Patient Support Program

Dosing and Vial Size Considerations

KYPROLIS® REIMBURSEMENT & ACCESS GUIDE

CONFIDENCE IN KYPROLIS® ACCESS

AMGEN Support⁺

Amgen SupportPlus – personalized support providers and patients can count on.

INDICATIONS

- KYPROLIS[®] (carfilzomib) is indicated in combination with dexamethasone, or with lenalidomide plus dexamethasone, or with daratumumab plus hyaluronidase-fihj plus dexamethasone, or with isatuximab plus dexamethasone for the treatment of adult 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), 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 reactions until recovery, and consider whether to restart at 1 dose level reduction based on a benefit/risk assessment.

Please see additional Important Safety Information for KYPROLIS on the next page.

Kyprolis[®] (carfilzomib) for Injection

KYPROLIS® OFFERS PROVEN EFFECTIVE TREATMENT OPTIONS IN RELAPSED OR **REFRACTORY MULTIPLE MYELOMA (RRMM)**

FDA-APPROVED KYPROLIS® TRIPLET REGIMENS:

Twice-weekly KRd27¹

10-Minute Infusion Time

20 mg/m² Priming Dose on Days 1 and 2 of Cycle 1 to evaluate tolerability

27 mg/m² Target Therapeutic Dose starting on Day 8 of Cycle 1

Administer on 2 consecutive days each week for 3 weeks, followed by a 12-day rest period as part of a 28-day treatment cycle. From Cycle 13, omit doses of KYPROLIS® on Days 8 and 9.

Continue until disease progression or until unacceptable toxicity occurs. Discontinue KYPROLIS® after Cycle 18.

Once-weekly DKd70¹



20 mg/m² 30-Minute Priming Dose Infusion Time on Day 1 of Cycle 1 to evaluate tolerability

70 mg/m² Target Therapeutic Dose starting on Day 8 of Cycle 1

Administer on 1 day each week for 3 weeks, followed by a 13-day rest period as part of a 28-day treatment cycle. Continue until disease progression or until unacceptable toxicity occurs.

Twice-weekly DKd56¹



20 mg/m² Priming Dose on Days 1 and 2 of Cycle 1 to evaluate tolerability

56 mg/m² Target Therapeutic Dose starting on Day 8 of Cycle 1

Administer on 2 consecutive days each week for 3 weeks, followed by a 12-day rest period as part of a 28-day treatment cycle. Continue until disease progression or until unacceptable toxicity occurs.

Twice-weekly Isa-Kd56¹

30-Minute



20 mg/m² **Priming Dose** on Days 1 and 2 of Cycle 1 to evaluate tolerability

56 mg/m² Target Therapeutic Dose starting on Day 8 of Cycle 1

Administer on 2 consecutive days each week for 3 weeks, followed by a 12-day rest period as part of a 28-day treatment cycle. Continue until disease progression or until unacceptable toxicity occurs.

IMPORTANT SAFETY INFORMATION FOR KYPROLIS

Cardiac Toxicities, continued

- 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 the next page.

FDA-APPROVED KYPROLIS® DOUBLET REGIMENS:

Once-weekly Kd70¹



20 mg/m² **Priming Dose** on Day 1 of Cycle 1 to evaluate tolerability

Administer on 1 day each week for 3 weeks, followed by a 13-day rest period as part of a 28-day treatment cycle. Continue until disease progression or unacceptable toxicity occurs.

Twice-weekly Kd56¹



30-Minute Infusion Time

20 mg/m² **Priming Dose** on Days 1 and 2 of Cycle 1 to evaluate tolerability

Administer on 2 consecutive days each week for 3 weeks, followed by a 12-day rest period as part of a 28-day treatment cycle. Continue until disease progression or unacceptable toxicity occurs.

4 carfilzomib (KYPROLIS®) combination therapies received Category 1 recommendations from the National Comprehensive Cancer Network® (NCCN[®]) for treating RRMM at first relapse and beyond.²

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) are used to inform payers of evidence supporting treatment recommendations.³

SELECT ADMINISTRATION PRECAUTIONS¹ Adequate hydration is required

- Adequate hydration is required prior to dosing in Cycle 1, especially in patients at high risk of tumor lysis syndrome or renal toxicity
- IV fluids prior to each dose in Cycle 1)
- If needed, give additional IV fluids following KYPROLIS® administration and continue oral and/or IV fluids, as needed, in subsequent cycles
- . Monitor patients for evidence of volume overload and adjust hydration to individual patient needs, especially in patients with or at risk for cardiac failure. Modify dosing based on toxicity

DKd56 = KYPROLIS[®] + IV daratumumab + dexamethasone; DKd70 = KYPROLIS[®] + IV daratumumab + dexamethasone; FDA = Food and Drug Administration; $IV = intravenous: Kd56 = KYPROLIS^{\circ} + dexamethasone: Kd70 = KYPROLIS^{\circ} + dexamethasone: Kd27 = KYPROLIS^{\circ} + lenalidomide + dexamethasone: Kd70 = KYPROLIS^{\circ} + dexamethasone: Kd70 = KYPROL$ NCCN = National Comprehensive Cancer Network.

