DASATINIB

Generic	Brand	HICL	GCN	Exception/Other
DASATINIB	SPRYCEL	33855		

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase and meet **ONE** of the following criteria?
   - The patient is 18 years of age or older **AND** is newly diagnosed
   - The patient is between 1 and 17 years of age

   If yes, **approve for all strengths for 12 months by GPID as follows:**
   - **SPRYCEL 20MG (GPID 27257) for a quantity limit of #3 tablets per day.**
   - **SPRYCEL 50MG (GPID 27258) for a quantity limit of #1 tablet per day.**
   - **SPRYCEL 70MG (GPID 27259) for a quantity limit of #1 tablet per day.**
   - **SPRYCEL 80MG (GPID 29405) for a quantity limit of #1 tablet per day.**
   - **SPRYCEL 100MG (GPID 99867) for a quantity limit of #1 tablet per day.**
   - **SPRYCEL 140MG (GPID 29406) for a quantity limit #1 tablet per day.**

   If no, continue to #2.

2. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is in chronic, accelerated, or myeloid or lymphoid blast phase
   - The patient has a resistance or intolerance to prior therapy including imatinib (Gleevec)
   - The patient has had Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that the patient is negative for the following mutations: T315I, V299L, T315A, or F317L/V/I/C

   If yes, **approve for all strengths for 12 months by GPID as follows:**
   - **SPRYCEL 20MG (GPID 27257) for a quantity limit of #3 tablets per day.**
   - **SPRYCEL 50MG (GPID 27258) for a quantity limit of #1 tablet per day.**
   - **SPRYCEL 70MG (GPID 27259) for a quantity limit of #1 tablet per day.**
   - **SPRYCEL 80MG (GPID 29405) for a quantity limit of #1 tablet per day.**
   - **SPRYCEL 100MG (GPID 99867) for a quantity limit of #1 tablet per day.**
   - **SPRYCEL 140MG (GPID 29406) for a quantity limit #1 tablet per day.**

   If no, continue to #3.

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GUIDELINES FOR USE (CONTINUED)

3. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a resistance or intolerance to prior therapy (e.g., imatinib (Gleevec), or nilotinib (Tasigna))

   If yes, **approve for all strengths for 12 months by GPID as follows:**
   - **SPRYCEL 20MG (GPID 27257) for a quantity limit of #3 tablets per day.**
   - **SPRYCEL 50MG (GPID 27258) for a quantity limit of #1 tablet per day.**
   - **SPRYCEL 70MG (GPID 27259) for a quantity limit of #1 tablet per day.**
   - **SPRYCEL 80MG (GPID 29405) for a quantity limit of #1 tablet per day.**
   - **SPRYCEL 100MG (GPID 99867) for a quantity limit of #1 tablet per day.**
   - **SPRYCEL 140MG (GPID 29406) for a quantity limit #1 tablet per day.**

   If no, continue to #4.

4. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) and meet **ALL** of the following criteria?
   - The patient is between 1 and 17 years of age
   - The patient is newly diagnosed
   - The patient is using Sprycel in combination with chemotherapy

   If yes, **approve for all strengths for 12 months by GPID as follows:**
   - **SPRYCEL 20MG (GPID 27257) for a quantity limit of #3 tablets per day.**
   - **SPRYCEL 50MG (GPID 27258) for a quantity limit of #1 tablet per day.**
   - **SPRYCEL 70MG (GPID 27259) for a quantity limit of #1 tablet per day.**
   - **SPRYCEL 80MG (GPID 29405) for a quantity limit of #1 tablet per day.**
   - **SPRYCEL 100MG (GPID 99867) for a quantity limit of #1 tablet per day.**
   - **SPRYCEL 140MG (GPID 29406) for a quantity limit #1 tablet per day.**

   If no, do not approve.
   DENIAL TEXT: The guideline named **DASATINIB (Sprycel)** requires a diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic, accelerated, or myeloid or lymphoid blast phase, OR Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL). In addition, the following criteria must be met:
   For the diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, approval requires ONE of the following:
   - The patient is 18 years of age or older AND is newly diagnosed
   - The patient is between 1 and 17 years of age

   (Denial text continued on the next page)

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DASATINIB

GUIDELINES FOR USE (CONTINUED)

For the diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, accelerated phase, or myeloid or lymphoid blast phase, approval requires:

- The patient is 18 years of age or older
- The patient has a resistance or intolerance to prior therapy including imatinib (Gleevec)
- The patient has had Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that the patient is negative for the following mutations: T315I, V299L, T315A, or F317L/V/I/C

For the diagnosis of Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL), approval requires ONE of the following:

- The patient is 18 years of age or older AND has a resistance or intolerance to prior therapy (e.g., imatinib (Gleevec) or nilotinib (Tasigna))
- The patient is newly diagnosed, is between 1 and 17 years of age, AND is using Sprycel in combination with chemotherapy

RATIONALE

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

REFERENCES

- Sprycel [Prescribing information]. Bristol-Myers Squibb. Princeton, NJ. December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/01/19
Created: 05/12
Client Approval: 01/19
P&T Approval: 01/19