CVS/caremark

PRIOR AUTHORIZATION CRITERIA

BRAND NAME	**SPRYCEL**
(generic)	**(dasatinib)**
Status: CVS Caremark Criteria	***MDC***
Type: Initial Prior Authorization	***Ref # 422-A***

FDA-APPROVED INDICATIONS[1]

Sprycel is indicated for the treatment of adults with:

- newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase.
- chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib.
- Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy.

COMPENDIAL USES[2,3]

- Treatment of patients with advanced phase CML (accelerated phase or blast phase)
- Follow-up therapy for CML patients after hematopoietic stem cell transplant (HSCT)
- Follow-up therapy for CML patients resistant or intolerant to primary treatment with alternative tyrosine kinase inhibitor(s) (TKIs)
- Ph+ acute lymphoblastic leukemia (ALL)
- Gastrointestinal stromal tumor (GIST) in patients with PDGFRA D842V mutation and disease progression on imatinib, sunitinib, or regorafenib

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of chronic myeloid leukemia (CML)? [If no, skip to question 9.]	Yes	No
2	Was the diagnosis confirmed by detection of the Philadelphia chromosome or BCR-ABL gene? [If no, no further questions.]	Yes	No
3	Does the patient have ANY of the following: 1) Accelerated phase (AP) or blast phase (BP) CML; OR 2) Chronic phase (CP)-CML AND age less than or equal to 21 years, OR 3) CP- CML with high or intermediate risk for disease progression; OR 4) patient has received a hematopoietic stem cell transplant? [If yes, no further questions.]	Yes	No
4	Does the patient have CP-CML with low risk for disease progression? [If no, no further questions.]	Yes	No
5	Has the patient experienced intolerance or toxicity to imatinib or an alternative tyrosine kinase inhibitor? [If yes, no further questions.]	Yes	No
6	Has the patient experienced resistance to imatinib? [If yes, skip to question 8.]	Yes	No
7	Has the patient experienced resistance to an alternative tyrosine kinase inhibitor? [If no, no further questions.]	Yes	No
8	Is the patient negative for the T315I mutation? [No further questions.]	Yes	No

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9	Does the patient have a diagnosis of Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)? [If no, skip to question 11.]	Yes	No
10	Was the diagnosis confirmed by detection of the Philadelphia chromosome or BCR-ABL gene? [No further questions.]	Yes	No
11	Does the patient have a diagnosis of gastrointestinal stromal tumor (GIST)? [If no, no further questions.]	Yes	No
12	Does the patient have the PDGFRA D842V mutation? [If no, no further questions.]	Yes	No
13	Did the patient have disease progression on imatinib, sunitinib, or regorafenib?	Yes	No

Guidelines for Approval							
Duration of Approval				**12 Months**			
Set 1: AP or BP-CML, CP-CML and ≤ 21 yrs., CP-CML with high or intermediate risk, or post-HSCT		**Set 2:** CP-CML, toxicity or intolerance to TKI		**Set 3:** CP-CML, resistance to imatinib		**Set 4:** CP-CML, resistance to alternative TKI	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**	**Yes to question(s)**	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
1	None	1	3	1	3	1	3
2		2		2	5	2	5
3		4		4		4	6
		5		6		7	
				8		8	
Set 5: ALL		**Set 6:** GIST					
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**				
9	1	11	1				
10		12	9				
		13					

Mapping Instructions		
	Yes	**No**
1	Go to 2	Go to 9
2	Go to 3	Deny
3	Approve, 12 months	Go to 4
4	Go to 5	Deny
5	Approve, 12 months	Go to 6
6	Go to 8	Go to 7
7	Go to 8	Deny
8	Approve, 12 months	Deny
9	Go to 10	Go to 11
10	Approve, 12 months	Deny
11	Go to 12	Deny
12	Go to 13	Deny
13	Approve, 12 months	Deny

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare-approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization. [Proceed with indication and rationale to explain the criteria for approval]

REFERENCES

1. Sprycel [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; November 2017.
2. The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 6, 2017
3. The NCCN Clinical Practice Guidelines in Oncology® Chronic Myelogenous Leukemia (Version 2.2017). © 2076 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 5, 2017.
4. The NCCN Clinical Practice Guidelines in Oncology® Acute Lymphoblastic Leukemia (Version 2.2016). © 2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 3, 2017.

DOCUMENT HISTORY

Written:	UM Development (MG) 07/2006
Revised:	Specialty Clinical Development (AK) 05/2007; HN 12/2007; AK 02/2008; AC 02/2009, 06/2009 (MDC-2 created); KR 06/2010, 11/2010 (new indication), KH 05/2011, LD 09/2012 (CMS), LD 05/2013, HY 09/2013 (CMS), IP 03/2014, 08/2015 (CMS, imatinib ST), DK 07/2016 (CMS), PK 05/2017 (NCCN update), PK 07/2017 (CMS), 11/2017 (label update for pediatric CP-CML)
Reviewed:	CDPR/MM 07/2006; WLF 05/2007, 12/2007, 02/2008, 03/2009, 06/2009; KP 06/2010, 07/2010, 05/2011, DR 05/2012; 05/2013, DNC 03/2014, 02/2015, 04/2015, LCB 04/2016, ME 03/2017, AN 11/2017
External Review:	08/2007, 04/2008, 07/2009, 08/2010, 07/2011, 09/2012, 07/2013, 07/2014, 03/2015, 06/2015, 06/2016, 03/2017, 03/2017