Refer to the full Prescribing Information and Dosing and Administration Guide for recommended actions and dose modifications.

70 mg/m² Target Therapeutic Dose starting on Day 8 of Cycle 1

56 mg/m² Target Therapeutic Dose starting on Day 8 of Cycle 1

• Consider hydration with both oral fluids (30 mL/kg at least 48 hours before Cycle 1, Day 1) and IV fluids (250 mL to 500 mL of appropriate



Dosing and Vial Size Considerations

KYPROLIS® OFFERS 3 SINGLE-DOSE VIAL SIZES

KYPROLIS® IS SUPPLIED IN 3 SINGLE-DOSE VIAL SIZES: 10 mg, 30 mg, **OR 60 mg OF CARFILZOMIB.**¹



It is important to bill for the correct number of units when submitting a claim—1 mg of KYPROLIS® corresponds to 1 unit of service.4,5

IMPORTANT SAFETY INFORMATION FOR KYPROLIS

Acute Renal Failure

 Cases of acute renal failure, including some fatal renal failure events, and renal insufficiency (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.

BILLING CONSIDERATIONS FOR KYPROLIS®



Correct conversion of used KYPROLIS® amount into billed units of service

Based on the assigned permanent J-code, 1 mg of KYPROLIS® corresponds to 1 unit of service: • J9047, injection, carfilzomib, 1 mg^{4,5}



Use of the JW modifier and appropriate documentation of discarded KYPROLIS® amount (if required by payer)

For drugs from single-use vials, Medicare* requires6:

- Reporting the JW modifier for claims with unused drug from single-use vials
- · Documenting the discarded amount in the patient's medical record

For examples, see Coding and Billing Information Sheets for KYPROLIS®.

NOTE: Effective for dates of service on or after July 1, 2023, Medicare Part B claims require the use of the new JZ modifier for single-use vials and containers when there are no discarded drug amounts. Medicare claims continue to require the use of the JW modifier (Drug amount discarded/not administered to any patient) for drugs and biologicals that are separately payable under Medicare Part B with discarded amounts from single-dose containers.⁶



Claim edits with a limit on the number of KYPROLIS® units to be billed per date of service (if implemented by payer)

KYPROLIS® claims submitted to Medicare* are subject to the Medically Unlikely Edit (MUE): • Based on the approved dosing range, Medicare will deny KYPROLIS® claims billed for more

than 210 units per date of service⁷⁻⁹

For considerations on vial size selection and related examples, see the next page.

* Applies to Medicare Fee-for-Service; requirements for Medicare Advantage may vary by plan. Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary: providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

IMPORTANT SAFETY INFORMATION FOR KYPROLIS

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.

Please see additional Important Safety Information for KYPROLIS on the next page.



KYPROLIS® DOSE IS CALCULATED BASED ON PATIENT BODY SURFACE AREA (BSA)¹

DOSE CALCULATION EXAMPLES FOR A HYPOTHETICAL PATIENT WITH A BSA OF 2 m²

| SELECTED KYPROLIS® DOSING ¹ | PATIENT BSA | = | CALCULATED KYPROLIS® DOSE PER ADMINISTRATION |
|--|--------------------|---|---|
| 27 mg/m ² (KRd) | x 2 m ² | = | 54 mg |
| 56 mg/m ² (DKd, Kd, or Isa-Kd) | x 2 m ² | = | 112 mg |
| 70 mg/m ² (DKd or Kd) | x 2 m ² | = | 140 mg |

For patients with a BSA greater than 2.2 m², calculate the dose based upon a BSA of 2.2 m².

IMPORTANT SAFETY INFORMATION FOR KYPROLIS

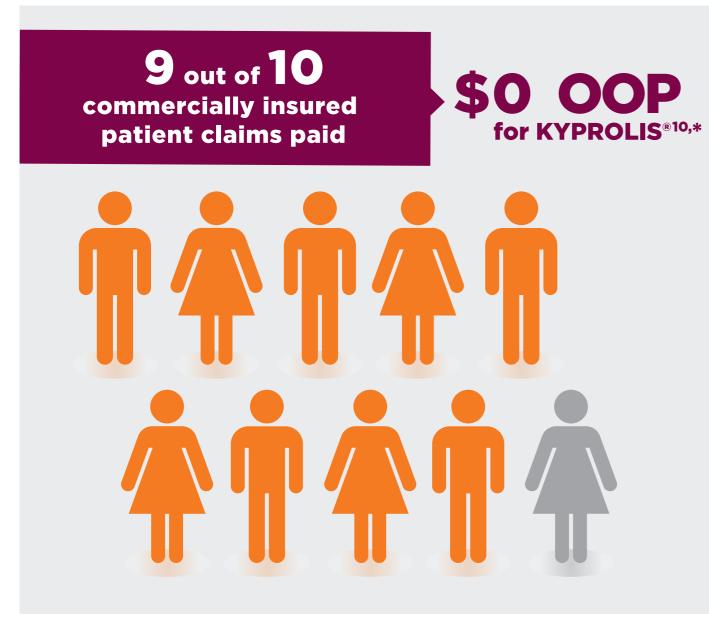
Pulmonary Toxicity

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.



