



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BOSUTINIB

| Generic | Brand | HICL | GCN | Medi-Span | Exception/Other |
|-----------|---------|-------|-----|---------------------|-----------------|
| BOSUTINIB | BOSULIF | 39590 | | GPI-10 (2153181200) | |

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 or GPI-14 with the following quantity limits:**

- **Bosulif 500mg: #1 per day.**
- **Bosulif 400mg: #1 per day.**
- **Bosulif 100mg: #3 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), Tassigna (nilotinib)]
- The patient had a mutational analysis prior to initiation **AND** Bosulif is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

If yes, **approve for 12 months by GPID or GPI-14 with the following quantity limits:**

- **Bosulif 500mg: #1 per day.**
- **Bosulif 400mg: #1 per day.**
- **Bosulif 100mg: #3 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 **BOSUTINIB (Bosulif)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:

1. Newly diagnosed, chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML; a type of blood cancer)
2. Chronic, accelerated, or blast phase Philadelphia chromosome-positive chronic myelogenous leukemia

B. You are 18 years of age or older

(Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

C. If you have chronic, accelerated, or blast phase Philadelphia chromosome-positive, approval also requires:

1. You have previously tried or have a contraindication to (a medical reason why you cannot use) other tyrosine kinase inhibitors such as Gleevec (imatinib), Sprycel (dasatinib), Tassigna (nilotinib)
2. You had a mutational analysis prior to initiation of therapy AND Bosulif is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1; a type of abnormal gene) profile

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.

RATIONALE

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

REFERENCES

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

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| Library | Commercial | NSA |
| Yes | Yes | No |

Part D Effective: N/A

Commercial Effective: 04/01/22

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P&T Approval: 01/22