Imlunestrant (INLURIYO)
Criteria for Use
August 2026

VA Pharmacy Services and National Formulary Committee

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 ANY of the following are selected, the patient will NOT meet criteria for Imlunestrant.

- ☐ Unmanageable drug-drug interactions
- ☐ Pregnancy
- ☐ Lactating

Inclusion Criteria

All the following must be selected to meet criteria.

- ☐ Advanced or metastatic breast cancer
- ☐ Hormone receptor (HR) positive, HER2-negative breast cancer
- ☐ *ESR1*-mutation positive as detected by an approved test
- ☐ Progressive disease on or after at least one endocrine-based regimen (i.e. aromatase inhibitor +/- CDK 4/6 inhibitor)

Additional Inclusion Criteria

All of the following criteria must be selected to meet criteria.

- ☐ Care is provided by a VA or VA Community Care oncology provider
- ☐ Eastern Cooperative Oncology Group (ECOG) performance status 0 - 1
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented

Additional Inclusion Criteria – Select If Applicable

- ☐ For females who can become pregnant and males with partners who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for one week after stopping treatment.
- ☐ For females who are lactating / providing breastmilk to an infant or planning to do so: Counseling provided to avoid breastfeeding during treatment and for one week after stopping treatment.

Other Justification

- ☐ _____

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