Drug Therapy Guidelines

Piqray® (alepelisib)

### I. Medication Description

Alpelisib is an inhibitor of phosphatidylinositol-3-kinase (PI3K) with inhibitory activity predominantly against PI3Kα. PI3K inhibition by alpelisib treatment has been shown to induce an increase in estrogen receptor (ER) transcription in breast cancer cells. The combination of alpelisib and fulvestrant demonstrated increased anti-tumor activity compared to either treatment alone in xenograft models derived from ER-positive, PIK3CA mutated breast cancer cell lines.

### II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

### III. Policy

Coverage of Piqray is available when the following criteria have been met:

- Member is at least 18 years of age AND
- The medication is prescribed by a hematologist/oncologist AND
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

### IV. Quantity Limitations

Coverage is provided as follows:

- 200mg tablets: up to 28 tablets per 28 days
- 250mg dose blister pack: up to 56 tablets per 28 days
- 300mg dose blister pack: up to 56 tablets per 28 days

### V. Coverage Duration

Coverage is provided for 6 months and may be renewed.

### VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Stabilization of disease or in absence of disease progression AND
• Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

Available as:
• 200mg oral tablets
• 250mg daily dose blister pack containing 200mg and 50mg oral tablets
• 300mg daily dose blister pack containing 150mg oral tablets

VIII. Summary of Policy Changes

• 10/15/19: new policy

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.