PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Orserdu Prior Authorization Policy
- Orserdu™ (elacestrant tablets – Stemline/Menarini)

REVIEW DATE: 02/18/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Orserdu, an estrogen receptor antagonist, is indicated for the treatment of estrogen receptor-positive (ER+), human epidermal growth factor receptor 2 (HER2)-negative, estrogen receptor 1 gene (*ESR1)*-mutated **advanced or metastatic breast cancer with disease progression** following at least one line of endocrine therapy in postmenopausal women or adult men.[1]

Guidelines

National Comprehensive Cancer Network (NCCN) breast cancer guidelines (version 4.2025 – April 17, 2025) recommend Orserdu for hormone receptor-positive (HR+), HER2-negative, *ESR1*-mutated recurrent, unresectable or metastatic breast cancer for disease progression during or after prior line of aromatase inhibitor plus cyclin-dependent kinase (CDK) 4/6 inhibitor in the adjuvant or metastatic setting as "Other Recommended Regimen" (category 2A).[2]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Orserdu. All approvals are provided for the duration noted below. In the clinical criteria, as appropriate, an asterisk (*) is noted next to the specified gender. In this context, the specified gender is defined as follows: a woman is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression; a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.

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is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Breast Cancer** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, F, and G):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has recurrent or metastatic disease; AND
   - **C)** Patient has hormone receptor-positive (HR+) disease; AND
   - **D)** Patient has human epidermal growth factor receptor 2 (HER2)-negative disease; AND
   - **E)** Patient has estrogen receptor 1 gene (*ESR1)*-mutated disease; AND
   - **F)** Patient has tried at least one endocrine therapy; AND
     Note: Examples of endocrine therapy include fulvestrant, anastrozole, exemestane, letrozole, and tamoxifen.

   - **G)** Patient meets ONE of the following (i or ii):
     - **i.** Patient is a postmenopausal woman* or man*; OR
     - **ii.** Patient is a pre/perimenopausal woman* and meets ONE of the following (a or b):
       - **a)** Patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist; OR
         Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), and Zoladex (goserelin acetate subcutaneous injection).
       - **b)** Patient has had surgical bilateral oophorectomy or ovarian irradiation.

***** Refer to the Policy Statement.

CONDITIONS NOT COVERED

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is(are) considered experimental, investigational or unproven for ANY other use(s); criteria will be updated as new published data are available

REFERENCES

1. Orserdu™ tablets [prescribing information]. New York, NY: Stemline Therapeutics/Menarini Group; November 2023.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 4.2025 – April 17, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 30, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	02/08/2023
Selected Revision	**Breast Cancer in Postmenopausal Women or Men:** The criterion that the patient has tried at least one cyclin-dependent kinase (CDK) 4/6 inhibitor and note of examples of CDK4/6 inhibitors were removed.	02/15/2023
Annual Revision	No criteria changes.	02/07/2024
Annual Revision	No criteria changes.	02/12/2025
Early Annual Revision	**Breast Cancer:** The requirement that the patient has "estrogen receptor-positive (ER+)" disease was reworded to "hormone receptor-positive (HR+)" disease.	02/18/2026