JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS079
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	Subject **Revlimid, Thalomid, Pomalyst**	*Revision Date*	02/04/2022
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Pomalyst, Revlimid, Thalomid

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I. POLICY

A. Select oral medications commonly-used for multiple myeloma will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

1. **Revlimid** (lenalidomide) may be approved for the following:
   A. Patient is 18 years of age or older AND
   B. Documentation of one of the following diagnoses:
      i. Multiple myeloma, where Revlimid will be used concurrently with dexamethasone*
      ii. Multiple myeloma maintenance following autologous hematopoietic stem cell transplantation*
      iii. Transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities
      iv. Mantle cell lymphoma that has relapsed or progressed after two prior therapies, one of which included Velcade (bortezomib)
      v. Previously treated follicular lymphoma, where Revlimid will be used concurrently with a rituximab product
      vi. Previously treated marginal zone lymphoma, where Revlimid will be used concurrently with a rituximab product
2. **Thalomid** (thalidomide) may be approved for one of the following:
   A. Patient is 18 years of age or older AND
      i. Documentation that Thalomid will be used concurrently with dexamethasone for treatment of Multiple myeloma*
   B. Patient is 12 years of age or older AND one of the following

i. Documented diagnosis of acute cutaneous manifestations of moderate to severe erythema nodosum leprosum OR
ii. Documented diagnosis of prevention and suppression of the cutaneous manifestations of ENL recurrence

3. **Pomalyst** (pomalidomide) may be approved for All the following:
   A. Multiple Myeloma
      i. Patient is 18 years of age or older
      ii. Documentation that Pomalyst will be used concurrently with dexamethasone for treatment of Multiple myeloma*
      iii. Documented trial and failure of at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor (e.g. Velcade[bortezomib]) with disease progression on or within 60 days of completion of the last therapy
   B. Kaposi Sarcoma
      i. Patient is 18 years of age or older
      ii. Documentation of one of the following:
         a. Diagnosis of AIDS-related Kaposi sarcoma, AND:
            1. Patient has failed highly active antiretroviral therapy (HAART)
         b. Diagnosis of Kaposi sarcoma and the patient is HIV-negative
4. *All prior authorization requests for oral medications for multiple myeloma will be reviewed against the most recent version of the NCCN guidelines for multiple myeloma. Initial therapy will be approved if the treatment regimen is listed as preferred OR the treatment regimen is listed as other and the patient has a clinical contraindication to a preferred regimen in the applicable treatment category.
   A. Concurrent Prophylaxis
      i. Antithrombotic therapy is essential in patients receiving an immunomodulatory drug (such as thalidomide, lenalidomide or pomalidomide) with dexamethasone due to the high risk of thromboembolism. Patients should receive concurrent aspirin, warfarin or low molecular weight heparin unless they have an absolute contraindication to antithrombotic therapy.

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be for six months at the guideline-recommended dosage.
B. Approval for continuation of therapy can be extended for six month intervals. Approvals will be based on an efficient dose to maximize patient adherence and cost-effective therapy.

IV. EXCLUSIONS

A. If the request is for a diagnosis not listed above, a letter may be sent to the requesting physician to provide additional information.
B. Pomalidomide is considered not medically necessary when used in combination with bortezomib (Velcade) or carfilzomib (Kyprolis). Pomalidomide is considered investigational when used for all other conditions, including but not limited to myelofibrosis.
C. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. NCCN Guidelines Version 2.2019: Multiple Myeloma
2. Palumbo A et al.*J Clin Oncol* 2011; 29: 986-993.

3. Revlimid [prescribing information]. Summit, NJ: Celgene Corporation; May 2019.
4. Thalomid [prescribing information]. Summit, NJ: Celgene Corporation; June 2019.
5. Pomalyst [prescribing information]. Summit, NJ: Celgene Corporation; May 2020.

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2016	Removed background information
07/27/2017	Updated Exclusions section regarding physician samples
09/17/2018	Clarification of drugs covered under this policy
07/17/2019	Updated clinical criteria to include FDA-approved indications
02/04/2022	Updated clinical criteria for new FDA-approved usage

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