Dosing and Vial Size Considerations

MOST COMMERCIALLY INSURED PATIENTS HAVE A LOW OUT-OF-POCKET (OOP) COST¹⁰



* Based on the analysis of 8,287 KYPROLIS claims paid by commercial payers between January 2022 and December 2022 (as captured by IQVIA LAAD medical claims data). 91% of KYPROLIS® commercially insured patient claims paid \$0 per claim. The remaining 9% of commercially insured patient claims paid on average \$520 per claim. The actual cost may vary depending on the dose, insurance coverage, and eligibility for support programs.¹⁰

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.

Please see Important Safety Information for KYPROLIS on page 12.

60% of claims paid within

*Based on the analysis of 30,787 KYPROLIS claims paid by payers between January 2022 and December 2022 (as captured by IQVIA LAAD medical claims data), including commercial plans, MACs (fee-for-service), Medicare Advantage, and other government payers. The remaining 40% of claims (reimbursed in >21 days) received reimbursement within an average of 47 days.¹⁰





Dosing and Vial Size Considerations

AMGEN Support⁺

We're right here, right when you need us

Resources for your patients

Amgen[®] Nurse Partners

Dedicated Amgen Nurse Partners can offer supplemental support and provide information about resources to help patients access their prescribed medication.

Amgen Nurse Partners' can provide supplemental support, including:

- Guidance on resources that may help lower out-of-pocket medication costs
- Assistance to help your patients stay on track with their medication
- Answers to questions about Amgen SupportPlus

*Amgen Nurse Partners are only available to patients that are prescribed certain Amgen products. They are not part of your patient's treatment team and do not provide medical advice, nursing, or case management services. Amgen Nurse Partners will not inject patients with Amgen medications. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

AMGEN Support⁺ Co-Pay Program

Helping eligible patients save on out-of-pocket costs

The Amgen SupportPlus Co-Pay Program is here to help eligible commercially insured patients pay for their out-of-pocket prescription costs.

- Pay as little as \$0⁺ out-of-pocket for each dose or cycle
- Can be applied to deductible, co-insurance, and co-payment[†]
- No income eligibility requirement

Encourage your patients with private or commercial insurance to check eligibility and enroll at AmgenSupportPlus.com/copay

[†]Eligibility criteria and program maximums apply. See AmgenSupportPlus.com/copay for full Terms and Conditions.

What if my patient doesn't have private or commercial insurance?

Amgen SupportPlus can provide your patients with information about independent nonprofit foundations that may be able to help.*

*Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofit's criteria. Amgen has no control over these programs and provides information as a courtesy only.

Amgen[®] Access Specialists An Amgen Access Specialist can provide live or virtual coverage and access resources to support your patients.

CALL **866-264-2778** Monday to Friday, 9:00 am to 8:00 pm ET, or visit **www.AmgenSupportPlus.com**.





HCP Support Center

Our Amgen[®] SupportPlus Representatives can assist with issues around patient coverage, prior authorizations, co-pay programs, and more.

Patient Support Program

Dosing and Vial Size Considerations

Resources for healthcare professionals

Benefits Verification

- Verify patient's insurance plan coverage details
- **Prior Authorization Requirements**
- Provide payer-specific prior authorization forms **Amgen SupportPlus Customer Portal**
- A tool for managing patient benefits verification and more
- Submit, store, and retrieve benefit verifications electronically

Contact your Amgen Access Specialist for live or virtual support that includes:

- Help with navigating prior authorization, appeals, and fulfillment processes
- Educating on payer requirements and necessary documentation for individual patient support
- Guidance on general reimbursement questions, including product coding and billing information
- Answers to general questions about Amgen SupportPlus programs and other available resources



Patient Support Program

Dosing and Vial Size Considerations

IMPORTANT SAFETY INFORMATION FOR KYPROLIS

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. Provide thromboprophylaxis for patients being treated with the combination of KYPROLIS with dexamethasone or with lenalidomide plus dexamethasone or with daratumumab and dexamethasone. The thromboprophylaxis regimen should be based on an assessment of the patient's underlying risks.
- For patients using hormonal contraception associated with a risk of thrombosis, consider an alternative method of effective contraception during treatment.

Infusion-Related Reactions

 Infusion-related reactions, including life-threatening reactions, have occurred. Signs and symptoms include fever, chills, arthralgia, myalgia, facial flushing, facial edema, laryngeal 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-related reactions.

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.

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.

Progressive Multifocal Leukoencephalopathy (PML)

 Cases of PML, including fatal cases, have occurred. In addition to KYPROLIS, other contributary factors may include prior or concurrent use of immunosuppressive therapy. Consider PML in any patient with new onset of or changes in pre-existing neurological signs or symptoms. If PML is suspected, discontinue and initiate evaluation for PML including neurology consultation.

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 reactions 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.
- Advise pregnant women of the potential risk to a fetus. Females of reproductive potential should use effective contraception during treatment with KYPROLIS and for 6 months following the final dose. Males of reproductive potential should use effective contraception during treatment with KYPROLIS and for 3 months following the final dose.

