DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Tasigna Drug Quantity Management Policy – Per Rx
- Tasigna® (nilotinib capsules – Novartis)

REVIEW DATE: 06/03/2025

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Tasigna, a tyrosine kinase inhibitor (TKI), is indicated for the following uses:[1]
- **Chronic myeloid leukemia (CML)**, Philadelphia chromosome positive (Ph+), that is newly diagnosed in adult and pediatric patients ≥ 1 year of age in chronic phase.
- **CML**, Ph+, chronic phase and accelerated phase, in adults with resistance or intolerance to prior therapy that included imatinib.
- **CML**, Ph+, chronic phase and accelerated 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/m^2 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 Surface Area	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, pigmented villonodular synovitis/tenosynovial giant cell tumor, and cutaneous melanoma.[2-7] Dosing of Tasigna in these settings falls within the quantity limits outlined below.

POLICY STATEMENT

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	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Tasigna® (nilotinib capsules)	50 mg capsules	120 capsules	360 capsules
	150 mg capsules	112 capsules	336 capsules
	200 mg capsules	112 capsules	336 capsules

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

Tasigna 50 mg capsules

1. If the patient requires a dose of 250 mg twice daily, approve 300 capsules per dispensing at retail or 900 capsules per dispensing at home delivery.

2. If the patient requires a dose of 350 mg twice daily, approve 420 capsules per dispensing at retail or 1,260 capsules per dispensing at home delivery.

Tasigna 150 mg and 200 mg capsules

No overrides recommended.

REFERENCES

1. Tasigna® capsules [prescribing information]. East Hanover, NJ: Novartis; February 2024.
2. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 1.2025 – May 15, 2025). © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 23, 2025.
3. The NCCN Gastrointestinal Stromal Tumors Guidelines in Oncology (Version 1.2025 – Apil 17, 2025). © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 23, 2025.
4. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 2.2025 – April 4, 2025). © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 23, 2025.
5. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 1.2025 – May 2, 2025). © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 23, 2025.
6. The NCCN Melanoma: Cutaneous Clinical Practice Guidelines in Oncology (version 2.2025 – January 28, 2025). © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 23, 2025.

7. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 3.2025 – November 27, 2024). © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 23, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. No criteria changes.	06/08/2023
Annual Revision	No criteria changes.	06/19/2024
Annual Revision	No criteria changes.	06/03/2025