

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Inluriyo Prior Authorization Policy

- Inluriyo™ (imlunestrant tablets – Eli Lilly)

**REVIEW DATE:** 02/18/2026

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### OVERVIEW

Inluriyo, 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 adults.<sup>1</sup>

### Guidelines

The National Comprehensive Cancer Network (NCCN) breast cancer guidelines (version 1.2026 – January 16, 2026) have the following recommendations for hormone receptor (HR)+, HER2-negative recurrent unresectable (local or regional) or metastatic breast cancer: Inluriyo for *ESR1* mutation and disease progression during or after a prior line of aromatase inhibitor with or without cyclin dependent kinase 4 and 6 (CDK)4/6 inhibitor therapy in the adjuvant or metastatic setting as “other recommended regimen” (category 2A); Inluriyo + Verzenio® (abemaciclib tablets) as second- and/or subsequent-line therapy as “Useful in Certain Circumstances” (category 2A).

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Inluriyo. 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.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Inluriyo is recommended in those who meet the following criteria:

#### 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  $\geq 18$  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 meets ONE of the following (i or ii):
      - i. Patient has estrogen receptor 1 gene (*ESR1*)-mutated disease; OR
      - ii. The medication will be used in combination with Verzenio (abemaciclib tablets); AND
    - F) Patient has tried at least one endocrine therapy; AND
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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 man\* or postmenopausal woman\*; 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 RECOMMENDED FOR APPROVAL

Coverage of Inluriyo is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

### REFERENCES

1. Inluriyo™ tablets [prescribing information]. Indianapolis, IN: Eli Lilly; September 2025.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 1.2026 – January 16, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 3, 2026.

### HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	10/01/2025
Selected Revision	<b>Breast Cancer:</b> The requirement that the patient has “estrogen receptor-positive (ER+)” disease was reworded to “hormone receptor-positive (HR+)” disease.	10/22/2025
Early Annual Revision	<b>Breast Cancer:</b> An option for approval was added when the medication is used in combination with Verzenio (abemaciclib tablets).	02/18/2026