Aliqopa™ (copanlisib) 60 mg vial for injection

Reimbursement Guide

Physician Office/Freestanding Center

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 Aliqopa™ Resource Connections (ARC) is intended as legal advice or as a substitute for a provider's independent professional judgment.

Please see Important Safety Information on page 2 and click here for full Prescribing Information.

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. 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.

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.

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.

Please click here for full Prescribing Information.

Introduction

Bayer has developed this resource to provide healthcare professionals (HCPs) administering Aliqopa™ in a freestanding center with coverage, coding, and reimbursement information for Aliqopa.

The information in this resource provides information for accessing Aliqopa and the submission of claims for the appropriate services. Providers should confirm the appropriate coverage, coding, and reimbursement with the applicable payer or claims processor before submitting claims for an item or service. Providers must ensure that all claims submitted to payers are accurate, complete, and adequately supported by documentation in the medical record. The following content is for informational purposes only and does not guarantee that codes will be appropriate or that coverage and reimbursement will result. Final coding and billing decisions for any item or service must be made by the HCP after considering the medical necessity of the items and services, the policies and procedures of the payer, and the applicable local, state, or federal laws.

Provider and Patient Support Services for Aliqopa

Aliqopa™ Resource Connections

The ARC program is the central point of contact to facilitate Aliqopa access for patients. Access Counselors are available to provide support services Monday through Friday, 9:00 AM to 7:00 PM ET.

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)

Visit: www.aliqopa.com

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Billing and Coding for Aliqopa™ in the Physician Office/ Freestanding Center Site of Care

Healthcare Common Procedure Coding System (HCPCS) Codes

Claims for physician-administered drugs billed under the medical benefit must be submitted with a HCPCS code to identify the drug administered to the patient. Until a permanent HCPCS code is assigned to Aliqopa, providers will need to submit claims using an unclassified, or miscellaneous, HCPCS code. The following unclassified HCPCS codes may be reported:

Unclassified HCPCS Code[1]	Description	Site of Service
J9999	Not otherwise classified antineoplastic drugs	Physician Office
J3490	Unclassified drugs	

REMEMBER: It is important to confirm with the payer which unclassified HCPCS code will be accepted for Aliqopa claims.

National Drug Code (NDC)

Payers will often require claims for unclassified drugs to include the NDC for the administered drug. For drugs that do not have a permanent HCPCS code, the NDC should always be appended to the claim.

To convert the 10-digit NDC registered with the Food and Drug Administration (FDA) for Aliqopa to an 11-digit NDC, a payer may require you to add a leading 0 (zero) or an asterisk (*) to the first position in the middle set of numbers.

	Strength	FDA-specified 10-Digit NDC (5-3-2 format)[2]	11-Digit NDC (5-4-2 format)
Aliqopa	60 mg (one single-dose vial per carton)	50419-385-01	50419-0385-01

Drug Administration Services

To report the administration of an intravenous (IV) infusion of Aliqopa, with direct physician or other qualified HCP supervision, it may be appropriate to use the following Current Procedural Terminology (CPT)® Code:

CPT® Code[3]	Description
96413	Chemotherapy administration, IV infusion technique; up to 1 hour, single or initial substance/drug

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Diagnosis Codes

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

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The following International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes are listed in the table below may be appropriate for patients receiving Aliqopa:

ICD-10-CM[4]	Code Description
C82.00 – C82.09	Follicular lymphoma grade I
C82.10 – C82.19	Follicular lymphoma grade II
C82.20 – C82.29	Follicular lymphoma grade III
C82.30 – C82.39	Follicular lymphoma grade IIIa
C82.80 – C82.89	Other types of follicular
C82.90 – C82.99	Follicular lymphoma, unspecified

The 5th digit underlined in the table above should be reported to the highest level of specificity using the descriptions from the table below:

5th Digit[4]	Description
0	Unspecified site
1	Lymph nodes of head, face, and neck
2	Intrathoracic lymph nodes
3	Intra-abdominal lymph nodes
4	Lymph nodes of axilla and upper limb
5	Lymph nodes of inguinal region and lower limb
6	Intrapelvic lymph nodes
7	Spleen
8	Lymph nodes of multiple sites
9	Extranodal and solid organ sites

