**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:
   - Patient has relapsed or refractory disease who has received one to three lines of therapy:
     - Used in combination with lenalidomide plus dexamethasone OR
     - 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 and non-transplant patients with active multiple myeloma 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**

   **Dose**
   - Please refer to Kyprolis package insert
Applicable Procedure Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J9047</td>
<td>Injection, Carfilzomib, 1 mg</td>
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Applicable Diagnosis Codes

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

Revision History

10/30/2019 - Under Initial Approval Criteria, added: Patient has relapsed or refractory disease who has received one to three lines of therapy AND Used in combination with lenalidomide plus dexamethasone OR In combination with dexamethasone OR As a single agent.

- Used in combination with lenalidomide and dexamethasone for transplant candidates and non-transplant patients with active multiple myeloma after 6 months following primary chemotherapy with the same regimen.

References