

Harvard Pilgrim Health Care – Pharmacy Prior Authorization Guideline

Guideline Name	Addyi (flibanserin)
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1. Criteria

Product Name: Addyi	
Diagnosis	Hypoactive Sexual Desire Disorder (HSDD)
Approval Length	3 Month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization, Non-Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of hypoactive sexual desire disorder (HSDD)</p> <p style="text-align: center;">AND</p> <p>2 - Patient is a premenopausal female</p> <p style="text-align: center;">AND</p> <p>3 - Patient is between 18 and 56 years of age</p> <p style="text-align: center;">AND</p> <p>4 - Provider has indicated that coexisting medical or psychiatric conditions, problems within the relationship and the effects of other medications or drug substances, have been ruled out</p> <p style="text-align: center;">AND</p> <p>5 - Provider has indicated that the member does not have hepatic impairment and the member is not taking a moderate to strong CYP3A4 inhibitor (see examples noted in Notes), both conditions are contraindicated with the use of this medication</p>	
Notes	Moderate or Strong CYP3A4 Inhibitors (per the Addyi Prescribing information): The concomitant use of Addyi with moderate or strong CYP3A4 inhibitors is contraindicated. Examples of strong CYP3A4 inhibitors: Ketoconazole, itraconazole, posaconazole, clarithromycin, nefazodone, ritonavir, saquinavir, nelfinavir, indinavir, telaprevir, telithromycin and conivaptan. Examples of moderate CYP3A4 inhibitors: Amprenavir, atazanavir, ciprofloxacin, diltiazem, erythromycin, fluconazole, fosamprenavir, verapamil, and grapefruit juice.

Product Name: Addyi	
Diagnosis	Hypoactive Sexual Desire Disorder (HSDD)
Approval Length	12 Month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization, Non-Formulary
<p>Approval Criteria</p> <p>1 - Provider has indicated that the patient had a favorable response with the medication</p> <p style="text-align: center;">AND</p> <p>2 - Patient is a still premenopausal</p> <p style="text-align: center;">AND</p> <p>3 - Provider has indicated that the member does not have hepatic impairment and the member is not taking a moderate to strong CYP3A4 inhibitor (see examples noted in Notes), both conditions are contraindicated with the use of this medication</p>	
Notes	Moderate or Strong CYP3A4 Inhibitors (per the Addyi Prescribing information) The concomitant use of Addyi with moderate or strong CYP3A4 inhibitors is contraindicated. Examples of strong CYP3A4 inhibitors: Ketoconazole, itraconazole, posaconazole, clarithromycin, nefazodone, ritonavir, saquinavir, nelfinavir, indinavir, telaprevir, telithromycin and conivaptan. Examples of moderate CYP3A4 inhibitors: Amprenavir, atazanavir, ciprofloxacin, diltiazem, erythromycin, fluconazole, fosamprenavir, verapamil, and grapefruit juice.

2. Background

Benefit/Coverage/Program Information	
<p>RATIONALE To ensure the appropriate use of Addyi (flibanserin) for the treatment of hypoactive sexual desire disorder (HSDD).</p> <p>FDA APPROVED INDICATIONS Addyi (flibanserin) 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:</p> <ul style="list-style-type: none"> • A co-existing medical or psychiatric condition, • Problems within the relationship, or • The effects of a medication or other drug substance 	

CONTRAINDICATIONS

- Moderate or strong cytochrome P450 3A4 (CYP3A4) inhibitors
- Hepatic impairment

REFERENCES

- Addyi (flibanserin) [prescribing information]. Raleigh, NC: Sprout Pharmaceuticals Inc; October 2019.

Created: 04/16
Revised: <ul style="list-style-type: none">• Annual review (effective: 1/1/20)• 9/20/20 - Annual review: minor background updates; no criteria changes
P&T Approval: 12/7/20
Effective: 1/1/21