



Subject to: ☐ Site of Care  
☒ Medication Sourcing

## **Kyprolis® (carfilzomib)** **(Intravenous)**

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### **I. Length of Authorization** <sup>1,5,21,32,36,43</sup>

Coverage will be provided for 6 months and may be renewed (unless otherwise specified).

#### Multiple Myeloma

- Combination therapy with daratumumab/daratumumab and hyaluronidase, lenalidomide, and dexamethasone is limited to eight (8) 28-day treatment cycles
- Combination therapy with isatuximab, lenalidomide, and dexamethasone is limited to ten (10) 28-day treatment cycles.
- Combination therapy with isatuximab and lenalidomide as maintenance therapy is limited to twenty-six (26) 28-day treatment cycles.
- Combination therapy with lenalidomide as maintenance therapy is limited to a maximum of 2 years of treatment.

#### Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma

- Combination therapy with rituximab and dexamethasone (CaRD regimen) is limited to six (6) 21-day induction treatment cycles and eight (8) 56-day maintenance treatment cycles.

### **II. Dosing Limits**

**Max Units (per dose and over time) [HCPCS Unit]:**

- **Multiple Myeloma**
  - 720 billable units (720 mg) every 28 days
- **Systemic Light Chain Amyloidosis**
  - 480 billable units (480 mg) every 28 days
- **Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma**
  - 320 billable units (320 mg) every 21 days

### III. Initial Approval Criteria <sup>1</sup>

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

#### Multiple Myeloma † ‡ Φ <sup>1,2,7,9-11,13-17,19,20,22-29,32-37,39</sup>

- Used as primary therapy for symptomatic disease; **AND**
  - Used in combination with daratumumab/daratumumab and hyaluronidase, lenalidomide, and dexamethasone (*transplant candidates ONLY*); **OR**
  - Used in combination with isatuximab, lenalidomide, and dexamethasone (*transplant candidates ONLY*); **OR**
  - Used in combination with lenalidomide and dexamethasone; **OR**
  - Used in combination with dexamethasone and cyclophosphamide; **OR**
- Used for disease relapse after 6 months following primary induction therapy with the same regimen; **AND**
  - Used in combination with lenalidomide and dexamethasone; **OR**
  - Used in combination with dexamethasone and cyclophosphamide; **OR**
- Used for relapsed or refractory disease after 3 prior therapies; **AND**
  - Used in combination with bendamustine and dexamethasone; **OR**
- Used for previously treated relapsed, progressive, or refractory disease; **AND**
  - Used as a single agent †; **OR**
  - Used in combination with one of the following regimens:
    - Dexamethasone with or without lenalidomide †
    - Dexamethasone and daratumumab/daratumumab and hyaluronidase †
    - Dexamethasone and cyclophosphamide with or without thalidomide
    - Dexamethasone and isatuximab †
    - Dexamethasone and selinexor
    - Dexamethasone and pomalidomide with or without daratumumab/daratumumab and hyaluronidase
    - Dexamethasone and venetoclax (*patients with t(11:14) ONLY*); **OR**
- Used as maintenance therapy for symptomatic disease in transplant candidates; **AND**
  - Used in combination with lenalidomide; **AND**
    - Used after response to primary myeloma therapy; **OR**
    - Used for response or stable disease following an autologous hematopoietic cell transplant (HCT); **OR**
    - Used for response or stable disease following a tandem autologous or allogeneic HCT for high risk patients; **OR**

- Used in combination with lenalidomide and isatuximab following primary therapy with isatuximab, lenalidomide, and dexamethasone; **OR**
- Used for the management of POEMS (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, skin changes) syndrome; **AND**
  - Used in combination with dexamethasone as a replacement for bortezomib

#### **Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma ‡<sup>2,5,18,21</sup>**

- Used in combination with rituximab and dexamethasone (CaRD regimen); **AND**
  - Used as primary therapy; **OR**
  - Used for relapsed disease; **AND**
    - CaRD regimen was previously used as primary therapy; **AND**
    - Patient had a prolonged response (i.e., 24 months) to CaRD therapy

#### **Systemic Light Chain Amyloidosis ‡<sup>2,30,31,38</sup>**

- Patient has newly diagnosed disease; **AND**
  - Used in combination with dexamethasone; **AND**
  - Patient has significant neuropathy; **OR**
- Patient has relapsed or refractory disease; **AND**
  - Patient has non-cardiac disease; **AND**
    - Used as a single agent; **OR**
    - Used in combination with dexamethasone; **OR**
  - Patient has significant neuropathy; **AND**
    - Used as repeat of initial therapy if relapse-free for several years; **AND**
    - Used in combination with dexamethasone