Adverse Reactions

- The most common adverse reactions occurring in at least 20% of patients taking KYPROLIS in the combination therapy trials: anemia, diarrhea, hypertension, fatigue, upper respiratory tract infection, thrombocytopenia, pyrexia, cough, dyspnea, and insomnia.
- The most common adverse reactions occurring in at least 20% of patients taking KYPROLIS in monotherapy trials: anemia, fatigue, thrombocytopenia, nausea, pyrexia, dyspnea, diarrhea, headache, cough, edema peripheral.

Please click here for full Prescribing Information.



Patient Support Program

Dosing and Vial Size Considerations

KYPROLIS[®] CONFIDENCE ON KYPROLIS[®] ACCESS



A PROVEN EFFECTIVE TREATMENT OPTION FOR YOUR PATIENTS WITH RRMM

- NCCN-preferred or other recommended treatment option for previously treated MM²
- 3 single-dose vial sizes¹

AMGEN Support - personalized support providers and patients can count on.



- Amgen Nurse Partner[†]
- Benefit verification
- Amgen Access Specialists

Call **866-264-2778** Monday to Friday, 9:00 am to 8:00 pm ET, or visit **www.AmgenSupportPlus.com.**

NCCN=National Comprehensive Cancer Network® (NCCN®)

[†] Amgen Nurse Partners are only available to patients that are prescribed certain Amgen products. They are not part of your patient's treatment team and do not provide medical advice, nursing, or case management services. Amgen Nurse Partners will not inject patients with Amgen medications. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

References: 1. KYPROLIS[®] (carfilzomib) prescribing information. Onyx Pharmaceuticals, Inc., an Amgen Inc. subsidiary. **2.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Multiple Myeloma V.3.2023. © National Comprehensive Cancer Network, Inc. 2022. All rights reserved. Accessed June 1, 2023. To view the most recent and complete version of the guideline, 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. **3.** National Comprehensive Cancer Network. About Clinical Practice Guidelines. https://www.nccn.org/guidelines/guidelines-process/ about-nccn-clinical-practice-guidelines. Accessed June 1, 2023. **4.** CMS. 2020 Table of Drugs. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Downloads/2020-Table-of-Drugs.pdf. Accessed June 1, 2023. **5.** CMS. 2020 Alpha-Numeric HCPCS File. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2020-Alpha-Numeric-HCPCS-File. Accessed June 1, 2023. **6.** 2023 Physician Fee Schedule Final Rule (87 FR 79198, 72082 - 72083, November 18, 2022); 2023 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule (87 FR 71988, 72082 - 72083, November 23, 2022); Medicare Program, Discarded Drugs and Biologica/S—JW Modifier and JZ Modifier Policy, Frequently Asked Questions, available at https://www.cms.gov/medicare/fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf. Accessed June 1, 2023. **7.** CMS. Medically Unlikely Edits - Facility Outpatient Hospital Services MUE Table – Effective 07-01-2023. https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/MUE.html. Accessed June 12, 2023. **8.** CMS. Medically Unlikely Edits - Practitioner Services MUE Table – Effective 07-01-2023. https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/MUE.html. Accessed June 1, 2023. **10.** Dat



Oncology

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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 VIALS: 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 follows³: 60-mg vial: 76075-0101-01 30-mg vial: 76075-0102-01 10-mg vial: 76075-0103-01 MEDICARE MUE FOR KYPROLIS³⁻⁶: Under Medicare,* J9047 has a Medically Unlikely Edit (MUE). Based on the approved dosing range, Medicare will deny KYPROLIS claims billed for more than 210 units per date of service. For example, at the BSA of up to 2.2 m², the calculated dose for Kd70 is up to 154 mg JW/JZ MODIFIER⁷: For unused drug from single use vials, some payers (eg, Medicare*) require providers to report the JW modifier on a claim and to document the discarded amount in the patient's medical record. NOTE: Effective for dates of service on or after July 1, 2023, Medicare Part B claims require the use of the new JZ modifier for single-use vials and containers when there are no discarded drug amounts. Medicare Claims continue to require the use of the JW modifier or a resparately payable under Medicare Part B with discarded amounts from single-dose containers.^{11,†} |
| Administration | Appropriate revenue code for the cost center in which the service is performed | 96413, chemotherapy administration, IV infusion technique; up to 1 hour, single or initial substance/drug ¹² OR 96409, chemotherapy administration, intravenous push technique (including infusions less than 15 minutes), single or initial substance/drug ¹² | KYPROLIS[®] can be administered as a 10-minute or 30-minute IV infusion, depending on the selected regimen¹: At the priming dose of 20 mg/m² and at the therapeutic dose of 70 mg/m² once-weekly (Kd or DKd): KYPROLIS[®] is administered as a 30-minute IV infusion. At the priming dose of 20 mg/m² and at the therapeutic dose of 56 mg/m² twice-weekly (Kd, DKd, Isa-Kd, or K): KYPROLIS[®] is administered as a 30-minute IV infusion. At the priming dose of 20 mg/m² and at the therapeutic dose of 56 mg/m² twice-weekly (Kd or K): KYPROLIS[®] is administered as a 30-minute IV infusion. At the priming dose of 20 mg/m² and at the therapeutic dose of 27 mg/m² twice-weekly (KRd or K): KYPROLIS[®] is administered as a 10-minute IV infusion. |
| Diagnosis/ Condition | N/A | Appropriate diagnosis code(s) for patient condition | ICD-10-CM Examples: C90.00, multiple myeloma not having achieved remission C90.02, multiple myeloma in relapse ¹³ |

Beginning January 1, 2023, Medicare requires that all claims submitted by 340B covered entities on OPPS claims (bill type 13X) for separately payable Part B drugs and biologicals must include modifiers "JG" (Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes) or "TB" (Drug or biological acquired with 340B drug pricing program discount, reported for or drugs acquired through the 340B Drug Discount Program. Additional provider types will be required to use these modifiers in 2024.¹¹

*Applies to Medicare fee-for-service; requirements for Medicare Advantage may vary by plan.

