BOSUTINIB

Generic	Brand	HICL	GCN	Exception/Other
BOSUTINIB	BOSULIF	39590		

GUIDELINES FOR USE

1. Does the patient have a newly diagnosed, chronic phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by GPID with the following quantity limits:**
   - **Bosulif 500mg (GPID 33202): #1 tablet per day.**
   - **Bosulif 400mg (GPID 44162): #1 tablet per day.**
   - **Bosulif 100mg (GPID 33199): #3 tablets per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient previously tried or has a contraindication to other tyrosine kinase inhibitors [e.g., Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib)]
   - The patient had a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that the following mutations are **NOT** present: T315I, V299L, G250E, or F317L

   If yes, **approve for 12 months by GPID with the following quantity limits:**
   - **Bosulif 500mg (GPID 33202): #1 tablet per day.**
   - **Bosulif 400mg (GPID 44162): #1 tablet per day.**
   - **Bosulif 100mg (GPID 33199): #3 tablets per day.**

   If no, do not approve.
   DENIAL TEXT: The guideline named **BOSUTINIB (Bosulif)** requires that the requested medication is used for newly diagnosed, chronic phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) or for chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML). In addition, the patient must be 18 years of age or older. The following must also be met:
   For the diagnosis of chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML), approval requires:
   - The patient previously tried or has a contraindication to other tyrosine kinase inhibitors [e.g., Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib)]
   - The patient had a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that the following mutations are NOT present: T315I, V299L, G250E, or F317L

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RATIONALE

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

REFERENCES

- Bosulif [Prescribing Information]. New York, NY: Pfizer; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/20
Created: 09/12
Client Approval: 11/19
P&T Approval: 10/19