STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NILOTINIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NILOTINIB HCL	TASIGNA	35149		GPI-10 (2153186020)	

GUIDELINES FOR USE

1. Does the patient have a newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase **AND** meet the following criterion?
   - The patient is 1 year of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase or accelerated phase and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is resistant or intolerant to prior therapy that included imatinib (Gleevec)
   - The patient had a mutational analysis prior to initiation AND Tasigna is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #3.

3. Does the patient have a diagnosis of Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase or accelerated phase and meet **ALL** of the following criteria?
   - The patient is 1 to 17 years of age
   - The patient is resistant or intolerant to prior therapy with other tyrosine kinase inhibitors (TKI) [e.g., Gleevec (imatinib), Sprycel (dasatinib), Bosulif (bosutinib)]
   - The patient had a mutational analysis prior to initiation AND Tasigna is appropriate per the NCCN guideline table for treatment recommendations based on BCR-ABL1 mutation profile *(Please see header CML-5 of the current NCCN guidelines)*

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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NILOTINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **NILOTINIB (Tasigna)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML: a type of blood cell cancer) in chronic phase
   2. Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia in chronic or accelerated phase

B. **If you have newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, approval also requires:**
   1. You are 1 year of age or older

C. **If you have Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase or accelerated phase, approval also requires:**
   1. If you are 18 years of age or older, you are resistant or intolerant to prior therapy including Gleevec (imatinib)
   2. If you are 1 to 17 years of age, you are resistant or intolerant to prior therapy with other tyrosine kinase inhibitors (TKI) such as Gleevec (imatinib), Sprycel (dasatinib), Bosulif (bosutinib)
   3. You had a mutational analysis prior to initiation of therapy AND Tasigna is appropriate per the National Comprehensive Cancer Network (NCCN) guideline table for treatment recommendations based on BCR-ABL1 mutation (breakpoint cluster region-Abelson murine leukemia 1; a type of abnormal gene) profile

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tasigna.

REFERENCES

- Tasigna [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
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P&T Approval: 01/22