[†]Reporting policies for discard units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

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.

BSA = body surface area; $DKd = KYPROLIS^{\circ}$ (carfilzomib)+daratumumab and dexamethasone; IV = intravenous; $Kd = KYPROLIS^{\circ}$ and dexamethasone; $KRd = KYPROLIS^{\circ}$ +lenalidomide and dexamethasone.

IMPORTANT SAFETY INFORMATION FOR KYPROLIS, continued

Acute Renal Failure

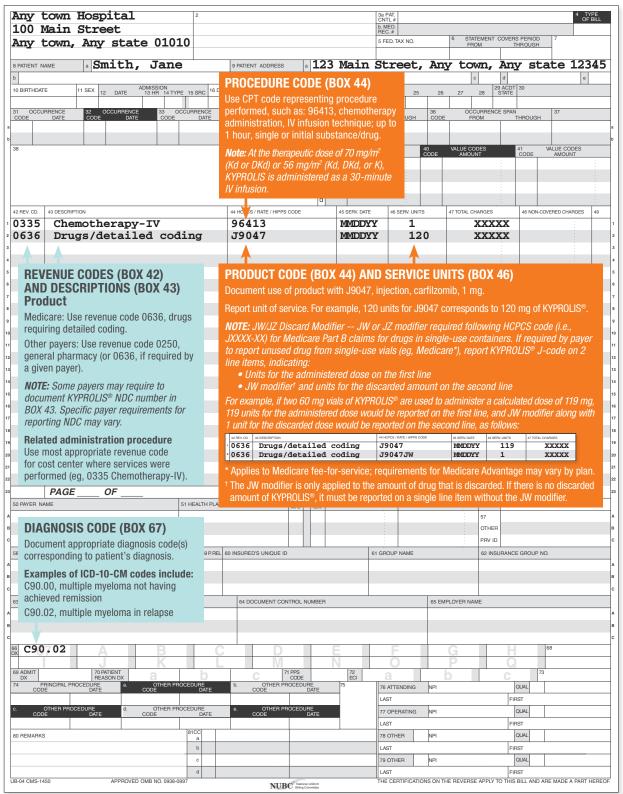
Cases of acute renal failure, including some fatal renal failure events, and renal insufficiency (including renal failure) have occurred. Acute renal failure was reported more frequently in patients with advanced relapsed and refractory multiple myeloma who received KYPROLIS monotherapy. Monitor renal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

Please see additional Important Safety Information for KYPROLIS on page 12 of the folder.



THE SAMPLE UB-04 (CMS 1450) FOR HOSPITAL OUTPATIENT — KYPROLIS[®] AT 70 mg/m² OR 56 mg/m²

Hospital Outpatient Administration of KYPROLIS[®] at the Therapeutic Dose of 70 mg/m² or 56 mg/m²



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.

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

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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.

THE SAMPLE UB-04 (CMS 1450) FOR HOSPITAL OUTPATIENT — **KYPROLIS® AT 27 mg/m²**

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RESOURCES

SUPPORT SERVICES

AMGEN[®] Support⁺

We're right here, right when you need us

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HCP Support Center

Our Amgen® SupportPlus Representatives can assist with issues around patient coverage, prior authorizations, co-pay programs, and more.

Benefits Verification

• Verify patient's insurance plan coverage details

Prior Authorization Requirements

- Provide payer-specific prior authorization forms
- Amgen SupportPlus Customer Portal
- A tool for managing patient benefits verification and more
- Submit, store, and retrieve benefit verifications electronically



Amgen® Access Specialists An Amgen Access Specialist can provide live or virtual coverage and access resources to support your patients.

Contact your Amgen Access Specialist for live or virtual support that includes:

- Help with navigating prior authorization, appeals, and fulfillment processes
- Educating on payer requirements and necessary documentation for individual patient support
- Guidance on general reimbursement questions, including product coding and billing information
- Answers to general questions about Amgen SupportPlus programs and other available resources

Amgen® Nurse Partners Dedicated Amgen Nurse Partners can offer supplemental support and provide information about resources to help patients access their prescribed medication.

Amgen Nurse Partners* can provide supplemental support, including:

- Guidance on resources that may help lower out-of-pocket medication costs
- Assistance to help your patients stay on track with their medication
- Answers to questions about Amgen SupportPlus

* Amgen Nurse Partners are only available to patients that are prescribed certain Amgen products. They are not part of your patient's treatment team and do not provide medical advice, nursing, or case management services. Amgen Nurse Partners will not inject patients with Amgen medications. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.