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

## **IV. Renewal Criteria<sup>1,2</sup>**

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Duration of authorization has not been exceeded (*refer to Section I*); **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: cardiac toxicity (e.g., CHF, pulmonary edema, decreased ejection fraction, cardiomyopathy, myocardial ischemia, myocardial infarction, etc.), pulmonary toxicity (e.g., acute respiratory

distress syndrome [ARDS], acute respiratory failure, etc.), pulmonary hypertension, dyspnea, severe infusion-related reactions, tumor lysis syndrome (TLS), thrombocytopenia, hepatic toxicity/failure, thrombotic microangiopathy (e.g., thrombotic thrombocytopenic purpura/hemolytic uremic syndrome [TTP/HUS], etc.), acute renal failure, severe hypertension, posterior reversible encephalopathy syndrome (PRES), venous thromboembolic events (e.g., deep venous thrombosis, pulmonary embolism, etc.), hemorrhage, progressive multifocal leukoencephalopathy (PML), etc.

## V. Dosage/Administration <sup>1,5,7,9,12,20-22,24-28,30,32-36,38-43</sup>

Indication	Dose*
Multiple Myeloma (primary therapy OR disease relapse ≥6 months following primary induction therapy with the same regimen)	<u>Combination with lenalidomide and dexamethasone (KRd)</u> <u>20/36 regimen:</u> <ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on days 1 and 2; if tolerated, increase to 36 mg/m<sup>2</sup> days 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycles 2 through 8: 36 mg/m<sup>2</sup> days 1, 2, 8, 9, 15, and 16 of a 28-day treatment cycle</li> </ul> <i>May proceed to maintenance therapy in combination with lenalidomide for up to 2 years (see maintenance dosing section in table below).</i>
	<u>Combination with cyclophosphamide and dexamethasone (KCd)</u> <u>20/36 regimen:</u> <ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on days 1 and 2; if tolerated, increase to 36 mg/m<sup>2</sup> days 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycles 2 through 9: 36 mg/m<sup>2</sup> days 1, 2, 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycle 10 and beyond: 36 mg/m<sup>2</sup> on days 1, 2, 15, and 16 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity</li> </ul>
	<u>20/70 regimen:</u> <ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on day 1; if tolerated, increase to 70 mg/m<sup>2</sup> days 8 and 15 of a 28-day treatment cycle</li> <li>– Cycles 2 through 9: 70 mg/m<sup>2</sup> days 1, 8, and 15 of a 28-day treatment cycle</li> <li>– Cycle 10 and beyond: 70 mg/m<sup>2</sup> on days 1 and 15 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity</li> </ul>
Multiple Myeloma (primary therapy-transplant candidates only)	<u>Combination with daratumumab/daratumumab and hyaluronidase, lenalidomide and dexamethasone (Dara-KRd)</u> <u>20/56 regimen:</u> <ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on day 1; if tolerated, increase to 56 mg/m<sup>2</sup> on days 8 and 15 of a 28-day treatment cycle</li> <li>– Cycles 2 through 8: 56 mg/m<sup>2</sup> on days 1, 8, and 15 of a 28-day treatment cycle</li> </ul>
	<u>Combination with isatuximab, lenalidomide, and dexamethasone (Isa-KRd)</u> <u>20/56 regimen:</u> <ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on day 1; if tolerated, increase to 56 mg/m<sup>2</sup> on days 8 and 15 of a 28-day treatment cycle</li> <li>– Cycles 2 through 10: 56 mg/m<sup>2</sup> on days 1, 8, and 15 of a 28-day treatment cycle</li> </ul>

