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5.21.077

Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	April 1, 2016
Subject:	Tasigna	**Page:**	1 of 6

Last Review Date: December 8, 2023

Tasigna

Description

Tasigna (nilotinib)

Background
Tasigna (nilotinib) is indicated for the treatment of chronic myeloid leukemia (CML), a blood and bone marrow disease that usually affects older adults. Tasigna works 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. Granulocytes fight infection (1-2).

Regulatory Status
FDA-approved indications: Tasigna is a kinase inhibitor indicated for: (1)

1. 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
2. Adult patients with chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib
3. 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

Off-Label Uses: (1-2)

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 includes boxed warnings for the risk of QT prolongation. Before initiation of Tasigna therapy, hypokalemia or hypomagnesemia should be corrected and deficiencies with these electrolytes should be monitored for and corrected as needed throughout therapy. ECGs should be obtained to monitor the QTc at baseline, seven days after starting therapy and periodically during therapy, as well as, after any dose adjustments. Tasigna is contraindicated in patients with hypokalemia, hypomagnesemia, or long QT syndrome. Also, Tasigna 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 (1).

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).

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

The safety and efficacy of Tasigna in patients less than 1 year of age have not been established (1).

Related policies
Bosulif, Gleevec, Iclusig, Scemblix, Sprycel

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

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

Prior-Approval Requirements

Age 1 year of age and older

Diagnoses

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

1. Chronic myeloid leukemia (CML)
    a. Patient **MUST** have tried **ONE** of the preferred products (Sprycel or generic Gleevec: imatinib) unless the patient has a valid medical exception (e.g. inadequate treatment response, intolerance, contraindication)

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 diagnoses:
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
    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

Prior – Approval *Renewal* Requirements

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)
3. Ph+ Acute lymphoblastic leukemia (ALL)
4. Ph+ Acute lymphoblastic leukemia (ALL) post hematopoietic stem cell transplant (HSCT)
5. Gastrointestinal stromal tumor (GIST)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

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

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Tasigna is a kinase inhibitor that inhibits the 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 treatment was also able to overcome imatinib resistance that resulted from BCR-ABL kinase mutations. Tasigna 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 (1-2).

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

References

1. Tasigna [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp; September 2021.
2. NCCN Drugs & Biologics Compendium® Nilotinib 2023. National Comprehensive Cancer Network, Inc. Accessed on October 12, 2023.

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
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

Keywords

This policy was approved by the FEP® Pharmacy Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.