AMGEN Support⁺ | Co-Pay Program

Helping eligible patients save on out-of-pocket costs

The Amgen SupportPlus Co-Pay Program is here to help eligible commercially insured patients pay for their out-of-pocket prescription costs.

- Pay as little as \$0⁺ out-of-pocket for each dose or cycle
- Can be applied to deductible, co-insurance, and co-payment[†]
- No income eligibility requirement

Encourage your patients with private or commercial insurance to check eligibility and enroll at AmgenSupportPlus.com/copay †Eligibility criteria and program maximums apply. See AmgenSupportPlus.com/copay for full Terms and Conditions.

What if my patient doesn't have private or commercial insurance?

Amgen SupportPlus can provide your patients with information about independent nonprofit foundations that may be able to help.* *Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofit's criteria. Amgen has no control over these programs and provides information as a courtesy only.

> CALL **866-264-2778** Monday to Friday, 9:00 am to 8:00 pm ET, or visit **www.AmgenSupportPlus.com.**



PHYSICIAN OFFICE CODING AND BILLING INFORMATION SHEET FOR KYPROLIS® (CARFILZOMIB) FOR INJECTION

| Item | Coding Information (HCPCS/CPT/ICD) | Notes |
|-------------------------|--|--|
| KYPROLIS | J9047, injection, carfilzomib, 1 mg ¹ | KYPROLIS VIALS: 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 |
| | | MEDICARE MUE FOR KYPROLIS ³⁻⁶ : |
| | | Under Medicare fee-for-service, J9047 has a Medically Unlikely Edit (MUE). Based on the approved dosing range, Medicare will deny KYPROLIS claims billed for more than 210 units per date of service. |
| | | - For example, at the BSA of up to 2.2 $m^2,$ the calculated dose for Kd70 is up to 154 mg |
| | | JW/JZ MODIFIER ⁷ : |
| | | For unused drug from single-use vials, some payers (eg, Medicare fee-for-service) require providers to report the JW modifier on a claim and to document the discarded amount in the patient's medical record. NOTE: Effective for dates of service on or after July 1, 2023, Medicare Part B claims require the use of the new JZ modifier for single-use vials and containers when there are no discarded drug amounts. Medicare claims continue to require the use of the JW modifier (Drug amount discarded/not administered to any patient) for drugs and biologicals that are separately payable under Medicare Part B with discarded amounts from single-dose containers. [‡] |
| Administration | 96413, chemotherapy administration, IV infusion technique; up to 1 hour, single or initial substance/drug ¹² OR 96409, chemotherapy administration, | KYPROLIS[®] can be administered as a 10-minute or 30-minute IV infusion, depending on the selected regimen¹: At the priming dose of 20 mg/m² and at the therapeutic dose of 70 mg/m² once-weekly (DKd or Kd): KYPROLIS[®] is administered as a 30-minute IV infusion. At the priming dose of 20 mg/m² and at the therapeutic dose of 56 mg/m² |
| | intravenous push technique (including infusions less than 15 minutes), single or initial substance/drug ¹² | twice-weekly (DKd, Kd, Isa-Kd, or K): KYPROLIS[®] is administered as a 30-minute IV infusion. At the priming dose of 20 mg/m² and at the therapeutic dose of 27 mg/m² twice-weekly (KRd or K): KYPROLIS[®] is administered as a 10-minute IV infusion. |
| Office visit | Relevant Evaluation and Management (E&M) code*:^ $\!\!\!\!^{\dagger}$ | See payer guidelines. |
| Diagnosis/ Condition | Appropriate diagnosis code(s) for patient condition | ICD-10-CM Example: C90.00, multiple myeloma not having achieved remission C90.02, multiple myeloma in relapse ¹³ |

* Bill relevant E&M code only if a separately identifiable E&M service is performed. Document accordingly.

⁺ Some payers, including Medicare, will not allow a Level 1 office visit to be billed with an injection/infusion code for the same date of service, and only allow for other levels when Modifier 25 is billed.

[‡]Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

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.

BSA = body surface area; DKd = KYPROLIS[®] (carfilzomib)+daratumumab and dexamethasone; IV = intravenous; Kd = KYPROLIS[®] and dexamethasone; KRd = KYPROLIS[®]+lenalidomide and dexamethasone.

IMPORTANT SAFETY INFORMATION FOR KYPROLIS, continued

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.

Please see additional Important Safety Information for KYPROLIS on page 12 of the folder.



