Clinical Policy Title:	dasatinib
Policy Number:	RxA.470
Drug(s) Applied:	Sprycel®
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Chronic Myeloid Leukemia and Acute Lymphoblastic Leukemia (must meet all)**:**

1. Diagnosis of Ph+ (BCR-ABL1-positive) CML or Ph+ (BCR-ABL1-positive) ALL;
2. Prescribed by or in consultation with an oncologist or a hematologist;
3. Age ≥ 1 year;
4. Member does not have the following mutations: T315I/A, F317L/V/I/C or V299L;
5. Request meets one of the following (a, b, or c):*
   a. Pediatrics, age < 18 years: Dose does not exceed the weight-based dosing mentioned in Dosing Information section;
   b. Adults, age ≥ 18 years: Dose does not exceed 180 mg per day;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration
Commercial: 12 months
Medicaid: 6 months

B. Gastrointestinal Stromal Tumor (off-label) (must meet all)**:**

1. Diagnosis of unresectable, recurrent, progressive or metastatic gastrointestinal stromal tumor (GIST; a soft tissue sarcoma);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Trial and failure of single agent therapy with imatinib (Gleevec®) or Ayvakit™, unless contraindicated or clinically significant adverse effects are experienced;
   *Prior authorization may be required for imatinib and Ayvakit™.
5. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence)

   *Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration
Commercial: 12 months
Medicaid: 6 months

C. Bone Cancer (off-label) (must meet all)**:**

1. Diagnosis of metastatic chondrosarcoma or recurrent chordoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 13 years;
4. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration
Commercial: 12 months
Medicaid: 6 months

D. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes (off-label) (must meet all):

1. Diagnosis of Myeloid/Lymphoid Neoplasms with eosinophilia and tyrosine kinase gene fusions;
2. Prescribed by or in consultation with an oncologist or a hematologist;
3. Age ≥ 18 years;
4. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).*
   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration
Commercial: 12 months
Medicaid: 6 months

E. Melanoma (off-label) (must meet all):

1. Diagnosis of unresectable or metastatic melanoma tumors with activating mutations of KIT;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is BRAF mutation positive;
5. Used as a single agent for second line or subsequent therapy;
6. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).*
   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration
Commercial: 12 months
Medicaid: 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy; or documentation supports that member is currently receiving Sprycel® for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a, b, or c):*
   a. Adults: Age 18 years age or older, bone cancer, GIST or Melanoma: New dose does not exceed 180 mg per day;
   b. Pediatrics: Age < 18 years for CML or ALL: New dose does not exceed weight: based dosing mentioned in Dosing Information section;

c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration
Commercial: 12 months
Medicaid: 6 months

References

1. National Comprehensive Cancer Network. Chronic Myeloid Leukemia Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf. Accessed April 27, 2023.
2. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed April 27, 2023.
3. National Comprehensive Cancer Network. Bone Cancer Version 3.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf. Accessed April 27, 2023.
4. Schuetze SM, Bolejack V, Choy E, et al. Phase 2 study of dasatinib in patients with alveolar soft part sarcoma, chondrosarcome, chordoma, epithelioid sarcoma, or solitary fibrous tumor. Cancer 2017;123(1): 90:97. doi: 10.1002/cncr.30379. Epub 2016 Oct 3. Available at: https://pubmed.ncbi.nlm.nih.gov/27696380/. Accessed April 27, 2023.
5. National Comprehensive Cancer Network. Pediatric Acute Lymphoblastic Leukemia Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed April 27, 2023.
6. National Comprehensive Cancer Network. Gastrointestinal Stromal Tumors Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/gist.pdf. Accessed April 27, 2023.
7. National Comprehensive Cancer Network. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes, Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf. Accessed April 27, 2023.
8. National Comprehensive Cancer Network. Melanoma: Cutaneous Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed April 27, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical policy title updated. 2. Line of Business Policy Applies to was updated to “All lines of business”. 3. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance”. 4. Commercial approval duration was updated for initial and continued therapy criteria and HIM deleted. 5. References were reviewed and updated. 6. Adjusted language for initial therapy criteria for GIST per NCCN recommendation.	10/14/2020	12/07/2020
Policy was reviewed:	8/29/2021	9/14/2021

