Effective Date..... 4/1/2023
Next Review Date..... 4/1/2024

Prior Authorization
Oncology – Verzenio® (abemaciclib tablets)

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Product Identifier(s)

60377

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National Formulary Medical Necessity

Cigna covers abemaciclib (Verzenio®) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

Prior Authorization is recommended for prescription benefit coverage of Verzenio. All approvals are provided for duration noted below. In the clinical criteria, as appropriate, an asterisk (*) is noted next to the specified gender. In this context, the specified gender is defined as follows: a woman is defined as an individual with the biological traits of a woman, regardless of the individual's gender identity or gender expression; men are defined as individuals with the biological traits of a man, regardless of the individual's gender identity or gender expression.

FDA Indication(s)

1. **Breast Cancer - Early.** Approve for 2 years if the individual meets the following criteria (A, B, C, D, and E):
   - **A)** Individual is ≥ 18 years of age; AND
   - **B)** Individual has hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}] disease; AND
   - **C)** Individual has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND

D) Individual has node-positive disease at high risk of recurrence; AND
Note: High risk includes individuals with ≥4 positive lymph nodes, or 1-3 positive lymph nodes with one or more of the following: grade 3 disease, tumor size ≥5 cm, or a Ki-67 score of ≥20%.

E) Individual meets ONE of the following criteria (i or ii):

i. Verzenio will be used in combination with anastrozole, exemestane, or letrozole AND individual meets one of the following (a ,b, or c):

a) Individual is a postmenopausal woman*; OR

b) Individual is a pre/perimenopausual woman* and meets one of the following [(1) or (2)]:

(1) Individual is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist; OR
Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous injection).

(2) Individual has had surgical bilateral oophorectomy or ovarian irradiation; OR

c) Individual is a man* and individual is receiving a gonadotropin-releasing hormone (GnRH) analog; OR
Note: Examples of a GnRH analog include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous injection), Firmagon (degarelix acetate subcutaneous injection), Orgovyx (relugolix tablet).

ii. Verzenio will be used in combination with tamoxifen AND individual meets one of the following (a or b):

a) Individual is a postmenopausal woman* or man*; OR

b) Individual is a pre/perimenopausual woman* and meets one of the following [(1) or (2)]:

(1) Individual is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist; OR
Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous injection).

(2) Individual has had surgical bilateral oophorectomy or ovarian irradiation.

***** Refer to the Policy Statement.

2. Breast Cancer – Recurrent or Metastatic in Women*. Approve for 1 year if the individual meets the following criteria (A, B, C, D, E, and F):

A) Individual is ≥ 18 years of age; AND

B) Individual has recurrent or metastatic breast cancer; AND

C) Individual has hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}] disease; AND

D) Individual has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND

E) Individual meets ONE of the following criteria (i or ii):

i. Individual is postmenopausal OR

ii. Individual is pre/perimenopausal and meets one of the following (a or b):

a) Individual is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist; OR
Note: Examples of a GnRH agonist include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant).

b) Individual has had surgical bilateral oophorectomy or ovarian irradiation; AND

F) Individual meets ONE of the following criteria (i, ii, or iii):

i. Verzenio will be used in combination with anastrozole, exemestane, or letrozole; OR

ii. Verzenio will be used in combination with fulvestrant; OR

iii. Individual meets the following conditions (a, b, and c):

a) Verzenio will be used as monotherapy; AND

b) Individual's breast cancer has progressed on at least one prior endocrine therapy; AND

Note: Examples of prior endocrine therapy include anastrozole, exemestane, letrozole, tamoxifen, toremifene, exemestane plus everolimus, fulvestrant, everolimus plus fulvestrant or tamoxifen, megestrol acetate, fluoxymesterone, ethinyl estradiol.

c) Individual has tried chemotherapy for metastatic breast cancer.

