DRUG QUANTITY MANAGEMENT POLICY – PER RX

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

REVIEW DATE: 11/16/2022

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.

Automation: None.

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)

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.