1. Initial Approval Criteria I.B.4 was updated to include " Request would be used as a single agent for unresectable, recurrent...". 2. Initial Approval Criteria I.B.4.a was updated to include new criteria " Patient is with generalized (widespread, systemic) disease with progression on imatinib has….". 3. Initial Approval Criteria I.B.4.b was updated to include new criteria "Patient has documented failure of response/progression on approved therapies ….". 4. Initial Approval Criteria I.C.4 was updated to include " Request will be used as a single-agent therapy for the treatment of (a or b)...". 5. Initial Approval Criteria I.C.4.a was updated to include new criteria " Metastatic and widespread disease for patients with (i or ii)….". 6. Initial Approval Criteria I.C.4.b was updated to include new criteria "Recurrent conventional or chondroid chordoma ….". 7. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance…". 8. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria for off-label indication Myeloid/Lymphoid Neoplasms with Eosinophilia added. 2. I.A.C: Updated age to ≥ 18 years. 3. References were reviewed and updated.	03/30/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.4: Updated to include new diagnostic criteria Member does not have the following mutations: T315I/A, F317L/V/I/C or V299L. 2. Initial Approval Criteria, I.B.1: Updated diagnostic criteria from Diagnosis of unresectable or metastatic gastrointestinal stromal tumor (GIST; a soft tissue sarcoma) to Diagnosis of unresectable, recurrent, progressive or metastatic gastrointestinal stromal tumor (GIST; a soft tissue sarcoma). 3. Initial Approval Criteria I.B.4: Updated to remove disease progression and documentation criteria to use as single agent	04/27/2023	07/13/2023

"Request would be used as a single agent for unresectable, recurrent, or metastatic disease and meets one of the following (a or b): a. Patient is with generalized (widespread, systemic) disease with progression on imatinib has PDGFRA D842V mutation and performance status 0-2; b. Patient has documented failure of response/progression on approved therapies (useful in certain circumstances for patients with PDGFRA D842V mutation);" 4. Initial Approval Criteria I.B.4: Updated trial and failure criteria from Failure of single agent therapy with imatinib (Gleevec®), Sutent® and Stivarga®, unless contraindicated or clinically significant adverse effects are experienced; *Prior authorization may be required for imatinib, Sutent®, and Stivarga® to Trial and failure of single agent therapy with imatinib (Gleevec®) or Ayvakit™, unless contraindicated or clinically significant adverse effects are experienced; *Prior authorization may be required for imatinib and Ayvakit™. 5. Initial Approval Criteria, I.C.3: Updated age criteria from Age ≥ 18 years to Age ≥ 13 years. 6. Initial Approval Criteria I.C.4: Updated to remove criteria to use as single agent "Request will be used as a single-agent therapy for the treatment of (a or b): a. Metastatic and widespread disease for patients with (i or ii): i. Metastatic disease at presentation; ii. Systemic recurrence of high grade (grade II or III), clear cell, or extra compartmental chondrosarcoma; b. Recurrent conventional or chondroid chordoma". 7. Initial Approval Criteria, I.D: Updated indication from Myeloid/Lymphoid Neoplasms with Eosinophilia (off-label) to Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes (off-label). 8. Initial Approval Criteria, I.D.1: Diagnosis criteria updated from "Diagnosis of myeloid/lymphoid neoplasms with eosinophilia and ABL1 rearrangement in chronic phase" to "Diagnosis		

of Myeloid/Lymphoid Neoplasms with eosinophilia and tyrosine kinase gene fusions.”. 9. Initial Approval Criteria I.A, I.B, I.C and I.D: Updated Approval duration from 6 to 12 months for Commercial. 10. Initial Approval Criteria, I.E: Updated to include approval criteria for indication, Melanoma (off-label). 11. Continued Approval Criteria, II.A.3.a: Updated dosing criteria from Adults: Age 18 years age or older, bone cancer, or GIST: New dose does not exceed 180 mg per day to Adults: Age 18 years age or older, bone cancer, or GIST or Melanoma: New dose does not exceed 180 mg per day. 12. Continued Therapy Approval Criteria II.A: Updated Approval duration from 6 to 12 months for Commercial. 13. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023