DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Copiktra Drug Quantity Management Policy – Per Rx
- Copiktra® (duvelisib capsules – Secura Bio)

REVIEW DATE: 09/11/2024

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

Copiktra, a phosphatidylinositol 3-kinase (PI3K) inhibitor, is indicated for the treatment of relapsed or refractory **chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)** after at least two prior therapies in adults.[1]

Dosing

The recommended dose of Copiktra is 25 mg twice daily (BID) in a 28-day cycle. Swallow capsules whole, do not open, break, or chew.[1] To manage adverse events, the dose of Copiktra may need to be reduced to 15 mg BID or Copiktra may need to be discontinued (details provided in the prescribing information.) The dose of Copiktra should also be reduced to 15 mg BID if it will be co-administered with a strong cytochrome P450 (CYP)3A4 inhibitor. Patients taking Copiktra should avoid taking a strong CYP3A4 inducer. If Copiktra will be used concomitantly with a moderate CYP3A4 inducer, the dose should be increased to 40 mg BID (if the original dose was 25 mg BID) or 25 mg BID (if the original dose was 15 mg BID).

Availability

Copiktra is available as a 15 mg and 25 mg capsule in cartons containing 56 capsules each (two 28-count blister packs).

Off-Label Dosing

Copiktra is also used off-label for the treatment of T-cell lymphoma.[2] The NCCN guidelines on T-cell lymphoma (version 04.2024 – May 28, 2024) recommend Copiktra as "preferred" initial palliative intent therapy or second-line or and subsequent therapy for peripheral T-cell lymphoma; as second-line and subsequent therapy for relapsed/refractory disease for breast implant-associated anaplastic large cell lymphoma; and for hepatosplenic T-cell lymphoma as a single agent for refractory disease after two first-line therapy regimens (all category 2A). According to the guidelines, in the phase II study, the preferred dosing regimen of Copiktra was 75 mg BID for 2 cycles followed by 25 mg BID for long-term disease control.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Copiktra. 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 the duration noted below.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Copiktra® (duvelisib capsules)	15 mg capsules	56 capsules	168 capsules
	25 mg capsules	56 capsules	168 capsules

Oncology – Copiktra 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

Copiktra 15 mg capsules

No overrides recommended.

Copiktra 25 mg capsules

1. If the patient is initiating treatment for T-cell lymphoma or requires additional induction dosing for T-cell lymphoma, approve 168 capsules per dispensing at retail and a one-time override for 392 capsules at home delivery.
   Note: The approval duration at retail is 56 days to accommodate two 28-day dosing cycles. At home delivery, 392 capsules is a quantity sufficient for 2 cycles at 75 mg twice daily (BID), followed by 25 mg BID.

REFERENCES

1. Copiktra® capsules [prescribing information]. Las Vegas, NV: Secura Bio; July 2024.
2. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 4.2024 – May 28, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 6, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	New policy was created to provide overrides to existing quantity limits.	09/11/2024