HOSPITAL OUTPATIENT CODING AND BILLING INFORMATION SHEET FOR KYPROLIS® (CARFILZOMIB) FOR INJECTION

Item	Revenue Code	Coding Information (HCPCS/CPT/ICD)	Notes
KYPROLIS	**Medicare:** 0636, drugs requiring detailed coding **Other Payers:** 0250, general pharmacy; **OR** 0636, if required by a given payer	J9047, injection, carfilzomib, 1 mg[1]	KYPROLIS is supplied in single-dose vials containing 60 mg, 30 mg, or 10 mg of carfilzomib.[3] The NDC numbers for KYPROLIS, in the 11-digit format, are as follows[3]: - 60-mg vial: 76075-0101-01 - 30-mg vial: 76075-0102-01 - 10-mg vial: 76075-0103-01
Administration	Appropriate revenue code for the cost center in which the service is performed	96409, chemotherapy administration, intravenous push technique (including infusions less than 15 minutes), single or initial substance/drug[2] OR 96413, chemotherapy administration, IV infusion technique; up to 1 hour, single or initial substance/drug[2]	KYPROLIS can be administered as a 10-minute or 30-minute IV infusion, depending on the selected regimen[3]: - At the priming dose of 20 mg/m^2 and at the therapeutic dose of 27 mg/m^2 twice-weekly (KRd or K): KYPROLIS is administered as a 10-minute IV infusion. - At the priming dose of 20 mg/m^2 and at the therapeutic dose of 70 mg/m^2 once-weekly (Kd): KYPROLIS is administered as a 30-minute IV infusion. - At the priming dose of 20 mg/m^2 and at the therapeutic dose of 56 mg/m^2 twice-weekly (Kd or K): KYPROLIS is administered as a 30-minute IV infusion.
Diagnosis/ Condition	N/A	Appropriate diagnosis code(s) for patient condition	**ICD-10-CM Example:** C90.02, multiple myeloma in relapse[4]

The information provided in this Coding and Billing Information document is of a general nature and for informational purposes only and is not intended to be a comprehensive list nor instructive. Coding and coverage policies change periodically and often without warning. The responsibility to determine coverage and reimbursement parameters, and appropriate coding for a particular patient and/or procedure, is always the responsibility of the provider or physician. The information provided in this section should in no way be considered a guarantee of coverage or reimbursement for any product or service.

INDICATIONS

- KYPROLIS® is indicated in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy.
- KYPROLIS® is indicated as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.

IMPORTANT SAFETY INFORMATION FOR KYPROLIS

Cardiac Toxicities

- New onset or worsening of pre-existing cardiac failure (e.g., congestive heart failure, pulmonary edema, decreased ejection fraction), restrictive cardiomyopathy, myocardial ischemia, and myocardial infarction including fatalities have occurred following administration of KYPROLIS. Some events occurred in patients with normal baseline ventricular function. Death due to cardiac arrest has occurred within one day of administration.
- Monitor patients for signs or symptoms of cardiac failure or ischemia. Evaluate promptly if cardiac toxicity is suspected. Withhold KYPROLIS for Grade 3 or 4 cardiac adverse events until recovery, and consider whether to restart at 1 dose level reduction based on a benefit/risk assessment.
- While adequate hydration is required prior to each dose in Cycle 1, monitor all patients for evidence of volume overload, especially patients at risk for cardiac failure. Adjust total fluid intake as clinically appropriate.
- For patients ≥ 75 years, the risk of cardiac failure is increased. Patients with New York Heart Association Class III and IV heart failure, recent myocardial infarction, conduction abnormalities, angina, or arrhythmias may be at greater risk for cardiac complications and should have a comprehensive medical assessment prior to starting treatment with KYPROLIS and remain under close follow-up with fluid management.

Please see additional Important Safety Information for KYPROLIS on pages 5-6.

Kyprolis™ (carfilzomib) for injection

Hospital Outpatient Administration of KYPROLIS at the Therapeutic Dose of 27 mg/m²

Anytown Hospital
100 Main Street
Anytown, Anystate 01010

8 PATIENT NAME: Smith, Jane
9 PATIENT ADDRESS: 123 Main Street, Anytown, Anystate 12345

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES
0636	Drugs/detailed coding	J9047	MMDDYY	60	XXXXX	
0335	Chemotherapy-IV	96409	MMDDYY	1	XXXXX	

PAGE ____ OF ____ CREATION DATE TOTALS

66 DX: C90.02

PRODUCT CODE (BOX 44)
Document use of product with J9047, injection, carfilzomib, 1 mg.

Note: *Payer requirements for documenting discarded drug amount, including use of the JW modifier, might vary.*

SERVICE UNITS (BOX 46)
Report unit of service. For example, 60 units for J9047 corresponds to 60 mg of KYPROLIS.

