I. Medication Description

Palbociclib is an oral, selective inhibitor of cyclin-dependent kinases (CDKs) 4 and 6, which are both involved in tumor cell progression during phase G1 to phase S in the cell cycle. By inhibiting CDK 4 and 6, palbociclib prevents the deactivation of the tumor suppressor protein known as retinoblastoma susceptibility gene protein, and interferes with tumor cell progression.

II. Position Statement

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

III. Policy

Coverage of Ibrance 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 for 21 capsules (75mg, 100mg and 125mg) every 28 days to accommodate the FDA-approved dosing.

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 75mg, 100mg and 125mg oral capsules

VIII. Summary of Policy Changes

- 6/15/15: new policy
- 7/1/15: formulary distinctions made
- 12/15/15: no policy changes
- 9/15/16: policy updated to correspond with current NCCN treatment guidelines
- 10/11/17: coverage criteria updated to allow use as supported by current NCCN guidelines
- 11/1/18: no policy changes
- 11/15/19: no policy changes

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.