AND
     - **iv.** Patient does **not** have a diagnosis of depression; AND
     - **v.** 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
     - **vi.** The prescriber has counseled the patient regarding the interaction with alcohol and Addyi, and the increased risk of hypotension and syncope.
   - **B)** Patient is Currently Receiving Addyi. Approve for 6 months if the patient meets the following (i, ii, and iii):
     - **i.** Patient is premenopausal; AND
     - **ii.** 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
     - **iii.** Patient has not reported any serious or concerning adverse events (e.g., hypotension, syncope, dizziness) while taking Addyi.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Addyi is not recommended in the following situations:

1. **Postmenopausal Patients.** Two published Phase III trials assessed the efficacy of Addyi in postmenopausal women with HSDD.[2,3] 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.[2] The PLUMERIA study was discontinued early by the study sponsor for commercial reasons; however, published data are available for up to Week 16.[3] 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.

REFERENCES

1. Addyi™ tablets [prescribing information]. Raleigh, NC: Sprout; September 2021.
2. 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.
3. 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.
4. 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 13, 2023.