REVENUE CODES (BOX 42) AND DESCRIPTIONS (BOX 43)
Product
Medicare: Use revenue code 0636, drugs requiring detailed coding.
Other payers: Use revenue code 0250, general pharmacy (or 0636, if required by a given payer).

Related administration procedure
Use most appropriate revenue code for cost center where services were performed (eg, 0335 Chemotherapy-IV).

PROCEDURE CODE (BOX 44)
Use CPT code representing procedure performed, such as: 96409, chemotherapy administration, intravenous push technique (including infusions less than 15 minutes), single or initial substance/drug.

Note: *At the therapeutic dose of 27 mg/m² (KRd or K), KYPROLIS is administered as a 10-minute IV infusion.*

DIAGNOSIS CODE (BOX 67)
Document appropriate diagnosis code(s) corresponding to patient's diagnosis.

An example of an ICD-10-CM code includes: C90.02, multiple myeloma in relapse.

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC National Uniform Billing Committee THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

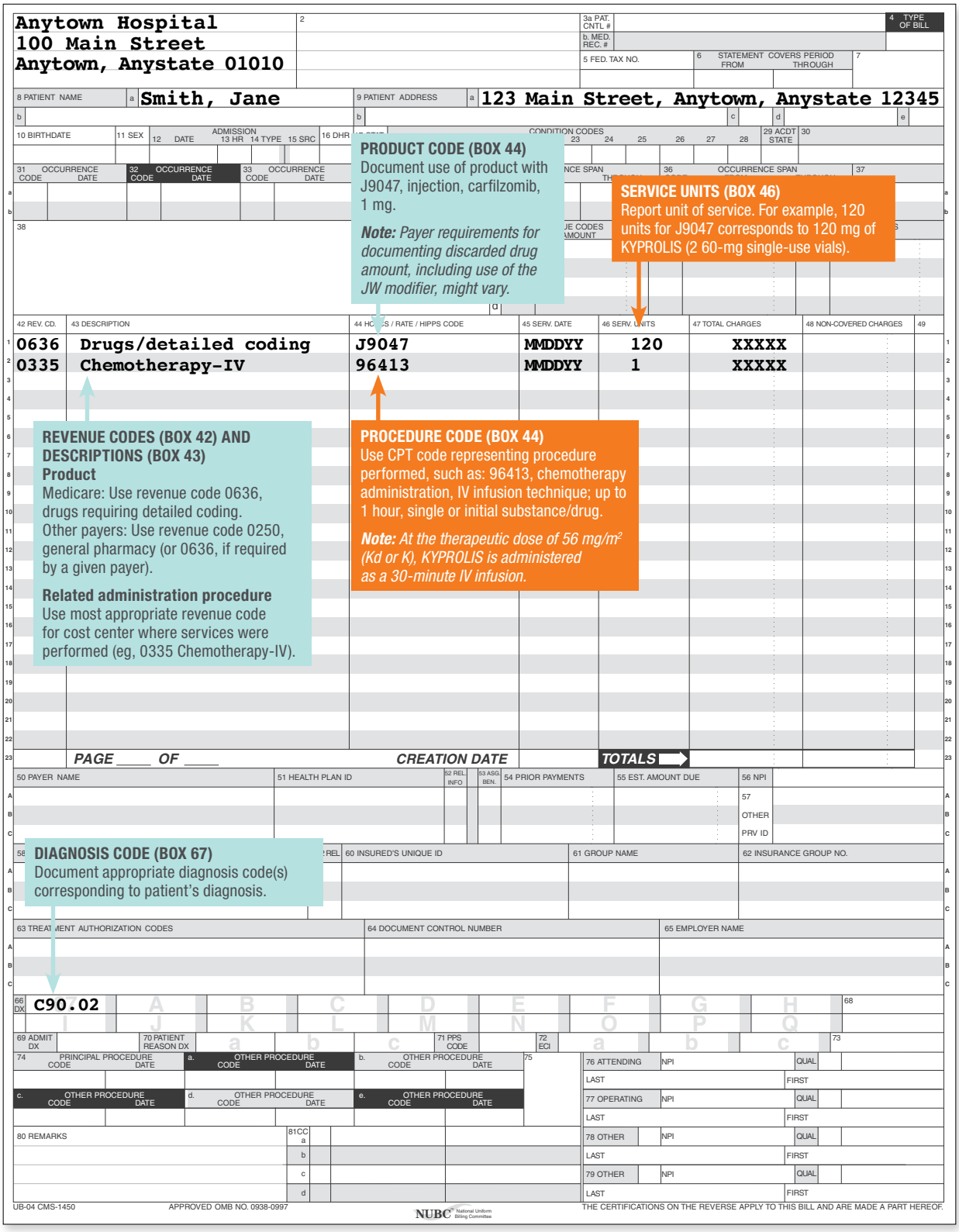
These sample forms are intended as a reference for coding and billing for product and associated services. They are not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

Please see Important Safety Information for KYPROLIS on pages 5-6.

