DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Alunbrig Drug Quantity Management Policy – Per Rx
- Alunbrig® (brigatinib tablets – ARIAD/Takeda)

REVIEW DATE: 11/21/2023

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

Alunbrig, a kinase inhibitor, is indicated for the treatment of adults with **anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC)** as detected by an FDA-approved test.[1]

Dosing

The recommended dose of Alunbrig for the treatment of ALK-positive, metastatic NSCLC is 90 mg once daily (QD) for the first 7 days, then, if tolerated, increased to 180 mg QD until disease progression or unacceptable toxicity.[1] If Alunbrig is interrupted for ≥ 14 days for reasons other than adverse reactions, the patient should resume dosing at 90 mg QD for 7 days prior to increasing to the previously tolerated dose.

The Alunbrig Prescribing Information provides recommendations for dose modifications to manage adverse reactions.[1] These recommendations are in Table 1. If a patient cannot tolerate a 60 mg QD dose, Alunbrig should be discontinued.

Table 1. Recommended Alunbrig Dose Reductions.[1]

Dosage	Dose Reduction		
	First	Second	Third

90 mg QD	60 mg QD	Permanently Discontinue	NA
180 mg QD	120 mg QD	90 mg QD	60 mg QD

QD – Once daily; NA – Not applicable.

If Alunbrig must be co-administered with a strong cytochrome P450 (CYP)3A4 inhibitor, reduce the daily dose by approximately 50% (i.e., 180 mg to 90 mg).[1] Reduce the dose by approximately 40% if Alunbrig is co-administered with a moderate CYP3A4 inhibitor (i.e., 180 mg to 120 mg). If co-administration of Alunbrig with a moderate CYP3A inducer cannot be avoided, increase the Alunbrig dose in 30 mg increments after 7 days of treatment, up to a maximum of twice the Alunbrig dose that was tolerated prior to initiating therapy with the inducer. Examples of CYP3A inducers include carbamazepine, rifampin, rifabutin, ritonavir, St. John's wort. Modifications of the daily dose are also needed for patient with severe hepatic impairment (40% reduction) and severe renal impairment (50% reduction).

Availability

Alunbrig is available as 30 mg tablets, 90 mg tablets, 180 mg tablets, and a Starter Pack containing 7 x 90 mg tablets and 23 x 180 mg tablets.[1]

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Alunbrig. 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, unless otherwise noted.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Alunbrig® (brigatinib tablets)	30 mg tablets	60 tablets	180 tablets
	90 mg tablets	30 tablets	90 tablets
	180 mg tablets	30 tablets	90 tablets
	Starter Pack (7 x 90 mg tablets and 23 x 180 mg tablets)	30 tablets (1 pack)	30 tablets (1 pack)

Oncology – Alunbrig 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

Alunbrig 30 mg tablets

1. If the patient requires a dose reduction to 120 mg once daily, approve 120 tablets per dispensing at retail or 360 tablets per dispensing at home delivery.
2. If the patient is taking a moderate or strong cytochrome P450 (CYP)3A inducer, approve the requested quantity not to exceed 360 tablets per dispensing at retail or 1,080 tablets per dispensing at home delivery.
   Note: Examples of CYP3A inducers include, but are not limited to, carbamazepine, rifampin, rifabutin, ritonavir, St. John's wort).

Alunbrig 90 mg tablets
No overrides recommended.

Alunbrig 180 mg tablets
1. If the patient is taking a moderate or strong cytochrome P450 (CYP)3A inducer, approve 60 tablets per dispensing at retail or 180 tablets per dispensing at home delivery.
   Note: Examples of CYP3A inducers include, but are not limited to, carbamazepine, rifampin, rifabutin, ritonavir, St. John's wort).

Alunbrig Starter Pack
No overrides recommended.

REFERENCES

1. Alunbrig® tablets [prescribing information]. Cambridge, MA: ARIAD/Takeda; February 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to include the existing quantity limits when the product is obtained via home delivery. **Alunbrig 30 mg tablets**: Criteria for a one-time override for patient taking a cytochrome P450 inducer was updated to approve an ongoing override for an additional quantity if the patient is taking a moderate or strong cytochrome P450 inducer.	11/16/2022
Annual Revision	No criteria changes.	11/21/2023