



## PREFERRED SPECIALTY MANAGEMENT POLICY

- POLICY:** Oncology – Nilotinib Preferred Specialty Management Policy
- Nilotinib D-Tartrate (nilotinib d-tartrate capsules, Cipla)
  - Tasigna® (nilotinib hydrochloride capsules – Novartis, generic)

**REVIEW DATE:** 02/11/2026

### 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 (nilotinib hydrochloride, generic), a tyrosine kinase inhibitor (TKI), is indicated for the following uses:<sup>1,2</sup>

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

Nilotinib D-Tartrate, a TKI, is indicated for the following uses:<sup>3</sup>

- **Chronic myeloid leukemia (CML)**, Philadelphia chromosome positive (Ph+), that is newly diagnosed, in chronic phase in adults.

- **CML**, Ph+, chronic phase and accelerated phase in adults with resistance or intolerance to prior therapy that included imatinib.

**POLICY STATEMENT**

This Preferred Specialty Management program has been developed to encourage the use of the Preferred Product. For all medications (Preferred and Non-Preferred), the patient is required to meet the standard *Oncology – Nilotinib Products Prior Authorization Policy* criteria. The program also directs the patient to try the Preferred Product prior to the approval of the Non-Preferred Product. Requests for the Non-Preferred Product will also be reviewed using the exception criteria (below). If the patient meets the standard *Oncology – Nilotinib Products Prior Authorization Policy* criteria but has not tried a Preferred Product, approval for the Preferred Product will be authorized. All approvals are provided for the duration noted below.

**Documentation:** Documentation will be required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, and prescription receipts. All documentation must include patient-specific identifying information.

**Preferred Product:** generic nilotinib hydrochloride capsules  
**Non-Preferred Product:** Tasigna, Nilotinib D-Tartrate

***Oncology – Nilotinib Preferred Specialty Management Policy non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.***

**NON-PREFERRED PRODUCT EXCEPTION CRITERIA**

<b>Non-Preferred Product</b>	<b>Exception Criteria</b>
Tasigna, Nilotinib D-Tartrate	<p><b>1.</b> Approve for 1 year if the patient meets ALL of the following (A, B, and C):</p> <p><b>A)</b> Patient meets the standard <i>Oncology – Nilotinib Products Prior Authorization Policy</i> criteria; AND</p> <p><b>B)</b> Patient has tried generic nilotinib hydrochloride capsules <b>[documentation required]</b>; AND</p> <p><b>C)</b> Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Non-Preferred and Preferred product which, according to the prescriber, would result in a significant allergy or serious adverse reaction <b>[documentation required]</b>.</p>

	<p><b>2.</b> For a patient who has met the <i>Oncology – Nilotinib Products Prior Authorization Policy</i> criteria (1A), but has not met exception criteria (1B) and (1C): approve generic nilotinib hydrochloride capsules.</p>
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**REFERENCES**

1. Tasigna® capsules [prescribing information]. East Hanover, NJ: Novartis; February 2024.
2. Nilotinib capsules [prescribing information]. Toronto, Ontario: Apotex; March 2024.
3. Nilotinib capsules [prescribing information]. Warren, NJ; Cipla; February 2025.

**HISTORY**

Type of Revision	Summary of Changes	Review Date
New Policy	Effective 09/01/2025.	06/04/2025
Early annual revision	Nilotinib D-Tartrate was added as a non-preferred product with the same exception criteria as Tasigna. The wording “between the non-preferred and preferred product” were added to the following, “Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the non-preferred and preferred product which, per the prescriber, would result in a significant allergy or serious adverse reaction.” Reference to the preferred product, nilotinib capsules, was updated to “nilotinib hydrochloride capsules” throughout the policy.	02/11/2026

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