Neighborhood Health Plan OF RHODE ISLAND™

New Century Health

Policy #UM ONC_1196
PROPRIETARY & CONFIDENTIAL

POLICY NUMBER UM ONC_1196	**SUBJECT** Sprycel™ (dasatinib)		**DEPT/PROGRAM** UM Dept	**Page 1 of 2**
DATES COMMITTEE REVIEWED 01/04/12, 01/08/14, 06/10/15, 06/28/17, 07/26/17, 07/03/18, 06/12/19, 12/11/19, 06/10/20	**APPROVAL DATE** June 10, 2020	**EFFECTIVE DATE** June 26, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 01/04/12, 01/08/14, 06/10/15, 06/28/17, 07/26/17, 07/03/18, 06/12/19, 12/11/19, 06/10/20	
PRIMARY BUSINESS OWNER: UM **APPROVED BY:** Dr. Andrew Hertler		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM 1	**NCQA STANDARDS** UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** All	

I. PURPOSE

To define and describe the accepted indications for Sprycel (dasatinib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. **PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:**
    a. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**
    b. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**
    c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies **AND**
    d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
    e. When available, generic alternatives are preferred over brand name drugs.
2. **Chronic Myeloid Leukemia (CML)**
    a. **NOTE: Per NCH Policy & NCH Pathway, generic imatinib is the preferred agent for first line therapy of BCR-ABL positive Chronic Myeloid Leukemia. Second generation TKIs- Tyrosine Kinase Inhibitors- such as Sprycel (dasatinib)- may be used if there is documented intolerance to generic imatinib OR documented disease progression on generic imatinib**.
    b. Sprycel (dasatinib) may be used as a single agent for members with newly diagnosed CML (Ph-1+ or BCR-ABL positive) who are intolerant/have a contraindication to generic matinib or have experienced disease progression on generic imatinib.

c. As initial or subsequent therapy for members with CML with any of the following mutations: Y253H or E255K/V.

3. **GIST**

   a. As a single agent for advance/metastatic GIST- Gastrointestinal Stromal Tumor- with a positivr PDGFRA D842V mutation when member has experienced disease progression on Gleevec (imatinib), Sutent (sunitinib), or Stivarga (regorafenib).

4. **Acute Lymphoblastic Leukemia (ALL)**

   a. The member has Ph Positive ALL with resistance or intolerance to prior therapy with generic imatinib.

III. EXCLUSION CRITERIA

1. Member has not had a trial of generic imatinib for first line therapy of BCR/ABL+ or Philadelphia Chromosome + CML.
2. Sprycel (dasatinib) is being used on Ph or BCR-ABL negative CML.
3. Members with GIST with no history of failure or intolerance to Sutent (sunitinib), Gleevec (imatinib), or Stivarga (regorafenib).
4. Sprycel (dasatinib) is being used concurrently with other tyrosine kinase inhibitors.
5. Member has disease progression while taking Sprycel (dasatinib).
6. Dosing exceeds single dose limit of Sprycel (dasatinib) 180 mg.
7. Do not exceed 30 (20 mg) tablets/month, 30 (50 mg) tablets/month, 30 (70 mg) tablets/month, 30 (80 mg), 30 (100 mg) tablets/month, or 30 (140 mg) tablets/month.
8. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Sprycel prescribing information. Bristol-Myers Squibb Company, Princeton, NJ. 2018.
2. Clinical Pharmacology Elsevier Gold Standard. 2018.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2018.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2018.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2018.