OVERVIEW
Pomalyst, a thalidomide analogue, is indicated for use in combination with dexamethasone for patients with multiple myeloma who have received at least two prior therapies including Revlimid® (lenalidomide capsules) and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.¹

Guidelines
The National Comprehensive Cancer Network (NCCN) guidelines on multiple myeloma (version 2.2019 – November 16, 2018) include Pomalyst.² Pomalyst is recommended in various clinical regimens in varying scenarios and with different agents among patients with multiple myeloma that has been previously treated. It can be used as a monotherapy for patients who are steroid-intolerant.

The NCCN has guidelines regarding acquired immune deficiency syndrome (AIDS)-related Kaposi Sarcoma (version 2.2019 – November 29, 2018).³ Pomalyst is cited as the preferred subsequent system therapy option for relapsed/refractory therapy. First-line systemic therapy options include liposomal doxorubicin (preferred) and paclitaxel.

The NCCN has guidelines regarding Central Nervous System (CNS) Cancers (version 1.2019 – March 5, 2018).⁴ Pomalyst is listed as a recommended regimen for patients with relapsed or refractory disease.

The NCCN has guidelines for systemic light chain amyloidosis (version 1.2019 – October 26, 2018).⁵ The guidelines list Pomalyst plus dexamethasone as one of several treatment options for patients with relapsed or refractory disease.

Other Uses with Supportive Evidence
Data are available with Pomalyst in myelofibrosis.⁶⁻¹¹ Some noted benefits with Pomalyst, used with or without prednisone, included red blood cell (RBC)-transfusion independence, improved platelet-response rates, and improved anemia response rates.

Safety
Pomalyst has a Boxed Warning regarding embryofetal toxicity and venous arterial thromboembolism.¹ The availability of Pomalyst is through a restricted program called Pomalyst REMS. Warnings and Precautions include hematologic toxicity, hepatotoxicity, hypersensitivity reactions, and tumor lysis syndrome.

POLICY STATEMENT
Prior authorization is recommended for prescription benefit coverage of Pomalyst. All approvals are provided for the duration noted below.
**Recommended Authorization Criteria**
Coverage of Pomalyst is recommended in those who meet the following criteria:

**FDA-Approved Indications**

1. **Multiple Myeloma.** Approve for 3 years.¹

**Other Uses with Supportive Evidence**

2. **Acquired Immune Deficiency Syndrome (AIDS)-Related Kaposi Sarcoma.** Approve for 3 years if the patient has relapsed or refractory disease.

3. **Central Nervous System (CNS) Lymphoma.** Approve for 3 years if the patient has relapsed or refractory disease.

4. **Myelofibrosis.** Approve for 3 years if the patient has tried one other therapy (e.g., Jakafi [ruxolitinib tablets], androgens [e.g., nandrolone, oxymetholone], danazol, Epogen®/Procrit® [epoetin alfa injection], Aranesp® [darbepoetin alfa injection], prednisone, Thalomid® [thalidomide capsules], Revlimid® [lenalidomide capsules], melphalan, Myleran® [busulfan tablets], alfa interferons, or hydroxyurea).

5. **Systemic Light Chain Amyloidosis.** Approve for 3 years.

**Conditions Not Recommended for Approval**
Pomalyst has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

**References**


**HISTORY**

<table>
<thead>
<tr>
<th>Type of Revision</th>
<th>Summary of Changes</th>
<th>TAC Approval Date</th>
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<tbody>
<tr>
<td>New Policy</td>
<td>Not applicable</td>
<td>09/27/2017</td>
</tr>
<tr>
<td>Early annual revision</td>
<td>No criteria changes.</td>
<td>03/07/2018</td>
</tr>
<tr>
<td>Annual revision</td>
<td>Criteria added to approve for patients with AIDS-related Kaposi’s sarcoma for 3 years if the patient has relapsed or refractory disease. Criteria added to approve for central nervous system lymphoma for 3 years if the patient has relapsed or refractory disease.</td>
<td>03/20/2019</td>
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* For a further summary of criteria changes, refer to respective TAC minutes available at: [http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx](http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx); TAC – Therapeutic Assessment Committee.