Criteria-Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

Alpelisib (Piqray)

Notes:

- Quantity Limits: Yes/No
- Type any relevant notes in this area in patient-friendly language
 - Relevant notes may include safety or any other important information relating to the medication or criteria details.
- Use Arial size 10 font for notes.
- ^ Adequate trial is defined as *** treatment duration
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

Initiation (new start) criteria: Non-formulary **alpelisib (Piqray)** will be covered on the prescription drug benefit when the following criteria are met:

- Diagnosis of metastatic or advanced, hormone receptor (HR) positive, Human Epidermal Growth Factor Receptor 2 (HER-2) negative breast cancer with Phosphoinositide 3-kinase (PI3K) mutation
- Male or postmenopausal female
- Adequate trial of aromatase inhibitor (anastrozole, exemestane, or letrozole) with documented intolerance or progression of disease
- Either of the following:
 - Adequate trial of fulvestrant in combination with Cyclin Dependent Kinase 4 and 6 (CDK 4/6) inhibitor (palbociclib or abemaciclib) with documented intolerance or progression of disease
 - Adequate trial of fulvestrant in combination with everolimus with documented intolerance or progression of disease

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