Sprycel® (dasatinib)
(Oral)

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I. Length of Authorization

Coverage is provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- 20 mg tablet: 2 tablets per day
- 50 mg tablet: 2 tablets per day
- 70 mg tablet: 2 tablets per day
- 80 mg tablet: 1 tablet per day
- 100 mg tablet: 2 tablets per day
- 140 mg tablet: 1 tablet per day

B. Max Units (per dose and over time) [Medical Benefit]:

Chronic Phase CML

- 100 mg per day

Other indications:

- 200 mg per day

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is 18 years or older (*unless otherwise specified*); **AND**

Chronic myelogenous leukemia (CML) †

- Patient's disease is confirmed by either a Philadelphia chromosome-positive (Ph+) or *BCR-ABL1* positive laboratory test result; **AND**
- Chronic phase disease in patients aged 1 years or older †; **OR**
- Chronic or accelerated or blast phase disease †; **AND**

- Patient is resistant, or intolerant, or had an inadequate response to prior tyrosine kinase inhibitor (TKI) therapies, consisting of a 3 month trial or longer, with any of the following: omacetaxine, imatinib, bosutinib, ponatinib, nilotinib, etc. ; **OR**

- Primary Treatment †
  - Used as single agent for newly diagnosed disease in chronic phase†; **OR**
  - Used as single agent for myeloid blast phase or accelerated phase disease; **OR**
  - In combination with steroids for lymphoid blast phase disease; **OR**
  - In combination with induction chemotherapy for lymphoid or myeloid blast phase disease; **OR**
- Switch Therapy ‡
  - Initial therapy was one of the following: imatinib, bosutinib or nilotinib; **AND**
  - Patient has *BCR-ABL1* transcript levels:
    - > 1% to 10% at 12 or >15 months
    - > 10% at any response milestone; **OR**
- Continued Therapy ‡
  - Patient has *BCR-ABL1* transcript levels:
    - ≤ 0.1% at any response milestone
    - > 1% to 10% at 3, 6, or 12 months
    - > 10% at 3 months; **OR**
- Post-allogeneic hematopoietic stem cell transplant (HCT) ‡
  - Used in patients with a complete cytogenetic response (CCyR) for accelerated or blast phase disease; **OR**
  - Used in patients with molecular relapse (BCR-ABL1 transcript positive) following CCyR; **OR**
  - Used in patients with relapse or those who are not in CCyR; **OR**
- Used in disease with any of the following BRC-ABL KD mutations: Y253H, E255K/V, or F359V/C/I ‡

Acute Lymphoblastic Leukemia (ALL) †

- Patients disease is Philadelphia chromosome-positive (Ph+); **AND**
- Newly diagnosed disease in patients age 1 year and older in combination with chemotherapy †; **OR**
- Relapsed-Refractory Treatment
  - Patient is resistant, or intolerant, or had an inadequate response to prior tyrosine kinase inhibitor (TKI) therapies, consisting of a 3 month trial or longer, with any of the following: omacetaxine, imatinib, bosutinib, ponatinib, nilotinib, etc.; **OR**
  - Used as a single agent therapy; **OR**
  - Used in combination with an induction therapy not previously used; **OR**
  - Used in patients with any of the following BCR-ABL1 mutations: Y253H or E255K/V or F359V/C/I; **OR**
  - Used in pediatric patients (age is 18 years or younger); **AND**

- Used in combination with a cytotoxic chemotherapy regimen for B-cell ALL; **OR**
- Used as part of a TKI-based regimen for T-cell ALL with ABL-class translocations; **OR**

- Induction Treatment
  - Patient is aged at least 15 years old; **AND**
    - Used as part of a cytotoxic chemotherapy regimen for induction-consolidation; **OR**
    - Used alone or in combination with corticosteroids; **OR**
  - Patient is a pediatric (age is 18 years or younger); **AND**
    - Used as part of a cytotoxic chemotherapy regimen for B-cell ALL induction-consolidation; **OR**
- Maintenance Treatment
  - Used in combination with vincristine and prednisone; **OR**
  - Used in patients who are post-hematopoietic stem cell transplant

Gastrointestinal stromal tumors (GIST) ‡

- Patient's disease is progressive after prior therapies, consisting of a 3 month trial or longer, with at least ONE of the following: imatinib, regorafenib or sunitinib; **AND**
- Patient's BCR-ABL KD mutational analysis contains the PDGFRA D842V mutation

Bone Cancer (Chondrosarcoma and Chordoma) ‡

- Used as single agent; **AND**
  - Patient has Chondrosarcoma and widespread metastatic disease: **OR**
  - Patient has Chordoma and recurrent disease

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s)

IV. Renewal Criteria

- Patient continues to meet criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: pulmonary arterial hypertension, severe myelosuppression (neutropenia, anemia, thrombocytopenia), fluid retention, cardiovascular events (ischemia, conduction system abnormalities, arrhythmia/palpitations), cardiac dysfunction, QT prolongation, severe dermatologic reactions, tumor lysis syndrome, etc.; **AND**
- Patient has been adherent to therapy; **AND**

Acute lymphoblastic leukemia (ALL) only:

- Treatment response or stabilization of disease as indicated by CBC, bone marrow cytogenic analysis, QPCR, or FISH

Chronic Myelogenous Leukemia (CML) only:

- Treatment response as indicated by one of the following BCR-ABL1 transcript levels:
  - ≤ 10% at 3 months; **OR**
  - ≤ 10% at 6 months; **OR**
  - < 1% at 12 months; **OR**

- < 0.1% beyond 12 months

NOTE: cytogenetic assessment of response may be used if quantitative RT-PCR (QPCR) using International Scale (IS) for *BCR-ABL1* is not available