	<i>May proceed to maintenance therapy in combination with isatuximab and lenalidomide for up to 26 maintenance cycles (see maintenance dosing section in table below)</i>
Multiple Myeloma (relapsed, progressive, or refractory disease)	<p><u>Single agent</u></p> <p><u>20/27 regimen:</u></p> <ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on days 1 and 2; if tolerated, increase to 27 mg/m<sup>2</sup> on days 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycles 2 through 12: 27 mg/m<sup>2</sup> on days 1, 2, 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycle 13 and beyond: 27 mg/m<sup>2</sup> on days 1, 2, 15, and 16 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity</li> </ul> <p><u>20/56 regimen:</u></p> <ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on days 1 and 2; if tolerated, increase to 56 mg/m<sup>2</sup> on days 8, 9, 15, and 16 of a 28-day treatment cycle.</li> <li>– Cycles 2 through 12: 56 mg/m<sup>2</sup> on days 1, 2, 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycle 13 and beyond: 56 mg/m<sup>2</sup> on days 1, 2, 15, and 16 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity</li> </ul> <p><u>Combination with lenalidomide and dexamethasone (KRd)</u></p> <p><u>20/27 regimen:</u></p> <ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on days 1 and 2; if tolerated, increase to 27 mg/m<sup>2</sup> on days 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycles 2 through 12: 27 mg/m<sup>2</sup> on days 1, 2, 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycles 13 through 18: 27 mg/m<sup>2</sup> on days 1, 2, 15, and 16 of a 28-day treatment cycle; beginning with cycle 19, lenalidomide and dexamethasone may be continued (until disease progression or unacceptable toxicity) <b>without</b> carfilzomib</li> </ul> <p><u>Combination with dexamethasone (Kd)</u></p> <p><u>20/56 regimen:</u></p> <ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on days 1 and 2; if tolerated, increase to 56 mg/m<sup>2</sup> on days 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycle 2 and beyond: 56 mg/m<sup>2</sup> on days 1, 2, 8, 9, 15, and 16 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity</li> </ul> <p><u>20/70 regimen:</u></p> <ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on day 1; if tolerated, increase to 70 mg/m<sup>2</sup> on day 8 and 15 of a 28-day treatment cycle</li> <li>– Cycle 2 and beyond: 70 mg/m<sup>2</sup> on days 1, 8, and 15 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity</li> </ul> <p><u>Combination with daratumumab (or daratumumab and hyaluronidase-fihj) and dexamethasone (DKd)</u></p> <p><u>20/56 regimen:</u></p> <ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on days 1 and 2; if tolerated, increase to 56 mg/m<sup>2</sup> on days 8, 9, 15 and 16 of a 28-day treatment cycle</li> <li>– Cycle 2 and beyond: 56 mg/m<sup>2</sup> on days 1, 2, 8, 9, 15, and 16 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity</li> </ul>

