BlueCross BlueShield
Federal Employee Program

ORSERDU
(elacestrant)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Orserdu (elacestrant) is an estrogen receptor antagonist that binds to the estrogen receptor-alpha (ERα). In ER-positive (ER+) HER2-negative (HER2-) breast cancer cells, Orserdu inhibited 17β-estradiol mediated cell proliferation at concentrations inducing degradation of ERα protein mediated through proteasomal pathway. Orserdu demonstrated in vitro and in vivo antitumor activity including in ER+ HER2- breast cancer models resistant to fulvestrant and cyclin-dependent kinase 4/6 inhibitors and those harboring estrogen receptor 1 gene (*ESR1*) mutations (1).

Regulatory Status

FDA-approved indication: Orserdu is an estrogen receptor antagonist indicated for: (1)

- Treatment of postmenopausal women or adult men, with ER-positive, HER2-negative, *ESR1*-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

Orserdu may cause hypercholesterolemia and hypertriglyceridemia. Lipid profiles should be monitored prior to starting and periodically while taking Orserdu (1).

Orserdu can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception during treatment with Orserdu and for 1 week after the last dose. Male patients with female partners of reproductive potential should be advised to use effective contraception during treatment with Orserdu and for 1 week after the last dose (1).

The safety and effectiveness of Orserdu in pediatric patients less than 18 years of age have not been established (1).

Summary

Orserdu (elacestrant) is an estrogen receptor antagonist indicated for the treatment of ER-positive, HER2-negative, *ESR1*-mutated advanced or metastatic breast cancer. Orserdu contains warnings regarding dyslipidemia and embryo-fetal toxicity. The safety and effectiveness of Orserdu in pediatric patients less than 18 years of age have not been established (1).

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Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Orserdu while maintaining optimal therapeutic outcomes.

References

1. Orserdu [package insert]. New York, NY: Stemline Therapeutics, Inc.; November 2023.
2. NCCN Drugs & Biologics Compendium® Elacestrant 2025. National Comprehensive Cancer Network, Inc. Accessed on January 8, 2025.