Clinical Policy Title:	nilotinib
Policy Number:	RxA.515
Drug(s) Applied:	Nilotinib, Danziten
Original Policy Date:	03/06/2020
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Chronic Myeloid Leukemia (must meet all):

1. Diagnosis of one of the following:
   - **a.** Chronic phase, Philadelphia chromosome-positive chronic myeloid leukemia (CML);
   - **b.** Accelerated phase, Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CMLAP).

Initial Approval Duration

All Lines of Business (except Medicare): 12 months

Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Member is currently receiving medication or has been treated with this medication within the past 90 days, excluding manufacturer samples.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network Guidelines. Chronic Myeloid Leukemia Version 2.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf. Accessed April 9, 2024.
2.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed 1. Policy title table was updated. 2. Added initial therapy criteria for off label indication: Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes. 3. Commercial approval duration was updated for initial and Continued approval criteria	11/13/2020	12/7/2020

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from length of benefit to 6 months and 12 months respectively. 4. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 5. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria I.A.1.was updated from ‘Diagnosis of Ph+ (BCR-ABL1-positive) CML” to Diagnosis of one of the following: Newly diagnosed Ph+ (BCR-ABL1-positive) CML or Chronic phase and accelerated phase Philadelphia chromosome positive chronic myelogenous leukemia (Ph+ CML-CP)….” 2. Continued Therapy Approval II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3. References were reviewed and updated.	09/22/2021	12/07/2021
Policy was reviewed: 1. Initial Approval Criteria, I.C.4: Updated trial and failure criteria to include drug Sprycel®. 2. Initial Approval Criteria, I.E: Updated to include approval criteria for indication, Pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor (off-label). 3. References were reviewed and updated.	09/07/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed. 1. Removed reauthorization requirement for positive response to therapy. 2. Removed off-label indications. 3. References were reviewed and updated. 4. Revised approval indications	4/15/2024	

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