



Vasomotor Symptoms Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
01-01-2026

Date of Origin
08-17-2023

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Lynkuet	elinzanetant cap	60 MG	M ; N ; O ; Y	N		
Veozah	fezolinetant tab	45 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
Lynkuet	elinzanetant cap	60 MG	60	Capsules	30	DAYS			
Veozah	fezolinetant tab	45 MG	30	Tablet	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Lynkuet	elinzanetant cap	60 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; 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

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Veozah	fezolinetant tab	45 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; 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
Lynkuet	elinzanetant cap	60 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; 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
Veozah	fezolinetant tab	45 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; 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 BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed OR B. The patient has a diagnosis of vasomotor symptoms AND ALL of the following: <ol style="list-style-type: none"> 1. The patient is menopausal AND 2. The patient's symptoms are moderate to severe (i.e., 7 or more episodes per day or 50 or more episodes per week) AND 3. BOTH of the following: <ol style="list-style-type: none"> 1. Baseline (prior to starting the requested agent) hepatic function (i.e., serum ALT, serum AST, serum ALP, serum bilirubin [total and direct]) has been evaluated AND 2. Hepatic transaminases AND total bilirubin are less than 2 times the upper limit of normal (ULN) AND 4. The patient has ONE of the following: <ol style="list-style-type: none"> A. Tried and had an inadequate response to ONE hormonal therapy (i.e., estrogen therapy [ET] or estrogen plus progesterone therapy [EPT] including oral, transdermal patches, sprays and gels, and vaginal ring agents) used to treat vasomotor symptoms of menopause [chart notes required] OR B. An intolerance or hypersensitivity to ONE hormonal therapy used to treat vasomotor symptoms of menopause [chart notes required] OR C. An FDA labeled contraindication to ALL hormonal therapies used to treat vasomotor symptoms of menopause [chart notes required] OR D. An age over 60 years OR E. An onset of menopause that was at least 10 years prior [chart notes required] AND 5. The patient has ONE of the following: <ol style="list-style-type: none"> A. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR B. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR C. Tried and had an inadequate response to ONE nonhormonal therapy (i.e., paroxetine, escitalopram, citalopram, venlafaxine, desvenlafaxine, duloxetine, gabapentin, oxybutynin) used to treat vasomotor symptoms of menopause [chart notes required] OR D. ONE nonhormonal therapy (i.e., paroxetine, escitalopram, citalopram, venlafaxine, desvenlafaxine, duloxetine, gabapentin, oxybutynin) used to treat vasomotor symptoms of menopause was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR E. An intolerance or hypersensitivity to ONE nonhormonal therapy used to treat vasomotor symptoms of menopause [chart notes required] OR F. An FDA labeled contraindication to ALL nonhormonal therapies used to treat vasomotor symptoms of menopause [chart notes required] OR G. ONE nonhormonal therapy used to treat vasomotor symptoms of menopause is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant

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	<p>barrier to the patient’s adherence of care; OR worsen a comorbid condition; OR decrease the patient’s ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR</p> <p>H. ONE nonhormonal therapy used to treat vasomotor symptoms of menopause is not in the best interest of the patient based on medical necessity [chart notes required] OR</p> <p>I. Tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE nonhormonal therapy used to treat vasomotor symptoms of menopause and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR</p> <p>C. The patient has another FDA labeled indication for the requested agent AND route of administration AND</p> <p>2. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>BCBSIL and BCBSMT: 12 months</p> <p>ALL other plans: 3 months</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> <p>1. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following:</p> <ul 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: <ul 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 <p>2. ALL of the following:</p> <ul 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: <ul 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]

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	<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</p> <p>ALL other plans: 12 months</p> <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 has had clinical benefit with the requested agent AND 3. ALL of the following: <ol style="list-style-type: none"> A. Hepatic function (i.e., serum ALT, serum AST, serum ALP, serum bilirubin [total and direct]) has been evaluated since starting the requested agent AND B. Hepatic transaminases are less than 5 times the ULN AND C. Hepatic transaminase elevations are less than 3 times the ULN AND the total bilirubin level is less than 2 times the ULN AND 4. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>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 ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the program quantity limit OR 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication OR B. BOTH of the following: <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND

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	<p style="margin-left: 40px;">2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit OR</p> <p>c. BOTH of the following:</p> <p style="margin-left: 40px;">1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND</p> <p style="margin-left: 40px;">2. There is support for therapy with a higher dose for the requested indication</p> <p>Length of Approval:</p> <p>BCBSIL: 12 months</p> <p>All other plans: 3 months for Initial; 12 months for Renewal</p>