THE SAMPLE CMS 1500 FOR PHYSICIAN OFFICE — KYPROLIS® AT 70 mg/m² OR 56 mg/m²

Physician Office Administration of KYPROLIS[®] at the Therapeutic Dose of 70 mg/m² or 56 mg/m²

| PICA | | | | | | | | | | PICA |
|---|---|-------------------------------------|--|--|----------------|--|--|---------------------------------------|---|--------------------------------------|
| 1. MEDICARE MEDICA | _ | CHAMPV | - HEALTH PL | | _ | 1a. INSURED'S | I.D. NUMBER | 7 | (Fo | r Program in Item 1) |
| (Medicare#) (Medicaid | | (Member I | | | (ID#) | | | | | |
| 2. PATIENT'S NAME (Last Nam | | u) | 3. PATIENT'S BIRT | | | 4. INSURED'S I | | | e, Middle | e Initial) |
| 5. PATIENT'S ADDRESS (No., | | | XX XX | | F | 7. INSURED'S | Johr | | | |
| 5555 Any S | | | | | | 7. INSURED 57 | ADDHE55 (N | o., Street) | | |
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| Any town | | AS | 0. RESERVED FOR | NUCC USE | | CIT | | | | Ude Area Code) |
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| 01010 | (XXX) XXX | | | | | | | (|) | aao, waa ooao, |
| 9. OTHER INSURED'S NAME (| \ <i>\</i> | | | | | | ~ | | | |
| 3. OTHER INSORED STRAME (| _astrivanie, mistrivanie, wie | | PRODUCT C | ODE (BOX 24 | 4D) AN | ID SERVI | CE UNIT | IS (BOX) | 24G) | |
| a. OTHER INSURED'S POLICY | OR GROUP NUMBER | | | of product with J ervice. For exam | | | | | 120 (| ng of KYPROLIS®. |
| b. RESERVED FOR NUCC US | <u> </u> | f | or drugs in sing | gle-use containe | ers. If re | quired by pa | ayer to rep | oort unused | d drug | are Part B claims from single-use |
| c. RESERVED FOR NUCC USE | | | vials (eg, Medic | care*), report KYI he administered | PROLIS® | J-code on | 2 line iter | | | |
| d. INSURANCE PLAN NAME O | R PROGRAM NAME | F | | er ^t and units for two 60 mg vials | | | | | | ted dose of 119 mg. |
| DIAGNOSIS COL Document appropria corresponding to par Line A – primary dia Examples of ICD-10 C90.00, multiple my achieved remission C90.02, multiple my 21. DIAGNOS, JOR NATURE C C90.02 A | te diagnosis code(s tient's diagnosis. gnosis code. D-CM codes includ eloma not having eloma in relapse | elate A-L to se v G. G. K. | sxx: sxx: sxx: sxx: sxx: sxx: sxx: sxx: sxx: spplies to Meet modifia amount of KYP vice line below (24E) | scarded dose wo xx4 xx4 xx4 11 xx4 xx4 xx4 11 dicare fee-for-se ier is only applie PROLIS®, it must ICD Ind. L. L. | ould be r | reported on t 59047 59047 Jw equirements amount of o | the second for Medi drug that ngle line i | d line, as fo | illows: tage r d. If th ut the s | |
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| - (BOX 24A OR 24 | iD) 🔟 | | | | | | | NP | 1 | |
| 4 NOTE: Some payers | may require | 1 | I | | | OSIS COD | | | | |
| to document KYPRO | | | l i | i P | OINTE | R (BOX 2 | 24E) | NP | + | |
| 5 number in BOX 24A | or 24D. | | | | | iagnosis. fro | - | , NP | | |
| Specific payer requi | rements for | | | | 1 J . | o each CPT/ | | 7 140 | | |
| 6 reporting NDC may | | | 1 1 | | 0 | Box 24D. | | NP | | |
| 25. FEDERAL TAX I.D. NUMBE | | 26. PATIENT'S A | ACCOUNT NO. | 27. ACCEPT ASSIGN (For govt. claims, see | MENT? | 28. TOTAL CHA | ARGE | 29. AMOUNT I | | 30. Rsvd for NUCC Use |
| 31. SIGNATURE OF PHYSICIA INCLUDING DEGREES OR (I certify that the statements apply to this bill and are made | CREDENTIALS on the reverse | 32. SERVICE FA | ACILITY LOCATION I | | | 33. BILLING PF | ROVIDER INF | 0 & PH # (|) | |
| | - | a. N | D b. | | | a. N | DI | b. | | |
| SIGNED | DATE | 1.11 | | | _ | | | | | 500M (500 (00)) |
| NUCC Instruction Manua | I available at: www.r | nucc.org | PLEASE | E PRINT OR TYP | E | A | PPROVED | J OMR-0938 | 3-1197 | FORM 1500 (02-12) |

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.

