STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DASATINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DASATINIB	SPRYCEL	33855		GPI-10 (2153182000)	

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 or GPI-14 as follows:**
   - **SPRYCEL 20MG with a quantity limit of #3 per day.**
   - **SPRYCEL 50MG with a quantity limit of #1 per day.**
   - **SPRYCEL 70MG with a quantity limit of #1 per day.**
   - **SPRYCEL 80MG with a quantity limit of #1 per day.**
   - **SPRYCEL 100MG with a quantity limit of #1 per day.**
   - **SPRYCEL 140MG with a quantity limit #1 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 had a mutational analysis prior to initiation AND Sprycel 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 all strengths for 12 months by GPID or GPI-14 as follows:**
   - **SPRYCEL 20MG with a quantity limit of #3 per day.**
   - **SPRYCEL 50MG with a quantity limit of #1 per day.**
   - **SPRYCEL 70MG with a quantity limit of #1 per day.**
   - **SPRYCEL 80MG with a quantity limit of #1 per day.**
   - **SPRYCEL 100MG with a quantity limit of #1 per day.**
   - **SPRYCEL 140MG with a quantity limit #1 per day.**

   If no, continue to #3.

CONTINUED ON NEXT PAGE

DASATINIB

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 or GPI-14 as follows:**
   - **SPRYCEL 20MG with a quantity limit of #3 per day.**
   - **SPRYCEL 50MG with a quantity limit of #1 per day.**
   - **SPRYCEL 70MG with a quantity limit of #1 per day.**
   - **SPRYCEL 80MG with a quantity limit of #1 per day.**
   - **SPRYCEL 100MG with a quantity limit of #1 per day.**
   - **SPRYCEL 140MG with a quantity limit #1 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 or GPI-14 as follows:**
   - **SPRYCEL 20MG with a quantity limit of #3 per day.**
   - **SPRYCEL 50MG with a quantity limit of #1 per day.**
   - **SPRYCEL 70MG with a quantity limit of #1 per day.**
   - **SPRYCEL 80MG with a quantity limit of #1 per day.**
   - **SPRYCEL 100MG with a quantity limit of #1 per day.**
   - **SPRYCEL 140MG with a quantity limit #1 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 **DASATINIB (Sprycel)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML: a type of blood cancer) in chronic, accelerated, or myeloid or lymphoid blast phase
      2. Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL: a type of blood cancer)

(Denial text continued on the next page)
CONTINUED ON NEXT PAGE

DASATINIB

GUIDELINES FOR USE (CONTINUED)

B. **If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, approval also requires ONE of the following:**
   1. You are 18 years of age or older AND are newly diagnosed
   2. You are between 1 and 17 years of age

C. **If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, accelerated phase, or myeloid or lymphoid blast phase, approval also requires:**
   1. You are 18 years of age or older
   2. You have resistance or intolerance (side effect) to prior therapy including imatinib (Gleevec)
   3. You had a mutational analysis prior to initiation of therapy AND Sprycel 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

D. **If you have Philadelphia chromosome-positive acute lymphoblastic leukemia, approval also requires ONE of the following:**
   1. You are 18 years of age or older AND you have a resistance or intolerance (side effect) to prior therapy such as imatinib (Gleevec) or nilotinib (Tasigna)
   2. You are newly diagnosed, between 1 and 17 years of age, AND using Sprycel in combination with chemotherapy

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 Sprycel.

REFERENCES

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

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
Created: 05/12
Client Approval: 02/22
P&T Approval: 01/22