Kyprolis™ (carfilzomib) for injection

THE SAMPLE UB-04 (CMS 1450) FOR HOSPITAL OUTPATIENT — KYPROLIS AT 70 mg/m^2 OR 56 mg/m^2

Hospital Outpatient Administration of KYPROLIS at the Therapeutic Dose of 70 mg/m^2 or 56 mg/m^2



These sample forms are intended as a reference for coding and billing for product and associated services. They are not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

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Kyprolis™ (carfilzomib) for injection

AMGEN ASSIST 360™
Support, Simplified

SEE HOW WE CAN HELP YOUR PATIENTS

Offering the tools, information, and support for Amgen products that make a difference for your patients.

We've centralized the support your patients may need into a complete program that's designed with ease and simplicity in mind. When your patients enroll in Amgen Assist 360™, their **Amgen Nurse Ambassador*** is a single point of contact to help them find the resources† that are most important to them.

Co-Pay and Reimbursement Resources†

Connect patients to specialists to help with insurance benefit verification and put them in touch with programs that may help them afford their medication, such as Amgen FIRST STEP™.

Referrals to Resources† for Day-to-Day Living, Transportation, and Lodging

Refer patients to independent nonprofit organizations that may provide counseling, community resources, and assistance with treatment-related travel costs, such as gas, tolls, parking, airfare, and lodging.

Amgen FIRST STEP™ Is Streamlining Its Co-Pay Program for Eligible‡ Commercially Insured Patients

The Amgen FIRST STEP™ Program can help your eligible commercially insured patients cover their out-of-pocket prescription costs, including deductible, co-insurance, and co-payment. Nine Amgen brands, including KYPROLIS, have been consolidated into a single co-pay card program under Amgen FIRST STEP™.

To enroll your practice in the Amgen FIRST STEP™ Program, call **1-888-65-STEP1** (1-888-657-8371).

The Amgen FIRST STEP™ Prepaid MasterCard® is issued by Comerica Bank pursuant to license by MasterCard® International Incorporated. No cash or ATM access. MasterCard® is a registered trademark of MasterCard® International Incorporated. This card can be used only to cover the co-payment for eligible prescriptions covered under the program at participating merchant locations where Debit MasterCard® is accepted.

* Nurse Ambassadors are there to support, not replace, your treatment plan and do not provide medical advice or case management services. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

† Resources include referrals to independent nonprofit patient assistance programs. Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofits' criteria. Amgen has no control over these programs and provides referrals as a courtesy only.

‡ Terms, conditions, and program maximums apply. See AmgenFIRSTSTEP.com for details. This program is not open to patients receiving prescription reimbursement under any federal, state, or government-funded healthcare program. Not valid where prohibited by law.

Call **1-888-4ASSIST** (1-888-427-7478)
Monday to Friday, 9:00 am to 8:00 pm ET,
or visit **AmgenAssist360.com**

References:

1. CMS. 2018 Table of Drugs. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Downloads/2018-Table-of-Drugs.pdf. Accessed October 9, 2018.
2. American Medical Association. Current Procedural Terminology (CPT®) copyright 2017 American Medical Association. 2018. All rights reserved. **3.** KYPROLIS® (carfilzomib) prescribing information, Onyx Pharmaceuticals Inc., an Amgen Inc. subsidiary. **4.** American Medical Association. *ICD-10-CM*. 2018.

Please see Important Safety Information for KYPROLIS on pages 5-6.

Kyprolis™ (carfilzomib) for injection

Acute Renal Failure

- Cases of acute renal failure, including some fatal renal failure events, and renal insufficiency adverse events (including renal failure) have occurred. Acute renal failure was reported more frequently in patients with advanced relapsed and refractory multiple myeloma who received KYPROLIS monotherapy. Monitor renal function with regular measurement of the serum creatinine and/or estimated creatinine clearance. Reduce or withhold dose as appropriate.

Tumor Lysis Syndrome

- Cases of Tumor Lysis Syndrome (TLS), including fatal outcomes, have occurred. Patients with a high tumor burden should be considered at greater risk for TLS. Adequate hydration is required prior to each dose in Cycle 1, and in subsequent cycles as needed. Consider uric acid lowering drugs in patients at risk for TLS. Monitor for evidence of TLS during treatment and manage promptly, and withhold until resolved.

Pulmonary Toxicity

- Acute Respiratory Distress Syndrome (ARDS), acute respiratory failure, and acute diffuse infiltrative pulmonary disease such as pneumonitis and interstitial lung disease have occurred. Some events have been fatal. In the event of drug-induced pulmonary toxicity, discontinue KYPROLIS.