	<p><u>20/70 regimen:</u></p> <ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on day 1; if tolerated, increase to 70 mg/m<sup>2</sup> on day 8 and 15 of a 28-day treatment cycle</li> <li>– Cycle 2 and beyond: 70 mg/m<sup>2</sup> on days 1, 8, and 15 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity</li> </ul> <p><u>Combination with cyclophosphamide, thalidomide, and dexamethasone</u></p> <p><u>20/36 regimen:</u></p> <ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on days 1 and 2; if tolerated, increase to 36 mg/m<sup>2</sup> days 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycle 2 and beyond: 36 mg/m<sup>2</sup> days 1, 2, 8, 9, 15, and 16 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity</li> </ul> <p><u>Combination with cyclophosphamide and dexamethasone (KCd)</u></p> <p><u>20/36 regimen:</u></p> <p>Induction</p> <ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on days 1 and 2; if tolerated, increase to 36 mg/m<sup>2</sup> days 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycles 2 through 6: 36 mg/m<sup>2</sup> days 1, 2, 8, 9, 15, and 16 of a 28-day treatment cycle</li> </ul> <p>Maintenance</p> <ul style="list-style-type: none"> <li>– Cycles 7 through 12: 36 mg/m<sup>2</sup> on days 1, 2, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycle 13 and beyond: 36 mg/m<sup>2</sup> on days 1 and 2 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity</li> </ul> <p><u>Combination with isatuximab-irfc and dexamethasone (Isa-Kd)</u></p> <p><u>20/56 regimen:</u></p> <ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on days 1 and 2; if tolerated, increase to 56 mg/m<sup>2</sup> on days 8, 9, 15 and 16 of a 28-day treatment cycle</li> <li>– Cycle 2 and beyond: 56 mg/m<sup>2</sup> on days 1, 2, 8, 9, 15, and 16 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity</li> </ul> <p><u>Combination with selinexor and dexamethasone (XKd)</u></p> <p><u>20/56 regimen:</u></p> <ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on day 1; if tolerated, increase to 56 mg/m<sup>2</sup> on days 8 and 15 of a 28-day treatment cycle</li> <li>– Cycle 2 and beyond: 56 mg/m<sup>2</sup> on days 1, 8, and 15 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity</li> </ul> <p><u>Combination with pomalidomide and dexamethasone (KPd)</u></p> <p><u>20/27 regimen:</u></p> <ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on days 1 and 2; if tolerated, increase to 27 mg/m<sup>2</sup> on days 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycles 2 through 6: 27 mg/m<sup>2</sup> on days 1, 2, 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycle 7 and beyond: 27 mg/m<sup>2</sup> on days 1, 2, 15, and 16 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity</li> <li>– <b>NOTE:</b> If disease progression occurs while on maintenance dosing, resume full dosing of 27 mg/m<sup>2</sup> on days 1, 2, 8, 9, 15, and 16 of a 28-day treatment cycle</li> </ul> <p><u>20/36 regimen:</u></p>
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	<ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on days 1 and 2; if tolerated, increase to 36 mg/m<sup>2</sup> days 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycles 2 through 8: 36 mg/m<sup>2</sup> days 1, 2, 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycle 9 and beyond: 36 mg/m<sup>2</sup> days 1, 2, 15, and 16 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity</li> </ul> <p><u>Combination with pomalidomide, daratumumab/daratumumab and hyaluronidase, and dexamethasone:</u></p> <p><u>20/27 regimen:</u></p> <ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on days 1 and 2; if tolerated, increase to 27 mg/m<sup>2</sup> on days 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycles 2 through 8: 27 mg/m<sup>2</sup> on days 1, 2, 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycle 9 and beyond: 27 mg/m<sup>2</sup> on days 1, 2, 15, and 16 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity</li> </ul> <p><u>Combination with venetoclax and dexamethasone</u></p> <p><u>20/27 regimen:</u></p> <ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on days 1 and 2; if tolerated, increase to 27 mg/m<sup>2</sup> on days 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycles 2 through 12: 27 mg/m<sup>2</sup> on days 1, 2, 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycle 13 and beyond: 27 mg/m<sup>2</sup> on days 1, 2, 15, and 16 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity</li> </ul> <p><u>20/56 regimen:</u></p> <ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on days 1 and 2; if tolerated, increase to 56 mg/m<sup>2</sup> on days 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycle 2 and beyond: 56 mg/m<sup>2</sup> on days 1, 2, 8, 9, 15, and 16 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity</li> </ul> <p><u>20/70 regimen:</u></p> <ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on day 1; if tolerated, increase to 70 mg/m<sup>2</sup> on day 8 and 15 of a 28-day treatment cycle</li> <li>– Cycle 2 and beyond: 70 mg/m<sup>2</sup> on days 1, 8, and 15 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity</li> </ul>
Multiple Myeloma (relapsed or refractory disease after 3 prior therapies)	<p><u>Combination with bendamustine and dexamethasone</u></p> <p><u>20/27 regimen:</u></p> <ul style="list-style-type: none"> <li>– Cycle 1: 20 mg/m<sup>2</sup> on days 1 and 2; if tolerated, increase to 27 mg/m<sup>2</sup> on days 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycles 2 through 8: 27 mg/m<sup>2</sup> on days 1, 2, 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>– Cycle 9 and beyond: 27 mg/m<sup>2</sup> on days 1, 2, 15, and 16 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity</li> </ul>



