Aliqopa™ Resource Connections

Aliqopa™ (copanlisib) for Injection Sample Letter of Appeal

Aliqopa Resource Connections (ARC)

Phone: 833-ALIQOPA (833-254-7672), 9 AM–7 PM ET, Monday–Friday; Select Option 1 for Access Counselors, Option 2 for Aliqopa™ $0 Co-Pay Program, or Option 3 for Bayer Medical Information

Fax: 833-4ARC FAX (833-427-2329)

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Information provided in this resource is for informational purposes only and does not guarantee that codes will be appropriate or that coverage and reimbursement will result. Customers should consult with their payers for all relevant coverage, coding, and reimbursement requirements. It is the sole responsibility of the provider to select proper codes and ensure the accuracy of all claims used in seeking reimbursement. Neither this resource nor ARC is intended as legal advice or as a substitute for a provider's independent professional judgment.

Please see Important Safety Information on page 3 and click here for full Prescribing Information.

PP-860-US-0562 12/17

Sample Letter of Appeal

[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 requesting an appeal for the medical necessity of Aliqopa™ (copanlisib) for injection for [name of patient] on [dates of service]. [Name of health insurance company] denied a claim due to [summarize insurer's stated reason for claim denial].

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. 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®). [Name of patient] has been diagnosed with [patient's diagnosis] as of [date of diagnosis], and [provide patient's relevant medical history, condition/symptoms and therapy to date, including other treatments and results]. I believe Aliqopa is medically necessary and clinically appropriate for [name of patient].

Thank you in advance for your review and consideration for coverage. If you have any questions or require additional information regarding this patient, please contact me at [physician's telephone number].

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]

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. 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 maculo-papular 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^2/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 at least 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 at least 1 month after the last dose.

Please click here for full Prescribing Information.

Aliqopa™ (copanlisib) 60 mg vial for injection