Reference number(s)
7208-A

Specialty Guideline Management
Inluriyo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Inluriyo	imlunestrant

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication[1]

Inluriyo is indicated for the treatment of adults with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, estrogen receptor-1 (ESR1)-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Estrogen receptor (ER) status
- Human epidermal growth factor receptor 2 (HER2) status
- Estrogen receptor-1 (ESR1) mutation status

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Coverage Criteria

Breast Cancer[1]

Authorization of 12 months may be granted for treatment of breast cancer when all of the following criteria are met:

- The disease is ER-positive, HER2-negative, and ESR1-mutated
- The disease is either advanced or metastatic
- The member had disease progression following at least one line of endocrine therapy (e.g.; exemestane [Aromasin], fulvestrant [Faslodex])
- The requested medication will be used in combination with a gonadotrophin-releasing hormone agonist (GnRH) (e.g., leuprolide [Lupron]) if the member is not postmenopausal.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the Coverage Criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Inluriyo [package insert]. Indianapolis, IN: Lilly USA, LLC; September 2025.