

**Regence BlueCross BlueShield of Oregon · Regence BlueShield  
Regence BlueCross BlueShield of Utah · Regence BlueShield of Idaho  
Independent licensees of the Blue Cross and Blue Shield Association**

**Medication Policy Manual**

**Policy No:** dru137

**Topic:** Sprycel<sup>®</sup>, dasatinib

**Date of Origin:** November 17, 2006

**Revised/Effective Date:** November 14, 2008

**Next Review Date:** November 2009

**IMPORTANT REMINDER**

This Medical Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medical policy is to provide a guide to coverage. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

**Description**

Dasatinib (Sprycel<sup>®</sup>) is an oral cancer medication used to treat certain leukemias.

## **Policy/Criteria**

- I.** Most contracts require prior authorization approval of dasatinib prior to coverage. Dasatinib may be considered medically necessary when all of the following criteria A, B, and C below are met.
    - A.** Documentation of one of the following diagnoses:
      - 1.** Chronic myelogenous leukemia (CML).
    - OR**
    - 2.** Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL).
  - AND**
  - B.** Resistance or intolerance to treatment with imatinib (Gleevec<sup>®</sup>).
  - AND**
  - C.** A hematologist or oncologist prescribes dasatinib.
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- II.** Administration and Authorization Period
  - A.** Regence considers dasatinib to be a self-administered medication.
  - B.** Authorization may be reviewed at least annually to confirm that current medical necessity criteria are met and that the medication is effective.
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- III.** Dasatinib is considered investigational when used for all other conditions, including, but not limited to:
  - A.** Acute lymphoblastic leukemia without the Philadelphia chromosome (non-Ph+ ALL).
  - B.** Malignant melanoma.
  - C.** Multiple myeloma (MM).
  - D.** Myeloproliferative disorders (MPD).
  - E.** Solid tumors.

## Position Statement

- Several tyrosine kinase inhibitor medications have shown benefit in treating blood cancers, such as chronic myeloid leukemia (CML), that are associated with the Philadelphia chromosome.
- Imatinib (Gleevec<sup>®</sup>), a tyrosine kinase inhibitor medication, was the first new therapy found to be more effective than other kinds of medication treatment for CML. <sup>[8]</sup>
- Dasatinib (Sprycel<sup>®</sup>) and nilotinib (Tasigna<sup>®</sup>), also tyrosine kinase inhibitor medications, have demonstrated possible benefit in the small proportion of patients in whom imatinib stops working or is not tolerated. <sup>[1,17]</sup>
- There is no reliable information that shows how well any single tyrosine kinase inhibitor medication works relative to another.
- There are many studies looking to see if these medications work in other kinds of cancer; however, more information is needed before it is known whether they work in these cancers.

### *Background in CML Treatment*

- CML is a blood disease that is caused by a specific gene mutation that leads to the formation of the Philadelphia chromosome. Confirmation of the Philadelphia chromosome along with the presence of specific immature cells in the blood establishes a diagnosis of CML.
- Several medications belonging to the protein kinase inhibitor class (dasatinib, imatinib, and nilotinib) have been found to prevent the formation of the Philadelphia chromosome which prevents progression of CML and improves survival of patients when compared with patients who had CML before these medications became available.

### *Clinical Efficacy*

- Dasatinib was studied in several blood cancers that are associated with formation of the Philadelphia chromosome. <sup>[1-7]</sup>

- In these studies, dasatinib was found to lower the amount of Philadelphia chromosome present in the cells (cytogenetic response) and return blood counts to normal (hematologic response) in patients with CML and Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL). <sup>[1-7, 10-13]</sup>
- Patients in the dasatinib studies either experienced resistance to imatinib therapy (they did not achieve a hematologic or cytogenetic response or had progression of disease after an initial response) or could not tolerate imatinib doses of 400 mg or more per day. <sup>[1-7, 10-13]</sup>
- There is no reliable information directly comparing dasatinib with other therapies so it is not known how well it works relative to other medications (e.g., nilotinib).
- It is not known how much patients will benefit from dasatinib.

### *Safety*

- Adverse events commonly reported with dasatinib in clinical trials included: <sup>[1-7, 10-15]</sup>
  - \* Suppression of bone marrow including thrombocytopenia, neutropenia, and anemia.
  - \* Bleeding, including severe gastrointestinal hemorrhage.
  - \* Severe fluid retention, including pleural effusion.
  - \* Gastrointestinal events including diarrhea, nausea, abdominal pain and vomiting.
  - \* QT segment prolongation.

### *Dosing and administration*

- Dasatinib tablets should be swallowed whole. They may be taken with or without a meal. <sup>[1]</sup>
- Adjustment of the dasatinib dose is recommended for bone marrow suppression and during concomitant administration with strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, voriconazole, clarithromycin). <sup>[1]</sup>

### Other Conditions

- A small, preliminary trial studied dasatinib in patients with Philadelphia chromosome-negative (Ph-) chronic myeloproliferative disorders, including systemic mastocytosis (n = 33), acute myeloid leukemia (n = 9) and primary myelofibrosis (n = 9).<sup>[16]</sup> Larger, well-controlled trials are necessary before a clinical benefit can be established in these populations.
- Dasatinib is also being studied in several other types of cancers including, but not limited to, acute lymphoblastic leukemia, solid tumors, myeloproliferative disorders, malignant melanoma and multiple myeloma.<sup>[9]</sup> However, there is currently no evidence available for any of these conditions.

### References

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17. Tassigna (nilotinib) Prescribing Information. Novartis Pharmaceuticals Corporation; East Hanover, NJ, October 2007.

<b>Cross References</b>
Gleevec <sup>®</sup> , imatinib dru043
Tasigna <sup>®</sup> , nilotinib dru151

<b>Codes</b>	<b>Number</b>	<b>Description</b>
HCPCS	J8999	Oral chemotherapeutic drug, not otherwise classified