BlueCross BlueShield
Federal Employee Program

TASIGNA, DANZITEN
(nilotinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Tasigna and Danziten are indicated for the treatment of chronic myeloid leukemia (CML), a blood and bone marrow disease that usually affects older adults. Tasigna and Danziten work by blocking the signal of the tyrosine kinase that promotes the development of abnormal and unhealthy granulocytes. Most people with CML have a genetic mutation, called the Philadelphia chromosome, which causes the bone marrow to make an enzyme called tyrosine kinase. This enzyme triggers the development of too many abnormal and unhealthy white blood cells called granulocytes which fight infection (1-3).

Regulatory Status

FDA-approved indications (1-2):

1. **Tasigna** is a kinase inhibitor indicated for the treatment of:
    a. Adult and pediatric patients greater than or equal to 1 year of age with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase
    b. Adult patients with chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib
    c. Pediatric patients greater than or equal to 1 year of age with Ph+ CML-CP and CML-AP resistant or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy
2. **Danziten** is a kinase inhibitor indicated for the treatment of:
    a. Adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML) in chronic phase
    b. Adult patients with chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib

<u>Off-Label Uses for Tasigna Only</u>: (1,3)

1. Treatment of patients with advanced phase CML (accelerated phase or blast phase)
2. Follow-up therapy for CML patients after hematopoietic stem cell transplant (HSCT)
3. Follow-up therapy for CML patients resistant or intolerant to primary treatment with tyrosine kinase inhibitors (TKIs)

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4. Post-consolidation therapy for Ph+ ALL after complete response to induction chemotherapy following allogeneic hematopoietic stem cell transplant (HSCT)
5. Relapsed/ refractory Ph+ acute lymphoblastic leukemia for both adults and pediatrics
6. Gastrointestinal Stromal tumor (GIST) in patients with disease progression on imatinib, sunitinib or regorafenib

Tasigna and Danziten include boxed warnings for the risk of QT prolongation. Before initiation of Tasigna and Danziten therapy, hypokalemia or hypomagnesemia should be monitored and corrected as needed throughout therapy. ECGs should be obtained to monitor the QTc at baseline, seven days after starting therapy, periodically during therapy, and following any dose adjustments. Tasigna and Danziten are contraindicated in patients with hypokalemia, hypomagnesemia, or long QT syndrome. Tasigna and Danziten should not be used in combination with any drugs that are known to prolong the QT interval or strong CYP3A4 inhibitors. Food should be avoided 2 hours before and 1 hour after taking Tasigna or Danziten (1-2).

Thrombocytopenia, neutropenia, and anemia can occur; therefore, a complete blood count should be performed every 2 weeks for the 2 months and then monthly or as clinically indicated (1-2).

Hepatic function tests should be monitored for monthly or as clinically indicated. Tasigna and Danziten therapy have been associated with elevations in bilirubin, AST/ALT, and alkaline phosphatase. Patients with hepatic function impairment at baseline have increased exposure to Tasigna and Danziten and require a dose reduction and close monitoring of QT interval (1-2).

The safety and efficacy of Tasigna in patients less than 1 year of age have not been established. The safety and efficacy of Danziten in pediatric patients less than 18 years of age have not been established (1-2).

Summary

Tasigna and Danziten are kinase inhibitors that inhibit BCR-ABL kinase, an enzyme that promotes chronic myeloid leukemia (CML). In studies, treatment with nilotinib inhibited BCR-ABL mediated proliferation of murine leukemic cell lines and human cell lines derived from patients with Ph+ CML. Tasigna and Danziten treatment were also able to overcome imatinib resistance that resulted from

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BCR-ABL kinase mutations. Tasigna and Danziten treatment reduced tumor size in a murine BCR-ABL xenograft model. The safety and efficacy of Tasigna in patients less than 1 year of age have not been established. The safety and efficacy of Danziten in pediatric patients less than 18 years of age have not been established (1-3).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Tasigna and Danziten while maintaining optimal therapeutic outcomes.

References

1. Tasigna [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp; February 2024.
2. Danziten [package insert]. Woburn, MA: Azurity Pharmaceuticals, Inc.; November 2024.
3. NCCN Drugs & Biologics Compendium® Nilotinib 2025. National Comprehensive Cancer Network, Inc. Accessed on April 24, 2025.