NILOTINIB

Generic	Brand	HICL	GCN	Exception/Other
NILOTINIB HCL	TASIGNA	35149		

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 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 has a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that the following mutations are NOT present: T315I, Y253H, E255K/V, F359V/C/I, or G250E

   If yes, **approve for 12 months by HICL 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 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 [e.g., Gleevec (imatinib), Sprycel (dasatinib), Bosulif (bosutinib)]
   - The patient has a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that the following mutations are NOT present: T315I, Y253H, E255K/V, or F359V/C/I, or G250E

   If yes, **approve for 12 months by HICL 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: The guideline named **NILOTINIB (Tasigna)** requires a diagnosis of newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, OR Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic or accelerated phase. In addition, the following criteria must be met:

For patients with newly diagnosed Ph+ CML in chronic phase, approval requires:

- The patient is 1 year of age or older

For patients with Ph+ CML in accelerated phase or chronic phase, approval requires:

- The patient is 18 years of age or older
- The patient is resistant or intolerant to prior therapy that included imatinib (Gleevec)
- The patient has a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that the following mutations are NOT present: T315I, Y253H, E255K/V, F359V/C/I, or G250E

For patients with Ph+ CML in chronic phase, approval requires:

- The patient is 1 to 17 years of age
- The patient is resistant or intolerant to prior therapy with other tyrosine kinase inhibitors [e.g. Gleevec (imatinib), Sprycel (dasatinib), Bosulif (bosutinib)]
- The patient has a Breakpoint Cluster Region Abelson Murine Leukemia (BCR-ABL) mutational analysis confirming that the following mutations are NOT present: T315I, Y253H, E255K/V, F359V/C/I, or G250E

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 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/20
Created: 05/12
Client Approval: 11/19
P&T Approval: 10/19