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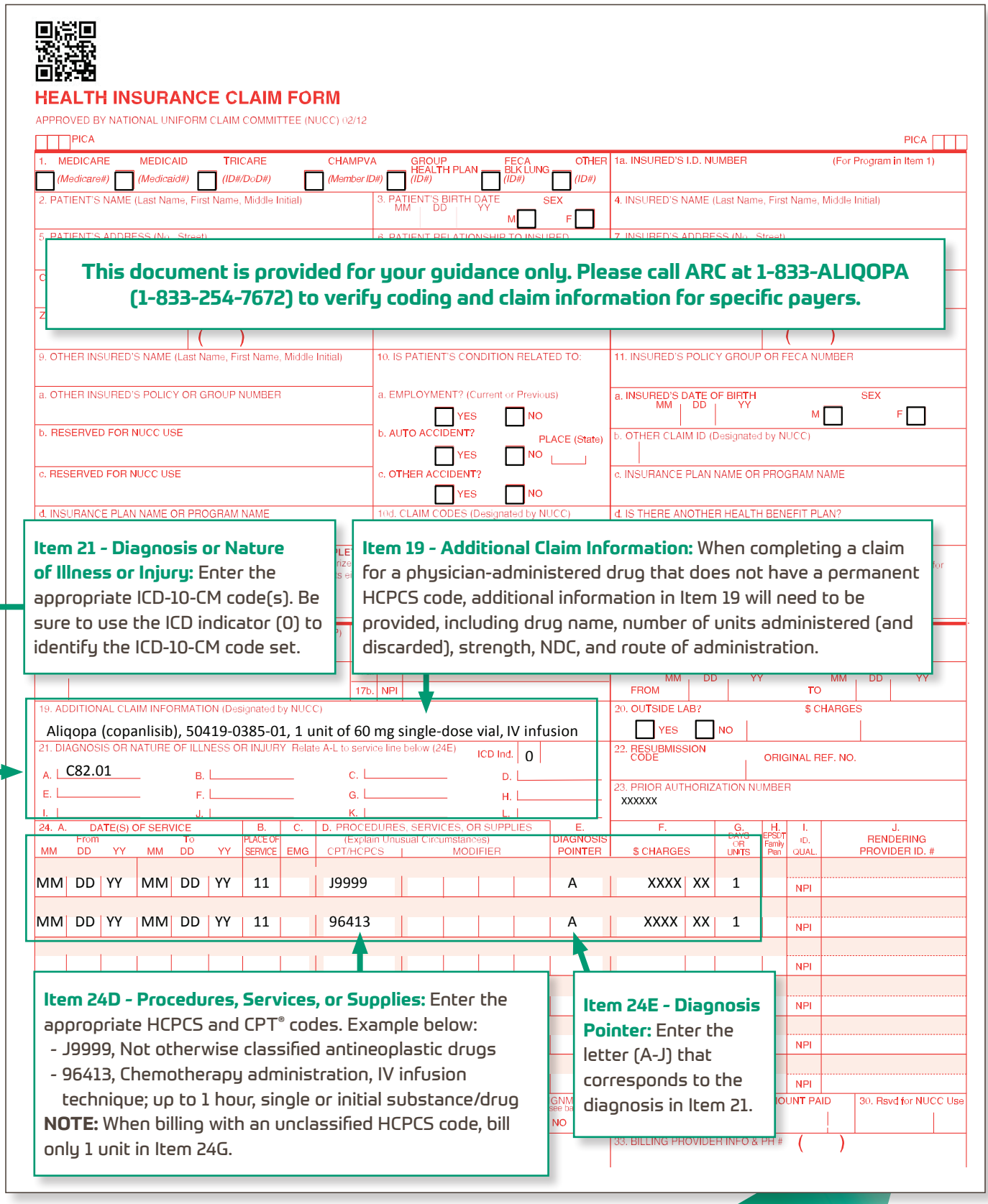
Please see additional Important Safety Information on page 2 and click here for full Prescribing Information.

Sample CMS-1500 Claim Form

The figure below is an example of a claim for Aliqopa™ administered in the physician office.



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Tips for Claim Submission

To accurately complete the claim form for patients receiving Aliqopa™, the following steps should be considered:

- Initiate a patient-specific insurance benefit verification through ARC or conduct a patient-specific insurance benefit verification through the patient's health insurance payer
- Confirm if prior authorization is required and follow steps needed to obtain (if applicable) and provide the prior authorization reference number when submitting a claim to the payer
- Review coding of the claim form before submitting to the payer
- Include additional documentation supporting medical necessity with the claim form if requested by the payer
- Track claim submission and provider reimbursement

Additional Documentation for Claim Filing

The following documentation may be requested by payers when processing a claim for Aliqopa:

- Patient medical history
- Physician clinical notes on the patient's condition and prior treatment for the condition
- Letter of medical necessity
- NDC for Aliqopa™ (copanlisib) for injection
- Prescribing Information
- FDA approval letter

References

1. 2017 HCPCS Level II Expert. Eden Prairie, MN. Optum360; 2017: pages 24, 88, 95.
2. Aliqopa™ (copanlisib) [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; 2017.
3. CPT® 2017 Professional Edition. Chicago, IL. American Medical Association; 2017: page 662.
4. 2017 ICD-10-CM Expert for Hospitals. Eden Prairie, MN. Optum360; 2017: pages 474-475.

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