***** Refer to the Policy Statement.

3. **Breast Cancer - Recurrent or Metastatic in Men*.** Approve for 1 year if the individual meets the following criteria (A, B, C, D, and E):
   - **A)** Individual is ≥ 18 years of age; AND
   - **B)** Individual has recurrent or metastatic breast cancer; AND
   - **C)** Individual has hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}]disease; AND
   - **D)** Individual has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
   - **E)** Individual meets ONE of the following criteria (i, ii, or iii):
     - **i.** Individual meets BOTH of the following conditions (a and b):
       - **a)** Individual is receiving a gonadotropin-releasing hormone (GnRH) analog; AND
         Note: Examples of a GnRH analog include leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Firmagon (degarelix acetate subcutaneous injection), Orgovyx (relugolix tablet).
       - **b)** Verzenio will be used in combination with anastrozole, exemestane, or letrozole; OR
     - **ii.** Verzenio will be used in combination with fulvestrant; OR
     - **iii.** Individual meets the following conditions (a, b, and c):
       - **a)** Verzenio will be used as monotherapy; AND
       - **b)** Individual's breast cancer has progressed on at least one prior endocrine therapy; AND
         Note: Examples are anastrozole, exemestane, letrozole, tamoxifen, toremifene, exemestane plus everolimus, fulvestrant, everolimus plus fulvestrant or tamoxifen, megestrol acetate, fluoxymesterone, ethinyl estradiol.
       - **c)** Individual has tried chemotherapy for metastatic breast cancer**.**

***** Refer to the Policy Statement.

Conditions Not Covered

Abemaciclib (Verzenio®) is considered experimental, investigational or unproven for ANY other use.

Background

Overview

Verzenio, a cyclin-dependent kinase (CDK) 4/6 inhibitor, is indicated for the treatment of adults with hormone receptor-positive (HR+), human epidermal growth factor receptor 2 (HER2)-negative **breast cancer** in the following settings:[1]

- **Early breast cancer**, in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for adjuvant treatment for node-positive disease at high risk of recurrence and a Ki-67 score ≥ 20%, as determined by an FDA approved test.
- **Advanced or metastatic breast cancer:**
  - In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women and men.
  - In combination with fulvestrant for disease progression following endocrine therapy.
  - As monotherapy for disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

Guidelines
The National Comprehensive Cancer Network (NCCN) guidelines on **breast cancer** (version 2.2023 – February 7, 2023) recommend Verzenio with aromatase inhibitor (category 2A) or fulvestrant (category 1) as a first-line "Preferred Regimen" for recurrent unresectable (local or regional) or Stage IV HR+ and HER2-negative disease in postmenopausal women or premenopausal patient receiving ovarian ablation or suppression.[2,3] The guidelines state in a footnote that in phase III randomized controlled trials, Kisqali® (ribociclib tablets) + endocrine therapy has shown overall survival benefit in the first-line setting. CDK4/6 inhibitor + fulvestrant is recommended for second- and subsequent-line therapy, if CDK4/6 inhibitor was not previously used (category 1) in this setting, which is a "Preferred Regimen". The guidelines state in a footnote that in phase III randomized controlled trials, fulvestrant in combination with a CDK4/6 inhibitor has shown overall survival benefit in the second-line setting. In this setting, single-agent Verzenio is recommended as a "Useful In Certain Circumstances" therapy (for subsequent treatment) if there is progression on prior endocrine therapy and prior chemotherapy in the metastatic setting (category 2A). For men with breast cancer, the compendium recommends they be treated similarly to postmenopausal women, except that the use of an aromatase inhibitor is ineffective without concomitant suppression of testicular steroidogenesis.[3] The guidelines also recommend Verzenio for 2 years as adjuvant therapy in combination with endocrine therapy in patients with HR+, HER2-negative, high risk (i.e., ≥4 positive lymph nodes, or 1-3 positive lymph nodes with one or more of the following: grade 3 disease, tumor size ≥5 cm, or a Ki-67 score of ≥20%) disease (category 2A).

References

1. Verzenio® tablets [prescribing information]. Indianapolis, IN: Eli Lilly; October 2021.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 2.2023 – February 7, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 10, 2023.
3. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 10, 2023. Search terms: abemaciclib.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	No criteria changes.	02/22/2023