STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

COBIMETINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
COBIMETINIB FUMARATE	COTELLIC	42796		GPI-10 (2153353020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of unresectable or metastatic melanoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient's tumor has a BRAF V600E OR V600K mutation
   - Cobimetinib will be used in combination with vemurafenib (Zelboraf)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #63 per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of histiocytic neoplasms and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Cobimetinib will be used as a single agent

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #63 per 28 days.**
   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 **COBIMETINIB (Cotellic)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Unresectable or metastatic melanoma (skin cancer that has spread or cannot be completely removed with surgery)
      2. Hystiocytic neoplasms (a type of white blood cell disorder)
   B. **If you have unresectable or metastatic melanoma, approval also requires:**
      1. You are 18 years of age or older
      2. Your tumor has a BRAF V600E OR V600K mutation (a type of gene mutation)
      3. Cobimetinib will be used in combination with vemurafenib (Zelboraf)
   C. **If you have histiocytic neoplasms, approval also requires:**
      1. You are 18 years of age or older
      2. Cobimetinib will be used as a single agent

   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 Cotellic.

REFERENCES

- Cotellic [Prescribing Information]; San Francisco, CA: Genentech USA, Inc.; October 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 11/21/22
Created: 11/15
Client Approval: 11/22
P&T Approval: 01/23