Clinical Policy: Thalidomide (Thalomid)

Reference Number: PA.CP.PHAR.78
Effective Date: 09/11
Last Review Date: 04/19

Revision Log

Description
Thalomid, α-(N-phthalimido) glutarimide, is an immunomodulatory agent.

FDA Approved Indication(s)
Thalomid is indicated:

- For the treatment of patients with newly diagnosed multiple myeloma (MM) in combination with dexamethasone
- For the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL)
- As maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence

Limitation of use: Thalomid is not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis.

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that Thalomid is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Multiple Myeloma (must meet all):

1. Diagnosis of multiple myeloma (MM);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥12 years;
4. Prescribed in combination with dexamethasone;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 200 mg/day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Erythema Nodosum Leprosum (must meet all):

1. Diagnosis of erythema nodosum leprosum (ENL);
2. Prescribed by or in consultation with an infectious disease specialist, immunologist, or dermatologist;
3. Age ≥12 years;
4. Dose does not exceed 400 mg/day.

Approval duration: 6 months

C. Myeloproliferative Neoplasms (off-label) (must meet all)**:**

1. Diagnosis of myeloproliferative neoplasms (myelofibrosis) with associated anemia;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥12 years;
4. Member meets one of the following (a or b):
   a. Serum EPO ≥ 500 mU/mL;
   b. Serum EPO < 500 mU/mL, and no response or loss of response to erythropoietic stimulating agents;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 400 mg/day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

D. Castleman's Disease (off-label) (must meet all)**:**

1. Diagnosis of multicentric Castleman's disease;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥12 years;
4. Prescribed as subsequent therapy with or without rituximab for disease that has progressed following treatment of relapsed/refractory or progressive disease;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 400 mg/day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

E. Kaposi Sarcoma (off-label) (must meet all)**:**

1. Diagnosis of AIDS-related Kaposi Sarcoma;
2. Prescribed by or in consultation with an oncologist or immunologist;
3. Age ≥12 years;
4. Prescribed in combination with antiretroviral therapy;
5. Disease has progressed or not responded to doxorubicin and paclitaxel;
6. Request meets one of the following (a or b):
   a. Dose does not exceed 400 mg/day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

F. Other diagnoses/indications (must meet all):

1. Refer to PA.CP.PMN.53

II. Continued Approval

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. Dose does not exceed 400 mg/day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PMN.53

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ENL: erythema nodosum leprosum
FDA: Food and Drug Administration
MM: multiple myeloma
NCCN: National Comprehensive Cancer Network

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Doxorubicin	Kaposi Sarcoma: 20 mg/m^2 IV every3 weeks	20 mg/m^2/dose
Paclitaxel	Kaposi Sarcoma: 100 mg/m^2 IV every 2 weeks	100 mg/m^2/dose

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): pregnancy; hypersensitivity
- Boxed warning(s): embryo-fetal toxicity and venous thromboembolism

Appendix D: General Information

- Thalomid is only available under a restricted distribution program called the Thalomid REMS program due to a black box warning for embryo-fetal toxicity. Patient and physician enrollment in the manufacturer's REMS program is required.

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
MM	200 mg PO QD	200 mg/day
ENL	100 to 300 mg PO QD	400 mg/day

V. Product Availability

Capsules: 50 mg, 100 mg, 150 mg, 200 mg

VI. References

1. Thalomid Prescribing Information. Summit, NJ: Celgene Corporation; December 2017. Available at http://media.celgene.com/content/uploads/thalomid-pi.pdf. Accessed February 4, 2019.
2. Thalidomide. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 4, 2019.
3. Multiple Myeloma (Version 2.2019). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed February 4, 2019.
4. AIDS-Related Kaposi Sarcoma (Version 2.2019). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed February 4, 2019.
5. B-cell Lymphomas (Version 1.2019). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed February 4, 2019.
6. Myeloproliferative Neoplasms (Version 2.2019). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed February 4, 2019.

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review:; added prescriber and age requirements; removed off label indication for systemic light chain amyloidosis that is no longer included in NCCN Compendium; added off-label use for Kaposi Sarcoma; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; references reviewed and updated.	01.22.18	04.18
2Q 2019 annual review: myeloproliferative neoplasms – removed requirement for use in combination with prednisone to align with NCCN compendium; removed Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma criteria set as this indication is no longer supported by NCCN compendium; expanded prescriber requirements for MM, MPN, Castleman's disease; references reviewed and updated.	04/19	