Clinical Policy: Asciminib (Scemblix)

Reference Number: ERX.SPA.464
Effective Date: 03.01.22
Last Review Date: 02.22
Line of Business: Commercial, 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, previously treated with two or more tyrosine kinase inhibitors (TKIs)*
- Ph+ CML in chronic phase with the T315I mutation

** This indication is approved under accelerated approval based on major molecular response (MMR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).*

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 Ph+ CML in chronic phase;
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 BCR-ABL T315I mutation;
5. For Scemblix requests, member must use asciminib, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. 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 (2 tablets) per day;
   b. For Ph+ CML with the T315I mutation: Dose does not exceed 400 mg (10 tablets) 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 – Length of Benefit
Medicaid – 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, 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. 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: New dose does not exceed 80 mg (2 tablets) per day;
   b. For Ph+ CML with the T315I mutation: New dose does not exceed 400 mg (10 tablets) 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 – Length of Benefit
Medicaid – 12 months

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CML: chronic myeloid leukemia
FDA: Food and Drug Administration
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 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® (dasatainib)	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

VII. References

1. Scemblix Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2021. Available at: https://www.novartis.us/sites/www.novartis.us/files/scemblix.pdf. Accessed November 16, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed November 16, 2021.
3. National Comprehensive Cancer Network. Cervical Cancer Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf/. Accessed November 16, 2021.

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	

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.