

5.21.077

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Subsection:	Antineoplastic Agents	Original Policy Date:	April 1, 2016
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Last Review Date: September 19, 2025

Tasigna

Description

Tasigna, Danziten (nilotinib)

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

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- b. Adult patients with chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib

Off-Label Uses for Tasigna Only: (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)
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).

Related policies

Bosulif, Gleevec, Iclusig, Scemblix, Sprycel

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Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Tasigna and Danziten may be considered **medically necessary** if the conditions indicated below are met.

Tasigna and Danziten may be considered **investigational** for all other indications.

Prior-Approval Requirements

Tasigna only

Age 1 year of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Chronic myeloid leukemia (CML)
2. Chronic myeloid leukemia (CML) with hematopoietic stem cell transplant (HSCT)
 - a. In combination with induction therapy
3. Ph+ Acute lymphoblastic leukemia (ALL)
4. Ph+ Acute lymphoblastic leukemia (ALL) post hematopoietic stem cell transplant (HSCT)
 - a. After achieving complete response to induction therapy

AND ALL of the following for **ALL** above indications:

1. Confirmed by molecular testing by the detection of the Ph chromosome or BCR-ABL gene prior to initiation of therapy
2. If the patient has had prior therapy with a TKI then **ONE** of the following requirements must be met:
 - a. Member experienced resistance to prior therapy with TKI
 - i. Results from mutational testing are negative for the T315I mutation

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- b. Member experienced toxicity or intolerance to prior therapy with a TKI

5. Gastrointestinal stromal tumor (GIST)

- a. Disease progression after prior therapy with imatinib, sunitinib or regorafenib

AND the following for **ALL** indications:

- a. **Brand Tasigna only:** Patient **MUST** have tried the preferred product (generic Tasigna: nilotinib) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Danziten only

Age 18 years of age and older

Diagnosis

Patient must have the following:

- 1. Chronic myeloid leukemia (CML)
 - a. Confirmed by molecular testing by the detection of the Ph chromosome or BCR-ABL gene prior to initiation of therapy
 - b. Patient **MUST** have tried the preferred product (generic Tasigna: nilotinib) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

AND ONE of the following:

- 1. Newly diagnosed with chronic phase
- 2. Resistant to or intolerant to prior therapy that included imatinib

Prior – Approval *Renewal* Requirements

Tasigna only

Age 1 year of age and older

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Diagnoses

Patient must have **ONE** of the following:

1. Chronic myeloid leukemia (CML)
 2. Chronic myeloid leukemia (CML) with hematopoietic stem cell transplant (HSCT)
 3. Ph+ Acute lymphoblastic leukemia (ALL)
 4. Ph+ Acute lymphoblastic leukemia (ALL) post hematopoietic stem cell transplant (HSCT)
 5. Gastrointestinal stromal tumor (GIST)
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Danziten only

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Chronic myeloid leukemia (CML)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Tasigna	
Strength	Quantity
50 mg	504 capsules per 84 days OR
150 mg	336 capsules per 84 days OR
200 mg	336 capsules per 84 days

Danziten	
Strength	Quantity
71 mg	336 tablets per 84 days OR

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95 mg	336 tablets per 84 days
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Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

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 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 August 14, 2025.

Policy History

Date	Action
April 2016	New addition
June 2016	Annual review
November 2016	Removal of the requirement for “first-line therapy” for CML
December 2016	Annual review

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March 2017	Annual editorial review and reference update Addition of no dual therapy with another tyrosine kinase inhibitor
May 2017	Additional requirement to chronic myeloid leukemia (CML) post hematopoietic stem cell transplant (HSCT) of in combination with induction therapy
September 2017	Annual review Addition of quantity limits
March 2018	Annual editorial review and reference update Change the wording for the mutational testing requirement to "If the patient has had prior therapy with a TKI then ONE of the following requirements must be met: member experienced resistance to prior therapy with TKI and results from mutational testing are negative for the T315I mutation or member experienced toxicity or intolerance to prior therapy with a TKI
April 2018	Change of age from 18 years to 1 year or older Addition of requirement for GIST: disease progression after prior therapy with imatinib, sunitinib or regorafenib Addition of 50mg capsules
June 2018	Annual editorial review
June 2019	Annual review and reference update
December 2019	Annual review and reference update. Addition of requirement to trial preferred product for initiation CML diagnosis and removed no dual therapy with another TKI requirement
March 2020	Updated requirement of trial preferred product for CML
June 2020	Annual review and reference update
December 2021	Annual editorial review and reference update
March 2022	Annual editorial review and reference update
December 2022	Annual review and reference update. Changed policy number to 5.21.077
December 2023	Annual review and reference update
December 2024	Annual review and reference update. Changed Medex requirement for CML to t/f dasatinib or imatinib
March 2025	Annual editorial review and reference update. Addition of Danziten to policy
June 2025	Annual review and reference update
August 2025	Changed Medex requirement so Tasigna and Danziten requests require t/f of generic Tasigna: nilotinib
September 2025	Annual review and reference update

Keywords

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 19, 2025 and is effective on October 1, 2025.