ABEMACICLIB

Generic	Brand	HICL	GCN	Exception/Other
ABEMACICLIB	VERZENIO	44537		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced or metastatic breast cancer that is hormone receptor positive (HR+) and human epidermal growth factor receptor 2 negative (HER2-) and meet **ALL** of the following criteria?
   - The patient is female
   - The medication will be used in combination with fulvestrant
   - The patient has had disease progression following endocrine therapy
   - The patient has NOT experienced disease progression following prior CDK inhibitor therapy (e.g., Ibrance)

   If yes, **approve for 12 months by HICL with a quantity limit of #56 tablets (four 7-day dose packs) per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of advanced or metastatic breast cancer that is hormone receptor positive (HR+) and human epidermal growth factor receptor 2 negative (HER2-) and meet **ALL** of the following criteria?
   - The medication will be used as monotherapy
   - The patient is 18 years of age or older
   - The patient has had disease progression following endocrine therapy AND prior chemotherapy in the metastatic setting
   - The patient has NOT experienced disease progression following prior CDK inhibitor therapy (e.g., Ibrance)

   If yes, **approve for 12 months by HICL with a quantity limit of #56 tablets (four 7-day dose packs) per 28 days.**
   If no, continue to #3.

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ABEMACICLIB

GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of advanced or metastatic breast cancer that is hormone receptor positive (HR+) and human epidermal growth factor receptor 2 negative (HER2-) and meet **ALL** of the following criteria?
   - The patient is a female and postmenopausal
   - The requested medication will be used in combination with an aromatase inhibitor (e.g., letrozole, anastrozole, or exemestane)
   - The patient has NOT received prior endocrine therapy for metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
   - The patient has NOT experienced disease progression following prior CDK inhibitor therapy

   If yes, **approve for 12 months by HICL with a quantity limit of #56 tablets (four 7-day dose packs) per 28 days.**
   If no, do not approve.
   DENIAL TEXT: The guideline named **ABEMACICLIB (Verzenio)** requires a diagnosis of advanced or metastatic breast cancer that is hormone receptor positive (HR+) and human epidermal growth factor receptor 2 negative (HER2-). In addition, **ONE** of the following criteria must be met:
   The medication will be used in combination with fulvestrant and meet ALL of the following:
   - The patient is female
   - The patient has had disease progression following endocrine therapy
   - The patient has NOT experienced disease progression following prior CDK inhibitor therapy

   The medication will be used as monotherapy and meet ALL of the following:
   - The patient is 18 years of age or older
   - The patient has had disease progression following endocrine therapy and prior chemotherapy in the metastatic setting
   - The patient has NOT experienced disease progression following prior CDK inhibitor therapy

   The medication will be used in combination with an aromatase inhibitor and meet ALL of the following:
   - The patient is a female and postmenopausal
   - The requested medication will be used in combination with an aromatase inhibitor (e.g., letrozole, anastrozole, or exemestane)
   - The patient has NOT received prior endocrine therapy for metastatic breast cancer (e.g., letrozole, anastrozole, tamoxifen, fulvestrant, exemestane)
   - The patient has NOT experienced disease progression following prior CDK inhibitor therapy

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ABEMACICLIB

RATIONALE
Promote appropriate utilization of **ABEMACICLIB** (Verzenio) based on FDA approved indications.

FDA APPROVED INDICATIONS
Verzenio is a kinase inhibitor indicated:
- 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
- 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.
- 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.

DOSAGE AND ADMINISTRATION
When used in combination with fulvestrant or an aromatase inhibitor, the recommended dose of Verzenio is 150 mg taken orally twice daily. When given with Verzenio, the recommended dose of fulvestrant is 500 mg administered on Days 1, 15, and 29; and once monthly thereafter. Pre/perimenopausal women treated with the combination of Verzenio plus fulvestrant should be treated with a gonadotropin-releasing hormone agonistaccording to current clinical practice standards.

When used as monotherapy, the recommended dose of Verzenio is 200 mg taken orally twice daily.

When given with VERZENIO, refer to the Full Prescribing Information for the recommended dose of the aromatase inhibitor being used.

Continue treatment until disease progression or unacceptable toxicity. Verzenio may be taken with or without food. Instruct patients to take their doses of Verzenio at approximately the same times every day. If the patient vomits after taking the dose, or misses a dose, no additional dose should be taken that day. The next prescribed dose should be taken at the usual time. Verzenio tablets should be swallowed whole (tablets should not be chewed, crushed or split prior to swallowing). No tablet should be ingested if it is broken, cracked, or otherwise not intact.

The recommended Verzenio dose modifications for adverse reactions are provided in the table below.

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ABEMACICLIB

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Dose Level	Verzenio Dose in Combination with Fulvestrant or an Aromatase Inhibitor	Verzenio Dose for Monotherapy
Recommended starting dose	150 mg twice daily	200 mg twice daily
First dose reduction	100 mg twice daily	150 mg twice daily
Second dose reduction	50 mg twice daily	100 mg twice daily
Third dose reduction	Not applicable	50 mg twice daily*

*If further dose reduction below 50 mg twice daily is required, discontinue the treatment.

Avoid concomitant use of the strong CYP3A inhibitor ketoconazole.

AVAILABLE STRENGTHS
Tablets: 50 mg, 100 mg, 150 mg, and 200 mg

REFERENCES

- Verzenio [Prescribing Information]. Indianapolis, IN. Eli Lilly and Company; February 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/18
Created: 10/17
Client Approval: 03/16
P&T Approval: 04/18