

# Drug Therapy Guidelines

Verzenio™ (abemaciclib)

*Applicable*

Medical Benefit		Effective: 1/18/18
Pharmacy- Formulary 1	x	Next Review: 12/18
Pharmacy- Formulary 2	x	Date of Origin: 1/18
Pharmacy- Formulary 3/Exclusive	x	Review Dates: 12/17
Pharmacy- Formulary 4/AON	x	

## I. Medication Description

Abemaciclib is an inhibitor of cyclin-dependent kinases 4 and 6 (CDK4 and CDK6). These kinases are activated upon binding to D-cyclins. In estrogen receptor-positive (ER+) breast cancer cell lines, cyclin D1 and CDK4/6 promote phosphorylation of the retinoblastoma protein (Rb), cell cycle progression, and cell proliferation. In vitro, continuous exposure to abemaciclib inhibited Rb phosphorylation and blocked progression from G1 into S phase of the cell cycle, resulting in senescence and apoptosis. In breast cancer xenograft models, abemaciclib dosed daily without interruption as a single agent or in combination with antiestrogens resulted in reduction of tumor size.

## II. Position Statement

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

## III. Policy

Coverage of Verzenio is provided when the following criteria are 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 Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

## IV. Quantity Limitations

- 50 mg tablets: covered at up to 56 tablets per each 28 days
- 100 mg tablets: covered at up to 56 tablets per each 28 days
- 150 mg tablets: covered at up to 56 tablets per each 28 days
- 200 mg tablets: covered at up to 56 tablets per each 28 days

## V. Coverage Duration

Coverage can be 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 the absence of disease progression **AND**
- Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

Verzenio is available as 50mg, 100mg, 150mg, and 200mg tablets (supplied as blister packs containing 14 tablets each).

VIII. Summary of Policy Changes

1/18/2018: new policy

IX. References

1. Clinical Pharmacology. Accessed online 1/2018. ([www.clinicalpharmacology.com](http://www.clinicalpharmacology.com)). Elsevier/Gold Standard.
2. Product Information. Verzenio™ (abemaciclib). Lilly USA, Indianapolis, IN 46285. Issued 9/2017.
3. NCCN Drugs & Biologics Compendium®: abemaciclib. Accessed 1/2018.
4. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Breast Cancer. Version 3.2017. Accessed 1/2018.

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