Gastrointestinal stromal tumors (GIST) only:

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

Bone Cancer (Chondrosarcoma and Chordoma) only:

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

V. Dosage/Administration

Indication	Dose
Accelerated, or myeloid or lymphoid blast phase CML	140 mg by mouth once daily
Chronic phase CML	Adult 100 mg by mouth once daily Pediatric ➢ 10 – <20 kg : 40 mg once daily ➢ 20 – <30 kg : 60 mg once daily ➢ 30 – <45 kg : 70 mg once daily ➢ ≥ 45 kg : 100 mg once daily
Philadelphia chromosome-positive (Ph+) acute lymphocytic leukemia (ALL)	Adult 140 mg by mouth once daily Pediatric ➢ 10 – <20 kg : 40 mg once daily ➢ 20 – <30 kg : 60 mg once daily ➢ 30 – <45 kg : 70 mg once daily ➢ ≥ 45 kg : 100 mg once daily
Gastrointestinal stromal tumors (GIST)	70 mg twice daily
Bone Cancer (Chondrosarcoma and Chordoma)	50-100 mg by mouth twice daily

VI. Billing Code/Availability Information

Jcode:

- J8999: Prescription drug, oral, chemotherapeutic, NOS

NDC:

- 20 mg tablet – 00003-0527-xx
- 50 mg tablet – 00003-0528-xx
- 70 mg tablet – 00003-0524-xx
- 80 mg tablet – 00003-0855-xx
- 100 mg tablet – 00003-0852-xx
- 140 mg tablet – 00003-0857-xx

VII. References

1. Sprycel [package insert]. Princeton, NJ; Bristol-Myers Squibb; December 2018. Accessed June 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) dasatinib. National Comprehensive Cancer Network, 2019. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2019.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Acute Lymphoblastic Leukemia. 2.2019. National Comprehensive Cancer Network, 2019. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2019.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Chronic Myelogenous Leukemia 1.2019. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2019.
5. Lilly MB, Ottmann OG, Shah NP et al. Dasatinib 140 mg once daily versus 70 mg twice daily in patients with Ph-positive acute lymphoblastic leukemia who failed imatinib: Results from a phase 3 study. Am J Hematol 2010;85(3):164-170.
6. J. C. Trent, K. Wathen, M. von Mehren, et al. A Phase II study of dasatinib for patients with imatinib-resistant gastrointestinal stromal tumor (GIST). J Clin Oncol 2011; 29:Abstract 10006.
7. Schuetze SM. Bolejack V, Choy E, et al. Phase 2 study of dasatinib in patients with alveolar soft part sarcoma, chondrosarcoma, chordoma, epithelioid sarcoma, or solitary fibrous tumor. Cancer 2017 Jan 1: 123(1)L90-97.
8. Villalobos VM, Hoffner B, Elias AD. We can study ultrarare tumors effectively in this day and age, it just takes a cooperative approach: The role of dasatinib in assorted indolent sarcomas. Cancer 2017;123(1):20-24.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C40.00	Malignant neoplasm of scapula and long bones of unspecified upper limb
C40.01	Malignant neoplasm of scapula and long bones of right upper limb
C40.02	Malignant neoplasm of scapula and long bones of left upper limb
C40.10	Malignant neoplasm of short bones of unspecified upper limb

C40.11	Malignant neoplasm of short bones of right upper limb
C40.12	Malignant neoplasm of short bones of left upper limb
C40.20	Malignant neoplasm of long bones of unspecified lower limb
C40.21	Malignant neoplasm of long bones of right lower limb
C40.22	Malignant neoplasm of long bones of left lower limb
C40.30	Malignant neoplasm of short bones of unspecified lower limb
C40.31	Malignant neoplasm of short bones of right lower limb
C40.32	Malignant neoplasm of short bones of left lower limb
C40.80	Malignant neoplasm of overlapping sites of bone and articular cartilage of unspecified limb
C40.81	Malignant neoplasm of overlapping sites of bone and articular cartilage of right limb
C40.82	Malignant neoplasm of overlapping sites of bone and articular cartilage of left limb
C40.90	Malignant neoplasm of unspecified bones and articular cartilage of unspecified limb
C40.91	Malignant neoplasm of unspecified bones and articular cartilage of right limb
C40.92	Malignant neoplasm of unspecified bones and articular cartilage of left limb
C41.0	Malignant neoplasm of bones of skull and face
C41.1	Malignant neoplasm of mandible
C41.2	Malignant neoplasm of vertebral column
C41.3	Malignant neoplasm of ribs, sternum and clavicle
C41.4	Malignant neoplasm of pelvic bones, sacrum and coccyx
C41.9	Malignant neoplasm of pelvic bones, sacrum and coccyx
C49.A0	Gastrointestinal stromal tumor unspecified site
C49.A1	Gastrointestinal stromal tumor of esophagus
C49.A2	Gastrointestinal stromal tumor of stomach
C49.A3	Gastrointestinal stromal tumor of small intestine
C49.A4	Gastrointestinal stromal tumor of large intestine
C49.A5	Gastrointestinal stromal tumor of rectum
C49.A9	Gastrointestinal stromal tumor of other sites
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C72.0	Malignant neoplasm of spinal cord
C72.1	Malignant neoplasm of cauda equina
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse
C92.10	Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission
C92.11	Chronic myeloid leukemia, BCR/ABL-positive, in remission
C92.12	Chronic myeloid leukemia, BCR/ABL-positive, in relapse
Z85.830	Personal history of malignant neoplasm of bone
Z85.831	Personal history of malignant neoplasm of soft tissue

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC