

# Sample Letter of Medical Necessity

[Date]

[Contact at Health Insurance Company]  
[Title]  
[Name of Health Insurance Company]  
[Address]  
[City, State, ZIP Code]

Insured: [First and last name]  
Patient: [First and last name]  
Policy Number: [Number]  
Group Number: [Number]  
Patient Date of Birth: [MM/DD/YYYY]

Dear [Name of Contact],

I am writing on behalf of my patient, [name of patient], to request that [name of health insurance company] approve coverage for Aliqopa™ (copanlisib) for injection. Aliqopa is indicated for the treatment of adult patients with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies. Accelerated approval was granted for this indication based on overall response rate.<sup>1</sup> Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. Copanlisib (Aliqopa™) is listed as a category 2A option for treating third-line follicular lymphoma (FL) within NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®).<sup>2</sup> This letter documents the medical necessity for use of Aliqopa with my patient and provides information about [name of patient]'s medical history and treatment, as well as a copy of the Aliqopa Prescribing Information.

[Name of patient] is a [age]-year-old [male or female] with a diagnosis of [patient's diagnosis] as of [date of diagnosis]. [Name of patient] has been in my care for [patient's diagnosis] since [date]. [Provide a brief discussion of patient's relevant medical history, condition/symptoms and therapy to date, including other treatments attempted and results].

Based on the above information, Aliqopa is indicated and medically necessary for [name of patient's] treatment. If you have any further questions, please contact me at [physician's telephone number]. Thank you in advance for your immediate attention to this request.

Sincerely,

[Physician's Name]  
[Physician's Practice Name]

Attachments: [original claim form, copy of denial or explanation of benefits (if applicable), copy of patient's insurance card, Aliqopa Prescribing Information, FDA approval letter, etc]

Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-cell Lymphomas. V.6.2017. © 2017 National Comprehensive Cancer Network, Inc. All rights reserved. Accessed [DATE], 2017. To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

**References:** 1. Aliqopa (copanlisib) for injection [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; February 2022. 2. Data on file. Bayer, Whippany, NJ  
2. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas V.4.2018. © National Comprehensive Cancer Network, Inc. 2018. All rights reserved. Accessed July 23, 2018. To view the most recent and complete version of the guideline, go online to NCCN.org.

## Indication

ALIQOPA (copanlisib) is indicated for the treatment of adult patients with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies.

Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

## Important Safety Information

**Infections:** Serious, including fatal, infections occurred in 19% of 317 patients treated with ALIQOPA monotherapy. The most common serious infection was pneumonia. Monitor patients for signs and symptoms of infection and withhold ALIQOPA for Grade 3 and higher infection.

Serious pneumocystis jiroveci pneumonia (PJP) infection occurred in 0.6% of 317 patients treated with ALIQOPA monotherapy. Before initiating treatment with ALIQOPA, consider PJP prophylaxis for populations at risk. Withhold ALIQOPA in patients with suspected PJP infection of any grade. If confirmed, treat infection until resolution, then resume ALIQOPA at previous dose with concomitant PJP prophylaxis.

**Hyperglycemia:** Grade 3 or 4 hyperglycemia (blood glucose 250 mg/dL or greater) occurred in 41% of 317 patients treated with ALIQOPA monotherapy. Serious hyperglycemic events occurred in 2.8% of patients. Treatment with ALIQOPA may result in infusion-related hyperglycemia. Blood glucose levels typically peaked 5 to 8 hours post-infusion and subsequently declined to baseline levels for a majority of patients; blood glucose levels remained elevated in 17.7% of patients one day after ALIQOPA infusion. Of 155 patients with baseline HbA1c <5.7%, 16 (10%) patients had HbA1c >6.5% at the end of treatment.

Of the twenty patients with diabetes mellitus treated in CHRONOS-1, seven developed Grade 4 hyperglycemia and two discontinued treatment. Patients with diabetes mellitus should only be treated with ALIQOPA following adequate glucose control and should be monitored closely.

