



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/16/17
LAST REVIEW DATE: 5/16/19
LAST CRITERIA REVISION DATE: 5/16/19
ARCHIVE DATE:

VERZENIO™ (abemaciclib) oral tablet

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

VERZENIO™ (abemaciclib) oral tablet (cont.)

Criteria:

- **Criteria for initial therapy:** Verzenio (abemaciclib) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Prescriber is an Oncologist
 2. Individual is 18 years of age or older
 3. A confirmed diagnosis of **ONE** of the following:
 - Recurrent or stage IV (M1) hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer with no visceral crisis in postmenopausal woman or premenopausal woman (receiving ovarian suppression or ablation with an LHRH agonist) used in combination with an aromatase inhibitor (anastrozole, letrozole, or exemestane) **or** in combination with fulvestrant
 - Recurrent or stage IV (M1) HR-positive, non-visceral or asymptomatic visceral HER2-negative breast cancer as a single agent if progression on prior endocrine therapy and prior chemotherapy in the metastatic setting
 - Recurrent or stage IV (M1) (HR)-positive, non-visceral or asymptomatic visceral (HER2)-negative breast cancer in a **male** used in combination with an aromatase inhibitor (anastrozole, letrozole, or exemestane) **or** fulvestrant and used with a drug for suppression of testicular steroidogenesis
 - Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A
 4. **ALL** of the following baseline tests have been completed before initiation of treatment:
 - Complete blood count
 - Comprehensive metabolic panel
 - Negative pregnancy test in a woman of child bearing age

Initial approval duration: 56 tabs per month for 6 months

- **Criteria for continuation of coverage (renewal request):** Verzenio (abemaciclib) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Individual continues to be seen by an Oncologist
 2. The cancer has not worsened while on therapy
 - Worsening is defined as:
 - Disease progressed while on Verzenio
 3. Individual has been adherent with the medication

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/16/17
LAST REVIEW DATE: 5/16/19
LAST CRITERIA REVISION DATE: 5/16/19
ARCHIVE DATE:

VERZENIO™ (abemaciclib) oral tablet (cont.)

4. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use
 - Significant adverse effect such as:
 - Hepatic impairment
 - Venous thromboembolism
 - Neutropenia
 - Thrombocytopenia
5. There are no significant interacting drugs

Renewal duration: 56 tabs per month for 12 months

Description:

Verzenio (abemaciclib) is indicated in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, in combination with fulvestrant for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

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, cell cycle progression, and cell proliferation. Abemaciclib inhibits phosphorylation and blocks progression cell cycle phases G1 moving into S phase, resulting in senescence and apoptosis. In breast cancer models, abemaciclib as a single agent or in combination with antiestrogens resulted in reduction of tumor size.

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/16/17
LAST REVIEW DATE: 5/16/19
LAST CRITERIA REVISION DATE: 5/16/19
ARCHIVE DATE:

VERZENIO™ (abemaciclib) oral tablet (cont.)

Definitions:

National Comprehensive Cancer Network (NCCN) Invasive Breast Cancer Guideline: Version 1.2019, Mar 14, 2019

Systemic Therapy ER and/or PR positive Recurrent of Stage IV (M1) disease	
<i>HER2 Negative and Postmenopausal or Premenopausal (receiving ovarian ablation or suppression)</i>	
	Alphabetically by generic name
Preferred Category 1	Verzenio (abemaciclib) + aromatase inhibitor Verzenio (abemaciclib) + Faslodex (fulvestrant) Faslodex (fulvestrant) Ibrance (palbociclib) + aromatase inhibitor Ibrance (palbociclib) + Faslodex (fulvestrant) Kisqali (ribociclib) + aromatase inhibitor Kisqali (ribociclib) + Faslodex (fulvestrant) Kisqali (ribociclib) + Tamoxifen – useful in certain circumstances
Preferred Category 2A	Non-steroidal aromatase inhibitor: (Arimidex or generic anastrozole or Femara or generic letrozole) Selective estrogen receptor modulator: Tamoxifen or Fareston (toremifene) Faslodex (fulvestrant) + Afinitor (everolimus) Tamoxifen + Afinitor (everolimus) Steroidal aromatase inactivator: Aromasin (exemestane) Exemestane + Afinitor (everolimus)
Useful in certain circumstances	Verzenio (abemaciclib) Ethinyl estradiol Fluoxmesterone Megestrol acetate
<i>HER2 Positive and Postmenopausal</i>	
	Alphabetically by generic name
Category 2A	Aromatase inhibitor ± Herceptin (trastuzumab) Aromatase inhibitor ± Tykerb (lapatinib) Aromatase inhibitor ± Tykerb (lapatinib) + Herceptin (trastuzumab) Faslodex (fulvestrant) ± Herceptin (trastuzumab) Tamoxifen ± Herceptin (trastuzumab)

Resources:

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.

Verzenio. Package Insert. Revised by manufacturer 2/2018. Accessed 3/23/18.

Verzenio. Package Insert. Revised by manufacturer 4/2017. Accessed 10/10/17.



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/16/17
LAST REVIEW DATE: 5/16/19
LAST CRITERIA REVISION DATE: 5/16/19
ARCHIVE DATE:

VERZENIO™ (abemaciclib) oral tablet (cont.)

NCCN Clinical Practice Guidelines in Oncology: Breast cancer. Version 1.2018, Mar 20, 2018.
https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf

UpToDate: Treatment protocols for breast cancer. Current through Oct 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/treatment-protocols-for-breast-cancer?source=see_link

UpToDate: Treatment approach to metastatic hormone receptor-positive, HER2-negative breast cancer: Endocrine therapy. Current through Oct 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/treatment-approach-to-metastatic-hormone-receptor-positive-her2-negative-breast-cancer-endocrine-therapy?source=search_result&search=breast%20cancer&selectedTitle=6~150

UpToDate: Adjuvant chemotherapy for HER2-negative breast cancer. Current through Oct 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/adjuvant-chemotherapy-for-her2-negative-breast-cancer?source=see_link§ionName=INDICATIONS%20FOR%20TREATMENT&anchor=H11555550#H11555550

UpToDate: Overview of the treatment of newly diagnosed, non-metastatic breast cancer. Current through Oct 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/overview-of-the-treatment-of-newly-diagnosed-non-metastatic-breast-cancer?source=search_result&search=breast%20cancer&selectedTitle=1~150

Verzenio (abemaciclib) product information accessed 03-22-19 at DailyMed:
<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=be4bc0de-0fdc-4d46-8d25-be43c79e6a06>

NCCN Compendium: Verzenio (abemaciclib) accessed 03-22-19



An Independent Licensee of the Blue Cross and Blue Shield Association

Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com. Call 866-325-1794 to check the status of a request. All requested data must be provided. Incomplete forms or forms without the chart notes will be returned. Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.

REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information			
Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information			
Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information		
Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information			
Medication Name:	Strength:	Dosage Form:	
Directions for Use:	Quantity:	Refills:	Duration of Therapy/Use:

Check if requesting **brand** only Check if requesting **generic**

Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review	
<input type="checkbox"/> Standard <input type="checkbox"/> Urgent. Sign here: _____	<input type="checkbox"/> Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**
 ICD-10 Code: _____ Diagnosis Description: _____

2. Yes No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. Yes No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
 Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature:	Date:
-----------------------------------	-------

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.