DRUG QUANTITY MANAGEMENT POLICY – PER RX

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

REVIEW DATE: 06/08/2022

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/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, and pigmented villonodular synovitis/tenosynovial giant cell tumor.[2-5] 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.

Automation: None.

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

Tasigna 50 mg capsules

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

Tasigna 150 mg and 200 mg capsules

No overrides recommended.

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.