Medimpact

STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

ABEMACICLIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ABEMACICLIB	VERZENIO	44537		GPI-10	
				(2153101000)	

GUIDELINES FOR USE

- 1. Does the patient have a diagnosis of early breast cancer and meet ALL of the following criteria?
 - The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive
 - Verzenio will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor such as anastrozole, letrozole, exemestane) for adjuvant treatment
 - The patient is at high risk of recurrence

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.** If no, continue to #2.

- 2. Does the patient have advanced or metastatic breast cancer and meet ALL of the following criteria?
 - The patient's cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative

If yes, continue to #3. If no, do not approve. **DENIAL TEXT:** See the denial text at the end of the guideline.

- 3. Will Verzenio be used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) **AND** the patient meets the following criterion?
 - Verzenio will be used as initial endocrine-based therapy

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.** If no, continue to #4.

- 4. Will Verzenio be used in combination with fulvestrant AND the patient meets the following criterion?
 - The patient has experienced disease progression following endocrine therapy (e.g., anastrozole, letrozole, tamoxifen)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.** If no, continue to #5.

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GUIDELINES FOR USE (CONTINUED)

- 5. Will Verzenio be used as monotherapy **AND** the patient meets the following criterion?
 - The patient has experienced disease progression following endocrine therapy (e.g., anastrozole, letrozole, tamoxifen) and prior chemotherapy in the metastatic setting

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.** If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ABEMACICLIB** (Verzenio) requires the following rules be met for approval:

- A. You have ONE of the following diagnoses:
 - 1. Early breast cancer (initial stage of breast cancer)
 - 2. Advanced or metastatic breast cancer (cancer that has progressed or has spread to other parts of the body)
- B. If you have early breast cancer, approval also requires:
 - 1. Your cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive (a type of protein)
 - 2. Verzenio will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor such as letrozole, anastrozole, exemestane) for adjuvant (add-on) treatment
 - 3. You are at high risk of recurrence (disease returning)
- C. If you have advanced or metastatic breast cancer, approval also requires:
 - 1. Your cancer is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (a type of protein)
 - 2. You meet ONE of the following:
 - a. Verzenio will be used in combination with an aromatase inhibitor (such as letrozole, anastrozole, exemestane) as initial endocrine-based therapy
 - b. Verzenio will be used in combination with fulvestrant, and you have had disease progression following endocrine therapy (such as letrozole, anastrozole, tamoxifen)
 - c. Verzenio will be used as monotherapy (one drug), and you have had disease progression following endocrine therapy (such as letrozole, anastrozole, tamoxifen) and prior chemotherapy (drugs used to treat cancer) in the metastatic setting (cancer that has spread to other parts of the body)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Verzenio.

REFERENCES

• Verzenio [Prescribing Information]. Indianapolis, IN. Eli Lilly and Company; March 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A Commercial Effective: 07/01/23 Created: 10/17 Client Approval: 05/23

P&T Approval: 04/23

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