Pulmonary Hypertension

- Pulmonary arterial hypertension (PAH) was reported. Evaluate with cardiac imaging and/or other tests as indicated. Withhold KYPROLIS for PAH until resolved or returned to baseline and consider whether to restart based on a benefit/risk assessment.

Dyspnea

- Dyspnea was reported in patients treated with KYPROLIS. Evaluate dyspnea to exclude cardiopulmonary conditions including cardiac failure and pulmonary syndromes. Stop KYPROLIS for Grade 3 or 4 dyspnea until resolved or returned to baseline. Consider whether to restart based on a benefit/risk assessment.

Hypertension

- Hypertension, including hypertensive crisis and hypertensive emergency, has been observed, some fatal. Control hypertension prior to starting KYPROLIS. Monitor blood pressure regularly in all patients. If hypertension cannot be adequately controlled, withhold KYPROLIS and evaluate. Consider whether to restart based on a benefit/risk assessment.

Venous Thrombosis

- Venous thromboembolic events (including deep venous thrombosis and pulmonary embolism) have been observed. Thromboprophylaxis is recommended for patients being treated with the combination of KYPROLIS with dexamethasone or with lenalidomide plus dexamethasone. The thromboprophylaxis regimen should be based on an assessment of the patient's underlying risks.
- Patients using hormonal contraception associated with a risk of thrombosis should consider an alternative method of effective contraception during treatment.

Infusion Reactions

- Infusion reactions, including life-threatening reactions, have occurred. Symptoms include fever, chills, arthralgia, myalgia, facial flushing, facial edema, vomiting, weakness, shortness of breath, hypotension, syncope, chest tightness, or angina. These reactions can occur immediately following or up to 24 hours after administration. Premedicate with dexamethasone to reduce the incidence and severity of infusion reactions. Inform patients of the risk and of symptoms and seek immediate medical attention if they occur.

Hemorrhage

- Fatal or serious cases of hemorrhage have been reported. Hemorrhagic events have included gastrointestinal, pulmonary, and intracranial hemorrhage and epistaxis. Promptly evaluate signs and symptoms of blood loss. Reduce or withhold dose as appropriate.

Thrombocytopenia

- KYPROLIS causes thrombocytopenia with recovery to baseline platelet count usually by the start of the next cycle. Monitor platelet counts frequently during treatment. Reduce or withhold dose as appropriate.

Please see additional Important Safety Information for KYPROLIS on page 6.

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Hepatic Toxicity and Hepatic Failure

- Cases of hepatic failure, including fatal cases, have occurred. KYPROLIS can cause increased serum transaminases. Monitor liver enzymes regularly regardless of baseline values. Reduce or withhold dose as appropriate.

Thrombotic Microangiopathy

- Cases of thrombotic microangiopathy, including thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS), including fatal outcome, have occurred. Monitor for signs and symptoms of TTP/HUS. Discontinue if diagnosis is suspected. If the diagnosis of TTP/HUS is excluded, KYPROLIS may be restarted. The safety of reinitiating KYPROLIS is not known.

Posterior Reversible Encephalopathy Syndrome (PRES)

- Cases of PRES have occurred in patients receiving KYPROLIS. If PRES is suspected, discontinue and evaluate with appropriate imaging. The safety of reinitiating KYPROLIS is not known.

Increased Fatal and Serious Toxicities in Combination with Melphalan and Prednisone in Newly Diagnosed Transplant-ineligible Patients

- In a clinical trial of transplant-ineligible patients with newly diagnosed multiple myeloma comparing KYPROLIS, melphalan, and prednisone (KMP) vs bortezomib, melphalan, and prednisone (VMP), a higher incidence of serious and fatal adverse events was observed in patients in the KMP arm. KMP is not indicated for transplant-ineligible patients with newly diagnosed multiple myeloma.

Embryo-fetal Toxicity

- KYPROLIS can cause fetal harm when administered to a pregnant woman.
- Females of reproductive potential should be advised to avoid becoming pregnant while being treated with KYPROLIS and for 6 months following the final dose. Males of reproductive potential should be advised to avoid fathering a child while being treated with KYPROLIS and for 3 months following the final dose. If this drug is used during pregnancy, or if pregnancy occurs while taking this drug, the patient should be apprised of the potential hazard to the fetus.

ADVERSE REACTIONS

- The most common adverse reactions in the combination therapy trials: anemia, neutropenia, diarrhea, dyspnea, fatigue, thrombocytopenia, pyrexia, insomnia, muscle spasm, cough, upper respiratory tract infection, hypokalemia.
- The most common adverse reactions in monotherapy trials: anemia, fatigue, thrombocytopenia, nausea, pyrexia, dyspnea, diarrhea, headache, cough, edema peripheral.

Please click here to see full Prescribing Information for KYPROLIS.

Kyprolis™ (carfilzomib) for injection