Caremark® Specialty Pharmacy Services

TrendsRx® Alert

What's new... What's next... What to do now JULY 2006

Sprycel™ (dasatinib)

DRUG APPROVAL

Sprycel (dasatinib, Bristol-Myers Squibb) received accelerated approval by the U.S. Food and Drug Administration (FDA) on June 28, 2006, for the treatment of all phases of chronic myeloid leukemia (CML) in adults who are resistant to or cannot tolerate prior therapy including imatinib (Gleevec®, Novartis). Sprycel was also approved for the treatment of adults with Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) with resistance or intolerance to prior therapy.[1] Sprycel inhibits multiple tyrosine kinases, including BCR-ABL. Serious side effects observed with Sprycel in clinical trials include severe myelosuppression (neutropenia, thrombocytopenia and anemia), central nervous system or gastrointestinal hemorrhage and fluid retention in the lungs and chest. The recommended dose of Sprycel is 70 mg orally twice a day.[2] Sprycel has been launched and is available in 20 mg, 50 mg and 70 mg tablets.

BACKGROUND

In 2006, there will be an estimated 4,600 new cases of CML and 3,970 new cases of ALL (about 20% to 25% of ALL cases are Ph+) in the United States.[3] CML and Ph+ ALL are cancers in which the bone marrow overproduces abnormal white blood cells. These abnormal cells accumulate and outnumber healthy cells, and may result in infections, bleeding and other serious problems. Most patients with CML and all patients with Ph+ ALL have a genetic mutation called the Philadelphia chromosome, which produces an abnormal gene called BCR-ABL. This gene creates the abnormal protein BCR-ABL tyrosine kinase that is responsible for the overproduction of white blood cells.[3,4]

For most patients with CML, the first-line of treatment is imatinib.[4,5] However, resistance to imatinib may develop due to mutations in the BCR-ABL gene or other mechanisms.[5,6] The relapse rate after about four and a half years is estimated to be 16% and is higher in those with advanced CML.[6,7] Resistance may also develop in patients with advanced Ph+ ALL and tends to occur more rapidly than in patients with CML.[1]

BUDGET IMPACT

Caremark estimates that Sprycel will have per Member per Month incremental budget impact of $0.02 to $0.04 ($0.20 to $0.46 PMPY).[8] This assumes that it would launch exclusively as a medication for second-line CML. It is expected to have a substantial market capture rate with a projected price per day of approximately $127 with an average length of therapy of three to six months.[8-10]

Further market penetration is likely in the future if Sprycel targets other forms of therapy such as first-line CML and gastrointestinal stromal tumors.[9,10]

CAREMARK RESPONSE

Caremark recognizes the unique needs of plan participants with CML or Ph+ ALL. Based on currently available data, Caremark recommends for your consideration and at your discretion, the management of Sprycel with the same clinical management tools you use for other oral oncology agents. Sprycel will be available from the Caremark Specialty Pharmacy Network. Caremark will continue to monitor the use of Sprycel to determine if additional clinical programs are necessary.

CAREMARK CONTACT

For more information, please contact your Caremark account representative or CaremarkConnect® toll-free at 1-800-237-2767.

Please note: *This document provides a brief overview of the subject. This review is provided as a reference only, and is based in part on information derived from third parties.*

References:

1. FDA Approves Sprycel (dasatinib) with two indications [press release]. Princeton, NJ: Bristol-Myers Squibb Company; June 28, 2006.
2. Sprycel prescribing information. Princeton, NJ: Bristol-Myers Squibb Company; June 2006.
3. American Cancer Society. Cancer Reference Information. Available at http://www.cancer.org/docroot/home/index.asp. Accessed June 23, 2006.
4. Mayo Foundation for Medical Education and Research. Diseases and conditions. Available at http://www.mayoclinic.com/health/DiseasesIndex/DiseasesIndex. Accessed June 23, 2006.
5. Talpaz M, Shah N, Kantarjian H et al. Dasatinib in imatinib-resistant Philadelphia chromosome-positive leukemias. N Engl J Med. 2006; 354:2531-41.
6. Shah N. Loss of response to imatinib: mechanisms and management. Hematology (Am Soc Hematol Educ Program). 2005:183-7.
7. Druker B. Circumventing resistance to kinase-inhibitor therapy. N Engl J Med. 2006; 354:24.
8. Caremark Internal Pharmacy Budget Forecast Model, Research and Development. July 2006.
9. Morgan Stanley. "Bristol-Meyers Squibb: Sprycel, a Potential Blockbuster?" May 25, 2005.
10. Bear Stearns. "Bristol-Meyers Squibb-Peer Performance." June 5, 2006.

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