

Elinzanetant (LYNKUET)

Criteria for Use

September 2026

VHA Pharmacy Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive elinzanetant.

- ☐ Baseline AST, ALT, or total bilirubin ≥ 2 times the upper limit of normal¹
- ☐ Concomitant use of strong and moderate CYP3A4 inducers and strong CYP3A4 inhibitors²
- ☐ Pregnancy
- ☐ History of seizures or a condition that lowers seizure threshold³
- ☐ Moderate or severe hepatic impairment (Child-Pugh B or C)

Inclusion Criteria

All of the following criteria must be met.

- ☐ Females with moderate to severe vasomotor symptoms (VMS) associated with menopause or due to endocrine treatment for hormone receptor positive breast cancer or its prevention⁴
- ☐ Contraindication or intolerance to menopausal hormone therapy (MHT) or patient preference to avoid
- ☐ Contraindication, intolerance, or insufficient response to one non-neurokinin pathway nonhormonal treatment for VMS⁵
- ☐ Potential for central nervous system depressant effects and impact on driving or hazardous work discussed

Additional Inclusion Criteria

- ☐ For females who can become pregnant: Exclude pregnancy prior to receiving elinzanetant
- ☐ For females who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 2 weeks after stopping treatment

1. Perform baseline liver function testing before initiating elinzanetant (ALT, AST, ALP, total and direct bilirubin). Perform follow-up liver function testing at 3 months (and if any signs or symptoms of liver injury occur). ALT=alanine aminotransferase; AST=aspartate aminotransferase; ALP=alkaline phosphatase.
2. For moderate CYP3A4 inhibitors, reduce dose of elinzanetant.
3. Precaution due to possible increased risk of seizures; consider alternative therapy as appropriate.
4. Patients studied in clinical trials had an average range of 11 to 16 moderate-to-severe VMS per day at baseline. Elinzanetant reduced hot flashes by about 3.2 per day compared to placebo.
5. Nonhormonal alternatives include selective serotonin reuptake inhibitors (SSRIs) (citalopram, escitalopram, paroxetine); serotonin and norepinephrine reuptake inhibitors (SNRIs) (venlafaxine, desvenlafaxine), gabapentin, and oxybutynin.

Supplemental Information

- **Menopause** is defined as spontaneous amenorrhea for at least 12 consecutive months (or at least 6 consecutive months with follicle stimulating hormone levels of 40 IU/L or greater) or bilateral oophorectomy.
- **VMS severity scale:** mild = sensation of heat without sweating; moderate = sensation of heat with sweating but able to continue activity; severe = sensation of heat with sweating, causing cessation of activity.
- **Reassessment of continued treatment:** Providers are advised to periodically reassess and discuss the need for continued treatment with patients, given the finite duration of VMS. Consider periodic assessment of liver function during extended treatment.
- **Hepatic transaminase elevation and hepatotoxicity:** Hepatic transaminase elevations and drug induced liver injury have occurred. Perform baseline and follow-up hepatic laboratory tests as recommended in the prescribing information. Do not initiate elinzanetant if AST, ALT, or total bilirubin is 2 times the upper limit of normal or greater. Discontinue elinzanetant if transaminase elevations are greater than 5 times upper limit of normal or if transaminase elevations are greater than 3 times upper limit of normal and the total bilirubin greater than 2 times upper limit of normal. Patients should be advised on signs and symptoms of hepatotoxicity and when to seek medical attention.

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