Multiple Myeloma (maintenance therapy for symptomatic disease in transplant candidates)	<p><u>Combination with lenalidomide</u></p> <ul style="list-style-type: none"> <li>36 mg/m<sup>2</sup> days 1, 2, 15, and 16 of a 28-day treatment cycle for up to 2 years</li> <li><b>NOTE:</b> lenalidomide may be continued until disease progression or unacceptable toxicity <b>without</b> carfilzomib</li> </ul> <p><u>Combination with lenalidomide and isatuximab (Isa-KR)</u></p> <ul style="list-style-type: none"> <li>56 mg/m<sup>2</sup> days 1 and 15 of a 28-day treatment cycle for up to 26 cycles</li> </ul>
Multiple Myeloma (management of POEMS)	<p><u>Combination with dexamethasone (Kd)</u></p> <p><u>20/56 regimen:</u></p> <ul style="list-style-type: none"> <li>Cycle 1: 20 mg/m<sup>2</sup> on days 1 and 2; if tolerated, increase to 56 mg/m<sup>2</sup> on days 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>Cycle 2 and beyond: 56 mg/m<sup>2</sup> on days 1, 2, 8, 9, 15, and 16 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity</li> </ul> <p><u>20/70 regimen:</u></p> <ul style="list-style-type: none"> <li>Cycle 1: 20 mg/m<sup>2</sup> on day 1; if tolerated, increase to 70 mg/m<sup>2</sup> on day 8 and 15 of a 28-day treatment cycle</li> <li>Cycle 2 and beyond: 70 mg/m<sup>2</sup> on days 1, 8, and 15 of a 28-day treatment cycle; continue until disease progression or unacceptable toxicity</li> </ul>
Waldenström Macroglobulinemia/ Lymphoplasmacytic Lymphoma	<p><u>CaRD regimen (carfilzomib, rituximab, dexamethasone)</u></p> <p><u>Induction</u></p> <ul style="list-style-type: none"> <li>Cycle 1: 20 mg/m<sup>2</sup> on days 1, 2, 8 and 9 of a 21-day treatment cycle</li> <li>Cycles 2 through 6: 36 mg/m<sup>2</sup> on days 1, 2, 8 and 9 of a 21-day treatment cycle; begin maintenance 8 weeks later</li> </ul> <p><u>Maintenance</u></p> <ul style="list-style-type: none"> <li>36 mg/m<sup>2</sup> on days 1 and 2 every 8 weeks for 8 cycles</li> </ul>
Systemic Light Chain Amyloidosis	<p><u>Single agent or combination with dexamethasone</u></p> <p><u>20/27/56 regimen:</u></p> <ul style="list-style-type: none"> <li>Cycle 1: 20 mg/m<sup>2</sup> on day 1; if tolerated, increase to 27 mg/m<sup>2</sup> days 8 and 15 of a 28-day treatment cycle</li> <li>Cycle 2 and beyond: up to 56 mg/m<sup>2</sup> days 1, 8, and 15 of a 28-day treatment cycle</li> </ul> <p><u>20/36 regimen:</u></p> <ul style="list-style-type: none"> <li>Cycle 1: 20 mg/m<sup>2</sup> on days 1 and 2; if tolerated, increase to 36 mg/m<sup>2</sup> days 8, 9, 15, 16 of a 28-day treatment cycle</li> <li>Cycles 2 through 8: 36 mg/m<sup>2</sup> days 1, 2, 8, 9, 15, and 16 of a 28-day treatment cycle</li> <li>Cycles 9 and beyond: 36mg/m<sup>2</sup> days 1, 2, 15, and 16 of a 28-day treatment cycle</li> </ul> <p><b>*Note:</b> For patients with body surface area (BSA) of 2.2 m<sup>2</sup> or less, calculate the Kyprolis dose using actual BSA. Dose adjustments do not need to be made for weight changes of 20% or less. For patients with a BSA greater than 2.2 m<sup>2</sup>, calculate the Kyprolis dose using a BSA of 2.2 m<sup>2</sup>.</p>

## VI. Billing Code/Availability Information

### HCPSC Code:

- J9047 – Injection, carfilzomib, 1 mg; 1mg = 1 billable unit



### NDC(s):

- Kyprolis 10 mg single-dose vial for injection: 76075-0103-xx
- Kyprolis 30 mg single-dose vial for injection: 76075-0102-xx
- Kyprolis 60 mg single-dose vial for injection: 76075-0101-xx

## **VII. References**

1. Kyprolis [package insert]. Thousand Oaks, CA; Onyx Pharmaceuticals, Inc.; June 2022. Accessed March 2025.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Carfilzomib. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed April 2025.
3. BGM Durie, J-L Harousseau, J S Miguel, et al on behalf of the International Myeloma Working Group. International uniform response criteria for multiple myeloma. *Leukemia*. 2006 Sep; 20(9):1467-73.
4. Dimopoulos MA, Kastiris E, Owen RG, et al. Treatment recommendations for patients with Waldenström's macroglobulinemia (WM) and related disorders: IWWM-7 consensus. *Blood*. 2014; 124(9):1404–1411.
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7. Shah JJ, Stadtmauer EA, Abonour R, et al. Carfilzomib, pomalidomide and dexamethasone for relapsed or refractory myeloma. *Blood* 2015; 126: 2284-2290.
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## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C88.0	Waldenström macroglobulinemia
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse

ICD-10	ICD-10 Description
C90.10	Plasma cell leukemia not having achieved remission
C90.12	Plasma cell leukemia in relapse
C90.20	Extramedullary plasmacytoma not having achieved remission
C90.22	Extramedullary plasmacytoma in relapse
C90.30	Solitary plasmacytoma not having achieved remission
C90.32	Solitary plasmacytoma in relapse
D47.9	Neoplasm of uncertain behavior of lymphoid, hematopoietic and related tissue, unspecified
D47.Z9	Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
E31.9	Polyglandular dysfunction, unspecified
E85.3	Secondary systemic amyloidosis
E85.4	Organ-limited amyloidosis
E85.81	Light chain (AL) amyloidosis
E85.89	Other amyloidosis
E85.9	Amyloidosis, unspecified
G62.9	Polyneuropathy, unspecified
G90.9	Disorder of the autonomic nervous system, unspecified
L98.9	Disorder of the skin and subcutaneous tissue, unspecified
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC