



Drug Coverage Policy

Effective Date4/1/2026

Coverage Policy Number.....IP0116

Policy Title.....Addyi

Hypoactive Sexual Desire Disorder – Addyi

- Addyi™ (flibanserin tablets - Sprout)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

OVERVIEW

Addyi is indicated for the **treatment of women < 65 years of age 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 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.

Medical Necessity Criteria

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.

Addyi is considered medically necessary when the following are met:

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 < 65 years of age; 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 < 65 years of age; 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 Covered

Addyi for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

References

1. Addyi™ tablets [prescribing information]. Raleigh, NC: Sprout; December 2025.
2. 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 29, 2025.

Revision Details

| Type of Revision | Summary of Changes | Date |
|------------------|---|-----------|
| Annual Revision | Updated policy title, was previously Flibanserin. Hypoactive Sexual Desire Disorder (HSDD)/Female Sexual Interest/Arousal Disorder (FSIAD): Removed "Female at birth;" updated "Not currently being treated for active depression" to "Patient does not have a diagnosis of depression;" added clarification to patient counseling requirement to specifically address the increased risk of hypotension and syncope with Addyi and alcohol. Added to Patient is Currently Receiving Addyi criteria the following: "Patient has not reported any serious or concerning adverse events (e.g., hypotension, syncope, dizziness) while taking Addyi." | 7/15/2024 |
| Annual Revision | No criteria changes. | 4/15/2025 |
| Annual Revision | For both initial and continuation criteria, the criterion related to premenopausal women was removed. Added a criterion that the patient is < 65 years of age. Removed the condition not recommended for approval related to postmenopausal women. | 4/1/2026 |

The policy effective date is in force until updated or retired.

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