Clinical Policy Title:	asciminib
Policy Number:	RxA.764
Drug(s) Applied:	Scemblix®
Original Policy Date:	07/18/2022
Last Review Date:	10/19/2023
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 Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase;
2. Prescribed by or in consultation with an oncologist or a hematologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a or b):
   a. Member has had previous treatment with two or more tyrosine kinase inhibitors (TKIs) (e.g., imatinib, Bosulif®, Iclusig®, Sprycel®, Tasigna®);
   b. Member has BCR-ABL T315I mutation;
5. Request meets one of the following (a, b, or c):*
   a. For Ph+ CML, previously treated with two or more TKIs: Dose does not exceed 80 mg per day;
   b. For Ph+ CML with the T315I mutation: Dose does not exceed 400 mg per day;
   c. Dose is supported by practice guideline or peer-reviewed literature for the relevant off label use (prescriber must submit supporting evidence).*

   *Prescribed regimen must be FDA-approved or recommended by NCCN

Approval Duration
Commercial: 6 months
Medicaid: 6 months

B. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusion (Off-label) (must meet all):

1. Diagnosis of one of the following (a or b):
   a. Myeloid/lymphoid neoplasms with eosinophilia and ABL1 rearrangement in chronic phase or blast phase;
   b. Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible) for lymphoid, myeloid or mixed lineage neoplasms with eosinophilia and ABL1 rearrangement in blast phase;
2. Prescribed by or in consultation with an oncologist or a hematologist;
3. Age ≥ 18 years;
4. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).*

   *Prescribed regimen must be FDA-approved or recommended by NCCN

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a, b, or c):*
   a. For Ph+ CML, previously treated with two or more TKIs: 80 mg per day;
   b. For Ph+ CML with the T315I mutation: 400 mg per day;
   c. New dose is supported by practice guideline or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval Duration
Commercial: 12 months
Medicaid: 12 months

References

1. National Comprehensive Cancer Network. Chronic Myeloid Leukemia. Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf. Accessed June 29, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	06/02/2022	07/18/2022
Policy was Reviewed: 1. Initial Approval Criteria, I.B: Updated to include approval criteria for off-label indication, "Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusion". 2. References were reviewed and updated.	6/29/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023