Scemblix® (asciminib)
(Oral)

Document Number: IH-0636

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Scemblix 20 mg tablets: 2 tablets per day
- Scemblix 40 mg tablets: 10 tablets per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- CML: 400 mg per day
- Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes: 80 mg per day

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patients who have the presence of a T315I mutation must have tried and failed or have a contraindication to therapy with Iclusig® (ponatinib); **AND**

- Patient is at least 18 years of age; **AND**

Universal Criteria [1]

- Patient serum lipase and amylase levels will be measured periodically during treatment; **AND**
- Patient does not have uncontrolled hypertension; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**

- Coadministration with itraconazole oral solution containing hydroxypropyl-ß-cyclodextrin; **AND**

Chronic Myeloid Leukemia (CML) † Φ [1-3]

- Patient has Philadelphia chromosome-positive (Ph+) or *BCR::ABL1* positive disease; **AND**
- Patient has chronic phase disease; **AND**
- Used as a single agent; **AND**
- Patient does not have any of the following *BCR::ABL1* mutations: A337T or P465S; **AND**
  - Patient is resistant, or intolerant, or had an inadequate response to prior therapy consisting of a 3 month trial or longer, with at least 2 tyrosine kinase inhibitor (e.g., imatinib, dasatinib, ponatinib, nilotinib, bosutinib, etc.); **OR**
  - Patient's disease has the presence of a T315I mutation

Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions ‡ [2]

- Patient has eosinophilia and ABL1 rearrangement; **AND**
  - Patient has chronic or blast phase myeloid or lymphoid neoplasms; **AND**
    - Used as a single agent; **OR**
  - Patient has blast phase lymphoid, myeloid, or mixed lineage neoplasms; **AND**
    - Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: myelosuppression (e.g., thrombocytopenia, neutropenia, and anemia), pancreatic toxicity, hypertension, cardiovascular toxicity (including ischemic cardiac and CNS conditions, arterial thrombotic and embolic conditions), severe hypersensitivity reactions (including rash, edema, and bronchospasm), etc.; **AND**

Chronic Myelogenous Leukemia (CML) [1,3]

- Treatment response as indicated by one of the following *BCR::ABL1* (IS) transcript levels:
  - ≤ 10% at 3 months or 6 months; **OR**
  - > 0.1% to 1% at 12 months and beyond (if treatment goal is long-term survival); **OR**
  - ≤ 0.1% at 12 months and beyond (if treatment goal is treatment-free remission)

NOTE: cytogenetic assessment of response may be used if quantitative RT-PCR (QPCR) using International Scale (IS) for *BCR::ABL1* is not available

Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes [6]

- Disease response as evidenced by at least one of the following:
  - Decrease in spleen size or improvements in other myelofibrosis symptoms (such as weakness, fatigue, cough, dyspnea, myalgias, angioedema, rash, fever, rhinitis, etc.)
  - Stabilization or improvement as evidenced by a complete response [CR] (i.e. morphologic, cytogenetic or molecular complete response CR), complete hematologic response, or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

V. Dosage/Administration [1]

Indication	Dose
CML	Patients with Ph+ CML-CP (as subsequent therapy): 80 mg taken orally once daily at approximately the same time each day or 40 mg twice daily at approximately 12-hour intervals. Continue treatment until unacceptable toxicity or treatment failure occurs. Patients with Ph+ CML-CP with the T315I Mutation: 200 mg taken orally twice daily at approximately 12-hour intervals. Continue treatment until unacceptable toxicity or treatment failure occurs.
Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes	80 mg taken orally once daily at approximately the same time each day or 40 mg twice daily at approximately 12-hour intervals. Continue treatment until unacceptable toxicity or treatment failure occurs.
Note: The recommended dose of Scemblix is taken orally without food. Avoid food consumption for at least 2 hours before and 1 hour after taking Scemblix.	

VI. Billing Code/Availability Information

HCPCS Code:

- J8999 – Prescription drug, oral, chemotherapeutic, NOS
- C9399 – Unclassified drugs or biologicals *(Hospital outpatient use only)*

NDC:

- Scemblix 20 mg tablet: 00078-1091-xx
- Scemblix 40 mg tablet: 00069-1098-xx

VII. References

1. Scemblix [package insert]. East Hanover, NJ; Novartis, Inc; October 2022. Accessed June 2023.
2. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) for asciminib. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2023.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Chronic Myelogenous Leukemia 2.2023. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2023.
4. Rea D, Mauro MJ, Boquimpani C, et al. A Phase 3, Open-Label, Randomized Study of Asciminib, a STAMP Inhibitor, vs Bosutinib in CML After ≥2 Prior TKIs. Blood. 2021 Aug 18. pii: blood.2020009984. doi: 10.1182/blood.2020009984.
5. Hughes TP, Mauro MJ, Cortes JE, et al. Asciminib in Chronic Myeloid Leukemia after ABL Kinase Inhibitor Failure. N Engl J Med. 2019 Dec 12;381(24):2315-2326. doi: 10.1056/NEJMoa1902328.
6. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions 1.2023. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2023.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C92.10	Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission
C94.8	Other specified leukemias
C94.80	Other specified leukemias not having achieved remission
C94.81	Other specified leukemias, in remission
C94.82	Other specified leukemias, in relapse
C95.1	Chronic leukemia of unspecified cell type

C95.10	Chronic leukemia of unspecified cell type not having achieved remission
C95.11	Chronic leukemia of unspecified cell type, in remission
C95.12	Chronic leukemia of unspecified cell type, in relapse
C96.Z	Other specified malignant neoplasms of lymphoid, hematopoietic and related tissue
C96.9	Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC