DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Scemblix Drug Quantity Management Policy – Per Rx
- Scemblix® (asciminib tablets – Novartis)

REVIEW DATE: 07/17/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Scemblix, a kinase inhibitor, is indicated for the following uses:[1]
- **Chronic myeloid leukemia** (CML), Philadelphia chromosome positive (Ph+), chronic phase, in adults previously treated with two or more tyrosine kinase inhibitors (TKIs).
- **CML**, Ph+, chronic phase with the T315I mutation in adults.

Dosing

Patients with Ph+ CML Chronic Phase Previously Treated with Two or More TKIs
- The recommended dose is 80 mg once daily (QD) at approximately the same time each day or 40 mg orally twice daily (BID) at approximately 12-hour intervals.
- To manage adverse events (AEs), adjust dose to 40 mg QD or 20 mg BID. Discontinue Scemblix in patients unable to tolerate this dose.

Patients with Ph+ CML Chronic Phase with the T315I Mutation
- The recommended dose is 200 mg BID at approximately 12-hour intervals.
- To manage AEs, adjust dose to 160 mg BID. Discontinue Scemblix in patients unable to tolerate this dose.

Availability
Scemblix is available as 20 mg, 40 mg, and 100 mg tablets supplied in bottles containing 60 tablets each.[1]

Off-Label Dosing
Guidelines also support the use of Scemblix for myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase gene fusions.[2] Doses used are similar to those for the FDA-approved indications.

POLICY STATEMENT
This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Scemblix. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Scemblix® (asciminib tablets)	20 mg tablets	60 tablets	180 tablets
	40 mg tablets	60 tablets	180 tablets
	100 mg tablets	120 tablets	360 tablets

Oncology – Scemblix Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA
Scemblix 20 mg tablets
No overrides recommended.

Scemblix 40 mg tablets
1. If the patient requires a dose of 160 mg twice daily to manage an adverse event, approve 240 tablets per dispensing at retail or 720 tablets per dispensing at home delivery.

Scemblix 100 mg tablets
No overrides recommended.

REFERENCES
1. Scemblix® tablets [prescribing information]. East Hanover, NJ: Novartis; April 2024.

2. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions Clinical Practice Guidelines in Oncology (version 2.2024 – June 19, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 10, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	New policy created to provide overrides to previously existing quantity limits. **Scemblix 20 mg tablets:** Quantity limits were changed from 600 tablets per dispensing at retail or 1,800 tablets per dispensing at home delivery to 60 tablets per dispensing at retail or 180 tablets per dispensing at home delivery. No clinical overrides apply. **Scemblix 40 mg tablets:** Quantity limits were changed from 300 tablets per dispensing at retail or 900 tablets per dispensing at home delivery to 60 tablets per dispensing at retail or 180 tablets per dispensing at home delivery. New clinical override criteria were added to approve 240 tablets per dispensing at retail or 720 tablets per dispensing at home delivery if the patient requires a dose of 160 mg twice daily to manage an adverse event. **Scemblix 100 mg tablets:** New quantity limits were added to approve 120 tablets per dispensing at retail or 360 tablets per dispensing at home delivery. No clinical overrides apply.	07/17/2024