

## **Clinical Policy: Thalidomide (Thalomid)**

Reference Number: CP.PHAR.78

Effective Date: 09.01.11

Last Review Date: 05.18

Line of Business: HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Thalomid,  $\alpha$ -(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**

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Thalomid is **medically necessary** when the following criteria are met:

#### **I. Initial Approval Criteria**

##### **A. Multiple Myeloma** (must meet all):

1. Diagnosis of MM;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq 12$  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 ENL;
2. Prescribed by or in consultation with an infectious disease specialist, immunologist, or dermatologist;

3. Age  $\geq$ 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);
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$ 12 years;
4. Prescribed in combination with prednisone for management of myelofibrosis-associated anemia;
5. Member meets one of the following (a or b):
  - a. Serum EPO  $\geq$  500 mU/mL;
  - b. Serum EPO  $<$  500 mU/mL, and no response or loss of response to erythropoietic stimulating agents;
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**

**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;
3. Age  $\geq$ 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  $\geq$ 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. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma (off-label) (must meet all):**

1. Diagnosis of Waldenstrom's macroglobulinemia or lymphoplasmacytic lymphoma;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$ 12 years;
4. Prescribed as a single agent or in combination with rituximab for one of the following (a or b):
  - a. Primary therapy;
  - b. Therapy for previously treated disease that does not respond to primary therapy or for progressive or relapsed 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**

**G. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

**II. Continued Therapy**

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

1. Currently receiving medication via Centene benefit or documentation supports that member is currently receiving Thalomid and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose 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 (must meet 1 or 2):**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.  
**Approval duration: Duration of request or 6 months (whichever is less);** or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid or evidence of coverage documents.

#### IV. 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 <sup>2</sup> IV every 3 weeks	20 mg/m <sup>2</sup> /dose
Paclitaxel	Kaposi Sarcoma: 100 mg/m <sup>2</sup> IV every 2 weeks	100 mg/m <sup>2</sup> /dose

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

##### *Appendix C: 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.

#### V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
MM	200 mg orally once daily	200 mg/day
ENL	100 to 300 mg orally once daily	400 mg/day

#### VI. Product Availability

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

#### VII. References

1. Thalomid Prescribing Information. Summit, NJ: Celgene Corporation; December 2017. Available at <http://media.celgene.com/content/uploads/thalomid-pi.pdf>. Accessed January 22, 2018.
2. Thalidomide. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at [www.nccn.org](http://www.nccn.org). Accessed January 22, 2018.
3. Multiple myeloma (Version 3.2017). In: National Comprehensive Cancer Network Guidelines. Available at [www.nccn.org](http://www.nccn.org). Accessed January 22, 2018.
4. AIDS-Related Kaposi Sarcoma (Version 1.2018). In: National Comprehensive Cancer Network Guidelines. Available at [www.nccn.org](http://www.nccn.org). Accessed January 31, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added background and safety information to include MOA and clinical response requirements. Added Appendix A and B Modified black box warning Changed approval period on algorithm Deleted “Intent to treat” question	08.14	08.14
Background: Edited for clarity Figure 1: Added REMS question and age requirement Updated safety information	06.15	06.15
Converted policy to new template. FDA approved uses: max dose added for multiple myeloma and ENL. Age requirement removed. NCCN recommended uses added. Added safety information to background.	05.16	06.16
Under multiple myeloma, NCCN recommended uses updated 1) maintenance therapy is removed, 2) non-transplant option removed under primary therapy or therapy 6 months after the same regimen, 3) for transplant candidates, “in combination with dexamethasone” is changed to “in combination with bortezomib and dexamethasone”, 4) under relapsed, progressive or refractory disease, uses as a single agent and in combination with dexamethasone are removed; subsequent therapy as part of the VTD-PACE regimen is added. Maximum dose added. Under “other indications”, myelofibrosis-associated anemia is added. Safety information removed. Global Biopharm language added under “Other Diagnoses/Indications”. Approval durations are increased from 3/6 to 6/12 months.	05.17	06.17
2Q 2018 annual review: added HIM line of business; 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	05.18

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health

plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**For Health Insurance Marketplace members**, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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