



Hypoactive Sexual Desire Disorder (HSDD) Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
11-01-2025

Date of Origin

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Vyleesi	bremelanotide acet subcutaneous soln auto-inj	1.75 MG/0.3ML	M ; N ; O ; Y	N		
Addyi	flibanserin tab	100 MG	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Addyi	flibanserin tab	100 MG	30	Tablets	30	DAYS			
Vyleesi	Bremelanotide Acet Subcutaneous Soln Auto-Inj 1.75 MG/0.3ML	1.75 MG/0.3 ML	8	Pens	30	DAYS	Quantity limit for Vyleesi will allow for 8 doses per 30 days		

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
6217351510D520	Vyleesi	Bremelanotide Acet Subcutaneous Soln Auto-Inj 1.75 MG/0.3ML	1.75 MG/0.3 ML	Quantity limit for Vyleesi will allow for 8 doses per 30 days			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Addyi	flibanserin tab	100 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Vyleesi	bremelanotide acet subcutaneous soln auto-inj	1.75 MG/0.3ML	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Addyi	flibanserin tab	100 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Vyleesi	Bremelanotide Acet Subcutaneous Soln Auto-Inj 1.75 MG/0.3ML	1.75 MG/0.3ML	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Initial Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. ALL of the following: <ol style="list-style-type: none"> 1. The patient's benefit plan covers the requested agent AND 2. The patient is premenopausal AND 3. BOTH of the following: <ol style="list-style-type: none"> A. ONE of the following: <ol style="list-style-type: none"> 1. The patient has a diagnosis of acquired, generalized hypoactive sexual desire disorder (HSDD) OR 2. The patient has had a diagnosis of female sexual interest/arousal disorder (FSIAD) AND B. BOTH of the following: <ol style="list-style-type: none"> 1. The patient's HSDD is characterized by low sexual desire that causes marked distress or interpersonal difficulty AND 2. The patient's symptoms of low sexual desire have been present for at least 6 months AND 4. The HSDD is NOT due to ANY of the following: <ol style="list-style-type: none"> A. A co-existing medical or psychiatric condition OR B. Problems within the relationship OR C. The effects of a medication or other drug substance OR B. Both of the following: <ol style="list-style-type: none"> 1. The patient's benefit plan covers the requested agent AND 2. The patient has another FDA labeled or compendia supported indication for the requested agent and route of administration AND 2. The patient has tried and had an inadequate response to other treatment modalities (e.g., education, modification factors thought to be contributing to HSDD/FSIAD, and sex therapy) AND

Module	Clinical Criteria for Approval
	<p>3. The patient will NOT be using the requested agent in combination with another target agent in this program for the requested indication AND</p> <p>4. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Compendia Allowed: AHFS, DrugDex 1, 2A, or 2B level of evidence, or NCCN 1, 2A, or 2B recommended use</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months BCBSIL and BCBSMT: 12 months BCBSNM: 3 months ALL other plans: 8 weeks</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following: <ol style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. The requested indication is a rare disease AND C. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 2. ALL of the following: <ol style="list-style-type: none"> A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND C. The patient does NOT have any FDA labeled contraindications to the requested agent AND D. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months ALL other plans: 12 months</p>

Module	Clinical Criteria for Approval
	<p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has been previously approved for the requested agent through the plan's prior authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] AND 2. The patient's benefit plan covers the requested agent AND 3. The patient is premenopausal AND 4. The patient has had clinical benefit with the requested agent AND 5. The patient will NOT be using the requested agent in combination with another target agent in this program for the requested indication AND 6. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval:</p> <p>BCBSOK: 36 months ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Quantity limit for the Target Agent(s) will be approved when the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the program quantity limit <p>Length of Approval:</p> <p>BCBSIL: 12 months</p> <p>All other plans: Initial: 8 weeks; Renewal: 12 months</p>