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) [NDC Unit]:

- 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) [HCPCS Unit]:

Chronic Phase CML

- 100 mg per day

Bone Cancer

- 200 mg per day

Accelerated Phase CML, Myeloid or Lymphoid Blast Phase CML, Ph+ ALL, GIST, and Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes

- 140 mg per day

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age unless otherwise specified; AND

Universal Criteria [1]

- Patient will avoid concomitant use with strong CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; AND

- Patient will avoid concomitant use with strong CYP3A inhibitors (e.g., itraconazole, ketoconazole, clarithromycin, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
- Patient will avoid concomitant use with proton pump inhibitors and H2 receptor antagonists, or if therapy is required, consider the use of antacids instead; **AND**

Chronic Myelogenous Leukemia (CML) † Φ [1,2,4,13-17]

- Patient's disease is confirmed by either a Philadelphia chromosome-positive (Ph+) or *BCR-ABL1* positive laboratory test result; **AND**
- Patient does not have any of the following *BCR-ABL1* mutations: T315I/A, F317L/V/I/C, or V299L (****NOTE:** This does not apply to patients receiving first-line or continued therapy); **AND**
    - Patient has chronic phase disease and is at least 1 year of age †; **OR**
    - Patient is resistant, intolerant, or had an inadequate response to prior therapy consisting of a 3 month trial or longer with a tyrosine kinase inhibitor (e.g., imatinib, bosutinib, ponatinib, nilotinib, etc.); **AND**
        - Patient has chronic, accelerated, or blast phase disease †; **OR**
    - Used as primary treatment † ‡; **AND**
        - Used as single agent for newly diagnosed chronic or accelerated or myeloid blast phase disease; **OR**
        - Used in combination with corticosteroids for lymphoid blast phase disease; **OR**
        - Used in combination with induction chemotherapy for disease in lymphoid blast phase or myeloid blast phase; **OR**
    - Used as switch therapy ‡; **AND**
        - Patient received initial therapy with one of the following: imatinib, bosutinib or nilotinib; **AND**
        - Patient has *BCR-ABL1* transcript levels:
            - > 0.1% to 1% at 12 months (if treatment goal is treatment-free remission); **OR**
            - > 1% to 10% at 12 months; **OR**
            - > 10% at any response milestone; **OR**
    - Used as continued therapy ‡; **AND**
        - Patient has *BCR-ABL1* transcript levels:
            - ≤ 10% at any response milestone; **OR**
            - > 10% at 3 months; **OR**
    - Used post-allogeneic hematopoietic stem cell transplant (HCT) ‡; **AND**
        - Used for at least one year in patients with prior complete cytogenetic response (CCyR) for accelerated or blast phase disease; **OR**

- Used as follow-up therapy in patients with molecular relapse (BCR-ABL1 transcript positive) following CCyR; **OR**
- Used as follow-up therapy in patients with relapse or those who are not in CCyR

Acute Lymphoblastic Leukemia (ALL) † Φ [1-3,5]

- Patient has Philadelphia chromosome-positive (Ph+) disease; **AND**
  - Used for newly diagnosed disease in patients at least 1 year of age in combination with chemotherapy †; **OR**
  - Patient has relapsed/refractory disease; **AND**
    - Patient does not have any of the following *BCR-ABL1* mutations: T315I/A, F317L/V/I/C, or V299L; **AND**
      - Patient is resistant, or intolerant, or had an inadequate response to prior therapy, consisting of a 3 month trial or longer, with any of the following: 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 combination with blinatumomab ‡; **OR**
  - Used as maintenance therapy; **AND**
    - Used in combination with vincristine and prednisone with or without methotrexate and mercaptopurine; **OR**
    - Used post-hematopoietic stem cell transplant; **OR**
  - Patient is at least 15 years of age and < 65 years of age; **AND**
    - Used in a multiagent chemotherapy regimen for induction or consolidation therapy; **OR**
    - Used in combination with a corticosteroid for induction or consolidation therapy; **OR**
    - Used in combination with vincristine and dexamethasone for induction therapy; **OR**
    - Used in combination with blinatumomab as consolidation therapy for persistent/rising minimal residual disease following a complete response (CR) to induction therapy; **OR**
  - Patient is ≥ 65 years of age or with substantial comorbidities; **AND**
    - Used as induction therapy as part of one of the following regimens:
      - As a single agent or in combination with a corticosteroid; **OR**
      - In combination with vincristine and dexamethasone; **OR**
      - In combination with a multiagent chemotherapy regimen; **OR**
    - Used as consolidation therapy; **AND**

- Patient has persistent/rising minimal residual disease following a complete response to induction therapy; **AND**
- Used in combination with blinatumomab

