



Drug Quantity Management – Per Rx Oncology – Tasigna® (nilotinib capsules)

Table of Contents

National Formulary Medical Necessity	1
Conditions Not Covered.....	2
Background.....	2
References	3
Revision History.....	3

Product Identifier(s)

Effective 1/1/23 to 4/11/23: 110156

Effective 4/12/23: 62235

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

This Drug Quantity Management program has been developed to manage potential dose escalation and provide a sufficient quantity of Tasigna. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Strength and Form	Maximum Quantity per Rx
Tasigna® (nilotinib capsules)	50 mg capsules	120 capsules
	150 mg capsules	112 capsules
	200 mg capsules	112 capsules

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

Tasigna 50 mg capsules

1. If the individual requires a dose of 250 mg twice daily, approve 300 capsules per dispensing.
2. If the individual requires a dose of 350 mg twice daily, approve 420 capsules per dispensing.

Tasigna 150 mg and 200 mg capsules

No overrides recommended.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

Tasigna, a tyrosine kinase inhibitor (TKI), is indicated for the following uses:¹

- **Chronic myeloid leukemia (CML)**, chronic phase, newly diagnosed and Philadelphia chromosome positive (Ph+), in adult and pediatric patients ≥ 1 year of age.
- **CML**, Ph+, chronic phase and accelerated phase, in adults with resistance to or intolerance to prior therapy that included imatinib.
- **CML**, Ph+, chronic phase, in pediatric patients ≥ 1 year of age with resistance or intolerance to prior TKI therapy.

Dosing

Tasigna is dosed twice daily (BID) at approximately 12-hour intervals and is given on an empty stomach.¹ Treatment is continued as long as clinical benefit is observed or until unacceptable toxicity. Capsules should be swallowed whole or the contents dispersed in 1 teaspoon of applesauce if the patient is unable to swallow capsules. The recommended dose of Tasigna is:

- Adults with newly diagnosed Ph+ CML in chronic phase: 300 mg BID.
- Adults with resistant or intolerant Ph+ CML in chronic phase and accelerated phase: 400 mg BID.
- Pediatric patients with newly diagnosed PH+ CML in chronic phase or resistant or intolerant Ph+ CML in chronic phase and accelerated phase: 230 mg/m² BID, rounded to the nearest 50 mg, up to a maximum single dose of 400 mg (refer to Table 1 below). Combining different strengths of Tasigna may be necessary to attain the desired dose.

Table 1. Tasigna Pediatric Dosing.¹

Body Area	Surface	Single Dose	Total Daily Dose	Quantity/Capsule Size Needed per Month* (Day Supply)
≤ 0.32 m ²		50 mg	100 mg	60 x 50 mg capsules (30-day supply)
0.33 to 0.54 m ²		100 mg	200 mg	120 x 50 mg capsules (30-day supply)
0.55 to 0.76 m ²		150 mg	300 mg	56 x 150 mg capsules (28-day supply)
0.77 to 0.97 m ²		200 mg	400 mg	56 x 200 mg capsules (28-day supply)
0.98 to 1.19 m ²		250 mg	500 mg	56 x 200 mg capsules + 56 x 50 mg capsules (28-day supply) OR 300 x 50 mg capsules (30-day supply)
1.20 to 1.41 m ²		300 mg	600 mg	112 x 150 mg capsules (28-day supply)
1.42 to 1.63 m ²		350 mg	700 mg	56 x 200 mg capsules + 56 x 150 mg capsules (28-day supply) OR 420 x 50 mg capsules (30-day supply)
≥ 1.64 m ²		400 mg	800 mg	112 x 200 mg capsules (28-day supply)

* Day supply varies based on how capsules are packaged.

Dose modifications should be made in patients with baseline hepatic impairment, myelosuppression, elevated liver function tests, elevated bilirubin, or taking concomitant strong cytochrome P450 (CYP)3A4 inhibitors or QT-prolonging medications.¹

Availability

Tasigna is available as 50 mg capsules in bottles of 120 capsules; 150 mg and 200 mg capsules are available in cartons of 112 capsules (4 blister packs x 28 capsules each).¹

Off-Label Use

Guidelines also support the use of Tasigna for acute lymphoblastic leukemia, gastrointestinal stromal tumor, myeloid/lymphoid neoplasms with eosinophilia, and pigmented villonodular synovitis/tenosynovial giant cell tumor.²⁻⁵ Dosing of Tasigna in these settings falls within the quantity limits outlined below.

References

1. Tasigna® capsules [prescribing information]. East Hanover, NJ: Novartis; September 2021.
2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 1.2022 – April 4, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on April 28, 2022.
3. The NCCN Gastrointestinal Stromal Tumors Guidelines in Oncology (Version 1.2022 – January 21, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on April 27, 2022.
4. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 1.2022 – April 14, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on April 28, 2022.
5. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2022 – May 17, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on May 31, 2022.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	Tasigna 50 mg capsules: Duration of approval changed to 1 year (previously 3 years). Override criteria were updated to allow for approval of 300 capsules per dispensing if the patient requires a dose of 250 mg twice daily and 420 capsules per dispensing if the patients requires a dose of 350 mg twice daily. Previously, criteria approved for up to 420 capsules per dispensing if the patient required a dose of 250 mg or 350 mg twice daily.	06/08/2022

“Cigna Companies” refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc. and HMO or service company subsidiaries of Cigna Health Corporation. The Cigna name, logo, and other Cigna marks are owned by Cigna Intellectual Property, Inc. © 2023 Cigna.