**Kyprolis™ (Carfilzomib)**

| Last Review Date: October 25<sup>th</sup>, 2018 | Number: MG.MM.PH.64 |

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**Definition**

Kyprolis (carfilzomib) is a proteasome inhibitor that irreversibly binds to the N-terminal threonine-containing active sites of the 20S proteasome, the proteolytic core particle within the 26S proteasome. Carfilzomib had antiproliferative and proapoptotic activities in vitro in solid and hematologic tumor cells. In animals, carfilzomib inhibited proteasome activity in blood and tissue and delayed tumor growth in models of multiple myeloma, hematologic, and solid tumors.

Kyprolis (carfilzomib) is FDA approved as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy. It is also 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.

**Length of Authorization**

a. Coverage will be provided for 6 months and may be renewed.

**Dosing Limits**

b. Cap dose at a single dose limit body surface area (BSA) of 2.2m²

**Initial Approval Criteria**
Kyprolis (carfilzomib) may be considered medically necessary when any of the following criteria is met:

**Indication**

1. **Multiple Myeloma†**

   - The member has multiple myeloma and Kyprolis (carfilzomib) is being used as ONE of the following:
     - In combination with lenalidomide and dexamethasone as primary chemotherapy for transplant candidates.
     - Relapse or refractory disease
   - In combination with dexamethasone OR
   - As a single agent OR
   - In combination with pomalidomide and dexamethasone for members who have received at least two prior therapies, including an immunomodulatory agent and a proteasome inhibitor, and have demonstrated disease progression on or within 60 days of completion of the last therapy OR
   - In combination with panobinostat in members who have received at least two prior regimens, including bortezomib and an immunomodulatory agent OR
   - Used in combination with lenalidomide and dexamethasone for transplant candidates after 6 months following primary chemotherapy with the same regimen.

**Limitations:**

Kyprolis (carfilzomib) is not considered medically necessary when any of the following selection criteria is met:

1. Member has disease progression while taking Kyprolis (carfilzomib).
2. Kyprolis (carfilzomib) exceeds single dose limit BSA of 2.2 m².
3. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

† FDA Approved Indication

I. **Renewal Criteria**

Same as initial prior authorization policy criteria.

II. **Dosage/Administration**

<table>
<thead>
<tr>
<th>Dose</th>
<th>Please refer to Kyprolis package insert</th>
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<tbody>
<tr>
<td></td>
<td><a href="https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/202714s010lbl.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/202714s010lbl.pdf</a></td>
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Applicable Procedure Codes
Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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<tbody>
<tr>
<td>C90.00</td>
<td>Multiple myeloma not having achieved remission</td>
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<tr>
<td>C90.02</td>
<td>Multiple myeloma in relapse</td>
</tr>
<tr>
<td>C90.20</td>
<td>Extramedullary plasmacytoma not having achieved remission</td>
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<td>C90.22</td>
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<tr>
<td>C90.30</td>
<td>Solitary plasmacytoma not having achieved remission</td>
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<tr>
<td>C90.32</td>
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</tbody>
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References