Achieve optimal blood glucose control before starting each ALIQOPA infusion. Withhold, reduce dose, or discontinue ALIQOPA depending on the severity and persistence of hyperglycemia.

**Hypertension:** Grade 3 hypertension (systolic 160 mmHg or greater or diastolic 100 mmHg or greater) occurred in 26% of 317 patients treated with ALIQOPA monotherapy. Serious hypertensive events occurred in 0.9% of 317 patients. Treatment with ALIQOPA may result in infusion-related hypertension. The mean change of systolic and diastolic BP from baseline to 2 hours post-infusion on Cycle 1 Day 1 was 16.8 mmHg and 7.8 mmHg, respectively. The mean BP started decreasing approximately 2 hours post-infusion; BP remained elevated for 6 to 8 hours after the start of the ALIQOPA infusion. Optimal BP control should be achieved before starting each ALIQOPA infusion. Monitor BP pre- and post-infusion. Withhold, reduce dose, or discontinue ALIQOPA depending on the severity and persistence of hypertension.

**Non-infectious Pneumonitis:** Non-infectious pneumonitis occurred in 5% of 317 patients treated with ALIQOPA monotherapy. Withhold ALIQOPA and conduct a diagnostic examination of a patient who is experiencing pulmonary symptoms such as cough, dyspnea, hypoxia, or interstitial infiltrates on radiologic exam.

Please click here for full [Prescribing Information](#).

Patients with pneumonitis thought to be caused by ALIQOPA have been managed by withholding ALIQOPA and administration of systemic corticosteroids. Withhold, reduce dose, or discontinue ALIQOPA depending on the severity and persistence of non-infectious pneumonitis.

**Neutropenia:** Grade 3 or 4 neutropenia occurred in 24% of 317 patients treated with ALIQOPA monotherapy. Serious neutropenic events occurred in 1.3%. Monitor blood counts at least weekly during treatment with ALIQOPA. Withhold, reduce dose, or discontinue ALIQOPA depending on the severity and persistence of neutropenia.

**Severe Cutaneous Reaction:** Grade 3 and 4 cutaneous reactions occurred in 2.8% and 0.6% of 317 patients treated with ALIQOPA monotherapy respectively. Serious cutaneous reaction events were reported in 0.9%. The reported events included dermatitis exfoliative, exfoliative rash, pruritus, and rash (including maculopapular rash). Withhold, reduce dose, or discontinue ALIQOPA depending on the severity and persistence of severe cutaneous reactions.

**Embryo-Fetal Toxicity:** Based on findings in animals and its mechanism of action, ALIQOPA can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of copanlisib to pregnant rats during organogenesis caused embryo-fetal death and fetal abnormalities in rats at maternal doses as low as 0.75 mg/kg/day (4.5 mg/m<sup>2</sup>/day body surface area) corresponding to approximately 12% the recommended dose for patients. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment and for one month after the last dose.

**Adverse Drug Reactions:** Serious adverse reactions were reported in 44 (26%) patients. The most frequent serious adverse reactions that occurred were pneumonia (8%), pneumonitis (5%) and hyperglycemia (5%). Adverse reactions resulted in dose reduction in 36 (21%) and discontinuation in 27 (16%) patients. The most frequently observed adverse drug reactions (≥20%) in ALIQOPA-treated patients were: hyperglycemia (54%), leukopenia (36%), diarrhea (36%), decreased general strength and energy (36%), hypertension (35%), neutropenia (32%), nausea (26%), thrombocytopenia (22%), and lower respiratory tract infections (21%).

**Drug Interactions:** Avoid concomitant use with strong CYP3A inducers. Reduce the ALIQOPA dose to 45 mg when concomitantly administered with strong CYP3A inhibitors.

**Lactation:** Advise women not to breastfeed. Advise a lactating woman not to breastfeed during treatment with ALIQOPA and for 1 month after the last dose.