Physician Office Administration of KYPROLIS® at the Therapeutic Dose of 27 mg/m²

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| Any town As 2P CODE TELEPHONE (include Area Code) 3. OTHER INSURED'S NAME (Last Name, Field Name, Model Initial PRODUCT CODE (BOX 240) AND SERVICE UNITS (BOX 246) 3. OTHER INSURED'S POLICY OR GROUP NUMBER Document use of product with J9047, injection, carfilzonib, 1 mg. Report unit of service. For example, 60 units for J9047 corresponds to 60 mg of NOTE: JWJZD Discard Modifier - JW or JZ modifier required in box for Medicare for drugs in single-use containers. If required by payer to report numsed drug for vials (eg, Medicare*), report KYPROLIS® J-code on 2 line items, indicating: - Units for the administered dose would be reported on the first line for example, if one 60 mg vial of KYPROLIS® is used to administer a calculated 46 units for the discarded dose would be reported on the second line. For examples of ICD-10-CM codes include: COB.0.0, multiple myeloma not having achieved remission 2DIAGNOS OR NATURE OF ILLNESS OR INJURY Fields A-L tox we have axis axis axis axis axis axis axis axis | STATE | | | | | | | | | 0.000 | | Other | | | · · · · · · · · · · · · · · · · · · · | | | 07475 | | | t | eet | Str | y S | \ny | A | | |
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| c. RESERVED FOR NUCC USE vials (ég, Medicare*), report KYPROLIS* J-code on 2 line items, indicating: unsurrance PLAN NAME OR PROGRAM NAME Units for the administered dose on the first line BEAD BACK OF FORM REFORE COMPLET Units for the administered dose on the first line DIAGNOSIS CODE (BOX 21) JW modifier* and units for the discarded dose would be reported on the first line and JW m with 14 units for the discarded dose would be reported on the second line, as for the administered dose would be reported on the second line, as for the administered dose would be reported on the second line, as for the administered dose would be reported on the first line and JW m with 14 units for the discarded dose would be reported on the second line, as for the administered for service; requirements for Medicare Advantage may achieved remission C09.0.0, multiple myeloma not having achieved remission Image: transmitter of the below (24E) is used to the amount of drug that is discarded. If there amount of KYPROLIS*, it must be reported on a single line item without the JW modifier is only applied to the amount of drug that is discarded. If there amount of KYPROLIS*, it must be reported on a single line item without the JW modifier is only applied to the amount of drug that is discarded. If there amount of KYPROLIS*, it must be reported on a single line item without the JW modifier is only applied to the amount of drug that is discarded. If there amount of KYPROLIS*, it must be reported on a single line item without the JW modifier is only applied to the amount of drug that is discarded. If there amount of KYPROLIS*, it must be reported on a single line item without the JW modifier is only applied to the amount of drug that is discarded. If there amount of VYPROLIS*, it must be reported on a s | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| PIEAD BACK OF FORM REFORE COMPLET DIAGNOSIS CODE (BOX 21) Document appropriate diagnosis code(s) Corresponding to patient's diagnosis. Line A - primary diagnosis code. Examples of ICD-10-CM codes include: C90.00, multiple myeloma in relapse. 21. DIAGNOS J. OR NATURE OF ILLNESS OR INJURY Felate A-L to service line below (24E) Locold B. L. A. A. DATE(S) OF SERVICE M. C. M. C. M. C. M. C. M. K. C. C. D. C. D. C. M. K. L. K. L. K. M. K. M. K. L. K. L. K. L. K. M. <t< td=""><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></t<> | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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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.

THE SAMPLE CMS 1500 FOR PHYSICIAN OFFICE — KYPROLIS® AT 27 mg/m²



RESOURCES

SUPPORT SERVICES

AMGEN Support

We're right here, right when you need us

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HCP Support Center

Our Amgen[®] SupportPlus Representatives can assist with issues around patient coverage, prior authorizations, co-pay programs, and more.

Benefits Verification

• Verify patient's insurance plan coverage details

Prior Authorization Requirements

- Provide payer-specific prior authorization forms
- Amgen SupportPlus Customer Portal
- A tool for managing patient benefits verification and more
- Submit, store, and retrieve benefit verifications electronically



Amgen® Access Specialists

An Amgen Access Specialist can provide live or virtual coverage and access resources to support your patients.

Contact your Amgen Access Specialist for live or virtual support that includes:

- Help with navigating prior authorization, appeals, and fulfillment processes
- Educating on payer requirements and necessary documentation for individual patient support
- Guidance on general reimbursement questions, including product coding and billing information
- Answers to general questions about Amgen SupportPlus programs and other available resources

Amgen[®] Nurse Partners Dedicated Amgen Nurse Partners can offer supplemental support and provide information about resources to help patients access their prescribed medication.

Amgen Nurse Partners* can provide supplemental support, includina:

- Guidance on resources that may help lower out-of-pocket medication costs
- Assistance to help your patients stay on track with their medication
- Answers to questions about Amgen SupportPlus

* Amgen Nurse Partners are only available to patients that are prescribed certain Amgen products. They are not part of your patient's treatment team and do not provide medical advice, nursing, or case management services. Amgen Nurse Partners will not inject patients with Amgen medications. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns



AMGEN Support⁺ | Co-Pay Program

Helping eligible patients save on out-of-pocket costs

The Amgen SupportPlus Co-Pay Program is here to help eligible commercially insured patients pay for their out-of-pocket prescription costs.

- Pay as little as \$0⁺ out-of-pocket for each dose or cycle
- Can be applied to deductible, co-insurance, and co-payment[†]
- No income eligibility requirement

Encourage your patients with private or commercial insurance to check eligibility and enroll at AmgenSupportPlus.com/copay *Eligibility criteria and program maximums apply. See AmgenSupportPlus.com/copay for full Terms and Conditions.

What if my patient doesn't have private or commercial insurance?

Amgen SupportPlus can provide your patients with information about independent nonprofit foundations that may be able to help.* *Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofit's criteria. Amgen has no control over these programs and provides information as a courtesy only.

> CALL 866-264-2778 Monday to Friday, 9:00 am to 8:00 pm ET, or visit www.AmgenSupportPlus.com.

