Clinical Policy: Asciminib (Scemblix)

Reference Number: CP.PHAR.565
Effective Date: 03.01.22
Last Review Date: 02.24
Line of Business: Commercial, HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Asciminib (Scemblix®) is a kinase inhibitor.

FDA Approved Indication(s)

Scemblix is indicated for the treatment of adult patients with:

- Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs)
- Ph+ CML in CP with the T315I mutation.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Scemblix is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chronic Myeloid Leukemia (must meet all)**:**

1. Diagnosis of one of the following (a or b):
   a. Ph+ CML in CP;
   b. *BCR*::*ABL1*-positive CML in CP (off-label);
2. Prescribed by or in consultation with an oncologist or 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 TKIs (e.g., imatinib, Bosulif®, Iclusig®, Sprycel®, Tasigna®);
   b. Member has the T315I mutation;
5. Member does not have the following mutations: A337T, P465S, or F359V/I/C;
6. For Scemblix requests, member must use generic asciminib, if available, unless contraindicated or clinically significant adverse effects are experienced;
7. 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 both of the following (i and ii):
      i. 80 mg per day;
      ii. 2 tablets per day;
   b. For Ph+ CML with the T315I mutation: Dose does not exceed both of the following (i and ii):

i. 400 mg per day;
ii. 8 tablets per day;

c. Dose 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*

Approval duration: 6 months

B. Myeloid/Lymphoid Neoplasm with Eosinophilia (off-label) (must meet all)**:**

1. Diagnosis of a myeloid/lymphoid neoplasm with eosinophilia (MLNE) in chronic phase or blast phase;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Documentation of an *ABL1* gene rearrangement;
5. For Scemblix requests, member must use generic asciminib, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. 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*

Approval duration: 6 months

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Scemblix for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. For Scemblix requests, member must use generic asciminib, if available, unless contraindicated or clinically significant adverse effects are experienced;

4. If request is for a dose increase, request meets one of the following (a or b):*
   a. For Ph+ CML**,** previously treated with two or more TKIs: New dose does not exceed both of the following (i and ii):
      i. 80 mg per day;
      ii. 2 tablets per day;
   b. For Ph+ CML with the T315I mutation: New does not exceed both of the following (i and ii):
      i. 400 mg per day;
      ii. 8 tablets per day;
   c. New dose 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*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CML: chronic myeloid leukemia
FDA: Food and Drug Administration
MLNE: myeloid/lymphoid neoplasm with eosinophilia
TKI: tyrosine kinase inhibitor

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Bosulif® (bosutinib)	400 mg PO QD	600 mg/day
Iclusig® (ponatinib)	Starting dose 45 mg PO QD	45 mg/day
imatinib (Gleevec®)	400-600 mg/day PO for chronic phase	800 mg/day
Sprycel® (dasatinib)	100-140 mg/day PO	180 mg/day
Tasigna® (nilotinib)	300 mg PO BID	600 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CML	80 mg PO QD or 40 mg PO BID	80 mg/day
CML with T315I mutation	200 mg PO BID	400 mg/day

VI. Product Availability

Tablets: 20 mg, 40 mg, 100 mg

VII. References

1. Scemblix Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2024. Available at: https://www.novartis.us/sites/www.novartis.us/files/scemblix.pdf. Accessed July 22, 2024.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed November 28, 2023.
3. National Comprehensive Cancer Network. Chronic Myeloid Leukemia Version 1.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf/. Accessed November 28, 2023.
4. National Comprehensive Cancer Network. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf. Accessed November 29, 2023.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.20.21	02.22
Dosing maximum for 400 mg corrected from 6 tabs to 10 tabs per day	03.22.22	
Template changes applied to other diagnoses/indications.	10.06.22	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2023 annual review: no significant changes; added exclusion for A337T or P465S contraindicated mutations per NCCN guidelines; references reviewed and updated.	11.22.22	02.23
1Q 2024 annual review: no significant changes; per NCCN recommendations added coverage for BCR::ABL1-mutated disease (off-label), excluded coverage for those with F359V/I/C mutations (contraindicated per NCCN), and added coverage criteria for myeloid/lymphoid neoplasm with eosinophilia (off-label); references reviewed and updated.	11.28.23	02.24
RT4: added new 100 mg tablet strength.	07.22.24	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible

for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.