Pediatric Acute Lymphoblastic Leukemia (ALL) ‡ [2,9]

- Patient is <18 years of age; **AND**
  - Patient has Ph-like B-ALL with ABL class kinase fusion or Ph+ B-ALL; **AND**
    - Used as part of a cytotoxic chemotherapy regimen as induction or consolidation therapy; **OR**
  - Patient has Ph+ B-ALL; **AND**
    - Used as part of a cytotoxic chemotherapy regimen for relapsed or refractory disease; **OR**
  - Patient has T-ALL with ABL-class translocation; **AND**
    - Used as part of a TKI-based regimen for relapsed/refractory disease

Gastrointestinal Stromal Tumors (GIST) ‡ [2,6,11,20]

- Patient has unresectable, recurrent, or metastatic disease; **AND**
- Used as a single agent; **AND**
- Patient's BCR-ABL KD mutational analysis contains the PDGFRA D842V mutation; **AND**
- Used after failure on approved therapies including each of the following: imatinib, avapritinib, sunitinib, regorafenib, and ripretinib

Bone Cancer (Chondrosarcoma and Chordoma) ‡ [2,7,8,12]

- Used as single agent; **AND**
  - Patient has chondrosarcoma and widespread metastatic disease: **OR**
  - Patient has conventional or chondroid chordoma and recurrent disease

Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes ‡ [2,18,19]

- Patient has eosinophilia and ABL1 rearrangement; **AND**
  - Patient has chronic phase myeloid or lymphoid neoplasms; **AND**
    - Used as a single agent; **OR**
  - Patient has blast phase lymphoid, myeloid, or mixed lineage neoplasms; **AND**
    - Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1-4,9,10,12]

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. 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, cardiac-related fluid retention, conduction system abnormalities, arrhythmia/palpitations), QT prolongation, severe dermatologic reactions, tumor lysis syndrome, serious bleeding-related events, etc.; **AND**
- Patient has been adherent to therapy; **AND**

Acute Lymphoblastic Leukemia (ALL) and Pediatric 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:
  - > 0.1% to 10% at 3 months or 6 months; **OR**
  - > 0.1% to 1% at 12 months and beyond (if treatment goal is long-term survival); **OR**
  - ≤ 0.1% at 12 months and beyond (if treatment goal is treatment-free remission)

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

Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes only:

- Disease response as evidenced by at least one of the following:
  - Decrease in spleen size or improvements in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding, etc.)
  - Stabilization or improvement as evidenced by a complete response [CR] (i.e. morphologic, cytogenetic or molecular complete response CR), complete hematologic response, or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

V. Dosage/Administration [1,6,7,19]

Indication	Dose
Accelerated phase CML and 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
Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes	Up to 140 mg by mouth once daily

VI. Billing Code/Availability Information

HCPCS Code:

- 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; March 2021. Accessed June 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) dasatinib. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are

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4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Chronic Myelogenous Leukemia 3.2021. National Comprehensive Cancer Network, 2021. 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 2021.
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associated PDGFRAD842V mutation. Clin Cancer Res. 2008;14(18):5749-5758. doi:10.1158/1078-0432.CCR-08-0533.
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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
C83.50	Lymphoblastic (diffuse) lymphoma, unspecified site
C83.51	Lymphoblastic (diffuse) lymphoma, lymph nodes of head, face, and neck

C83.52	Lymphoblastic (diffuse) lymphoma, intrathoracic lymph nodes
C83.53	Lymphoblastic (diffuse) lymphoma, intra-abdominal lymph nodes
C83.54	Lymphoblastic (diffuse) lymphoma, lymph nodes of axilla and upper limb
C83.55	Lymphoblastic (diffuse) lymphoma, lymph nodes of inguinal region and lower limb
C83.56	Lymphoblastic (diffuse) lymphoma, intrapelvic lymph nodes
C83.57	Lymphoblastic (diffuse) lymphoma, spleen
C83.58	Lymphoblastic (diffuse) lymphoma, lymph nodes of multiple sites
C83.59	Lymphoblastic (diffuse) lymphoma, extranodal and solid organ sites
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
C94.8	Other specified leukemias
C94.80	Other specified leukemias not having achieved remission
C94.81	Other specified leukemias, in remission
C94.82	Other specified leukemias, in relapse
C95.1	Chronic leukemia of unspecified cell type
C95.10	Chronic leukemia of unspecified cell type not having achieved remission
C95.11	Chronic leukemia of unspecified cell type, in remission
C95.12	Chronic leukemia of unspecified cell type, in relapse
C96.Z	Other specified malignant neoplasms of lymphoid, hematopoietic and related tissue
C96.9	Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified

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), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) 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/LCA): 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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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