STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

VEMURAFENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
VEMURAFENIB	ZELBORAF	37837		GPI-10 (2153208000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?
   - The patient has a genetic mutation called BRAF V600E as detected by an FDA-approved test
   - Zelboraf will be used alone or in combination with Cotellic (cobimetinib)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Erdheim-Chester Disease **AND** meet the following criterion?
   - The patient has a genetic mutation called BRAF V600

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 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 **VEMURAFENIB (Zelboraf)** requires the following rules be met for approval:
   A. You have ONE of the following diagnoses:
      1. Unresectable or metastatic melanoma (a type of skin cancer that cannot be removed with surgery or has spread to other parts of the body)
      2. Erdheim-Chester Disease (a type of multisystem mutation)
   B. **If you have unresectable or metastatic melanoma, approval also requires:**
      1. You have a BRAF V600E mutation (a type of gene mutation) as detected by a Food and Drug Administration (FDA)-approved test
      2. Zelboraf will be used alone or in combination with Cotellic (cobimetinib)
   C. **If you have Erdheim-Chester Disease, approval also requires:**
      1. You have a BRAF V600 mutation (a type of gene mutation)

   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 Zelboraf.

REFERENCES

- Zelboraf [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/22
Created: 08/11
Client Approval: 05/22
P&T Approval: 04/22